U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Aviation Rulemaking Committee Charter

Effective Date:
10/5/2012

SUBJ: 14 CFR 21 / Safety Management Systems Aviation Rulemaking Committee

1. **PURPOSE.** This Charter creates the Aviation Rulemaking Committee (ARC) for Part 21 / Safety Management Systems (SMS) according to the Administrator's authority under Title 49 of the United States Code (49 U.S.C.) 106(p)(5). This charter also outlines the committee's organization, responsibilities, and tasks.

2. **BACKGROUND.**

On May 22, 2012, the Aircraft Certification Process Review and Reform ARC submitted a report to the FAA recommending that we undertake a review to update part 21 certification procedures to reflect a systems safety approach to product certification processes and oversight of design organizations. Design organizations must have full responsibility and accountability through the establishment of regulatory requirements for minimum qualification, performance, and management systems.

Consistent with FAA Order VS 8000.367, and the International Civil Aviation Organization (ICAO) Annex 8, the Aircraft Certification Service (AIR) has been actively developing and implementing an internal and external SMS. The initial focus was primarily on developing an internal set of processes, tools, and methodologies that facilitate the transition into the future state. AIR began that effort in 2005 and has made progress in defining key processes and tools. Later, with support from industry participants, the activities expanded to include development of standards for design and manufacturing organizations. Through implementation of pilot SMS projects with certain companies, the FAA is collecting information that will help define the scope of the SMS for Design Approval Holders (DAHs), validate certain best practices, and expand the knowledge base within the workforce and industry with respect to the essential elements of a robust SMS for manufacturers.

SMS requires a proactive approach to discovering and addressing hazards before they exhibit safety consequences. SMS also includes processes that seek to identify potential organizational breakdowns and necessary process improvements which allow management to address a safety issue before a noncompliant or unsafe condition results. SMS is not a substitute for compliance with FAA regulations or FAA oversight activities.

3. **OBJECTIVES AND TASKS OF THE ARC.** AIR wants to evaluate certain improvements to the effectiveness and efficiency of existing "certification procedures for products and parts," along with incorporating SMS in the design and manufacturing environment. This includes considering the effects of certain changes to the existing regulations, such as applicant qualifications, hazard (or safety) reporting, compliance assurance, and continued operation safety assurance systems for

all DAHs. The intent is to facilitate shifting towards a systems approach for DAHs that is similar to that used for production approval holder requirements, which involves a clear understanding of roles, responsibilities, and privileges. As part of this evaluation, we want to determine the best way industry and the FAA can effectively fulfill their respective compliance and safety responsibilities.

The ARC will provide a forum for the U.S. aviation community to discuss and provide recommendations to the FAA. The committee is expected to provide general information and guidance regarding proposed changes to part 21 and the AVS SMS program as it relates to design and manufacturing certificate and approval holders.

a. The ARC will provide the FAA recommendations, which may include proposals for rulemaking, suggested processes, policies and guidance, and any further action it determines the agency should contemplate for part 21 to align with the SMS requirements documented in proposed 14 CFR part 5, which is the central component of the NPRM entitled *Safety Management Systems for Part 121 Certificate Holders* [Docket No. FAA–2009–0671; Notice No. 10–15].

b. The ARC, serving in an advisory capacity, is expected to present and discuss whatever input, guidance, and recommendations its members consider critical to the FAA's ultimate disposition, development, and implementation of proposed regulatory requirements and related guidance and policy as necessary to the future direction for part 21 to include applicant pre-qualifications, approval holder recognition, and SMS considerations.

c. The ARC will also consider proposed revisions to clarify and update engineering/design-oriented regulatory requirements to part 21. In support of design certification and continued airworthiness, the evaluation should include improvements in the areas of:

   1. Application process
   2. Applicant qualifications
   3. Standardized certification criteria
   4. Identifying design approval holder responsibilities and privileges
   5. Clarifying continued airworthiness requirements
   6. Clarifying design approvals needing Instructions for Continued Airworthiness
   7. Clarifying TSO design approval processes
   8. Process definition for determining eligibility of U.S. surplus military aircraft in the restricted category

   This proposal additionally corrects regulatory language, implements editorial changes for clarification, and standardizes regulatory language to reflect the global aviation environment. While this information will be shared with the ARC, responses to "clean-up" proposals are not required as part of the deliverables.

d. Proposed part 5 and International Civil Aviation Organization (ICAO) Annex 8 and Annex 19 (draft) serve as the foundation for the ARC's consideration regarding how the FAA will address its responsibilities for developing and implementing SMS

requirements and the management and oversight of its regulated product/service providers. The ARC must respect the framework outlined in proposed part 5 and the ICAO Annexes when it provides the FAA recommendations with respect to application of SMS. However, the FAA will consider proposed changes to part 5 as deemed necessary from a design and manufacturing perspective.

Recommendation Report. The ARC shall make recommendations and submit a report addressing the following:

a. Improvements, which may include proposals for rulemaking, processes, policies and guidance for 14 CFR part 21 that reflect a systems approach for safety. This will promote an effective and efficient certification process, which includes considering the effects of certain changes to the existing regulations, such as:
   1. Minimum qualifications and organizational requirements for design approval applicants and holders including responsibilities and privileges
   2. SMS for design approval holders
   3. Compliance assurance
   4. Continued operational safety assurance
   5. Hazard reporting

b. Cost and benefit and other impact information in support of developing the required Regulatory Evaluation(s) and Regulatory Flexibility economic analysis for applying any proposed changes to 14 CFR part 21 FAA certificate and approval holders. Cost and benefit analysis should include information obtained through the AIR SMS pilot project and should identify the specific areas of impact and present this information in quantitative terms to the extent possible.

c. Part 21 design and production approval holder organizations to which the proposed SMS requirements should apply, taking into consideration cost and benefit information as well as public comments to the part 5 NPRM and the SMS-ARC *Design and Manufacturing Working Group Report – High-Level Recommendations for SMS Requirements* dated March 12, 2010.

d. Changes to the FAA oversight methodology based on any recommendations for changes to part 21 that takes into account existing FAA processes and oversight and delegation programs for design and manufacturing related certificates and approvals and authorizations.

e. Definitions and processes to be included in advisory, policy, and procedures material for addressing safety risk management responsibilities within a design and/or manufacturing organization. These definitions and processes should include:

   1. An operational definition of a "hazard" throughout the life cycle of a product in safety risk management.
   2. Definition of the term "organization" with respect to design and production approval holders to identify the limits of applicability of proposed SMS requirements, in

consideration of the broad range of organizational structures and activities within modern design and/or manufacturing organizations.

3. Hazard identification procedures.
4. Processes for the determination of acceptable safety risk.
5. Procedures to be included in advisory, policy, and procedures material for addressing safety assurance responsibilities within a design and/or manufacturing organization, including specific recommendations regarding "employee reporting systems".

The Director of Aircraft Certification Service (AIR-1) may propose additional tasks as necessary in support of a potential part 21 rulemaking action. The ARC may also request that AIR-1 add other tasks deemed relevant to the success of this initiative.

4. ARC PROCEDURES

a. The ARC advises and provides written recommendations to AIR-1 and acts solely in an advisory capacity. Once the ARC recommendations are delivered to AIR-1, it is within his/her discretion to determine when and how the report of the ARC is released to the public.
b. The ARC may propose additional tasks as necessary to AIR-1 for approval.
c. The ARC will submit a report detailing recommendations within 18 months from the effective date of this charter. The chair of the ARC sends the recommendation report to both AIR-1 and the Director of the Office of Rulemaking.
d. The ARC may reconvene following the submission of its recommendations for the purposes of providing advice and assistance to the FAA, at the discretion of AIR-1, provided the charter is still in effect.

5. ARC ORGANIZATION, MEMBERSHIP, AND ADMINISTRATION. The FAA will establish a committee of members of the aviation community. Members will be selected based on their familiarity with 14 CFR part 21, Safety Management Systems analysis, and regulatory compliance. Membership will be balanced in viewpoints, interests, and knowledge of the committee's objectives and scope. ARC membership is limited to promote discussion. Active participation and commitment by members will be essential for achieving the ARC's objectives. Attendance is essential for continued membership on the committee. When necessary, the ARC may set up specialized work groups that include at least one ARC member and invited subject matter experts from industry and government.

This ARC will consist of members from U.S. and foreign industry including representatives from designers and manufacturers holding part 21 certificates and approvals and other private sector aviation industry associations and advocacy groups. Invited foreign authorities and International Civil Aviation Organization (ICAO) representatives provide a valuable perspective from the global aviation community. These representatives are encouraged to fully participate in committee discussions; however, their participation does not include voting privileges on committee issues. The FAA's participation and support for the ARC will come from all affected lines-of-business.

a. The ARC sponsor is AIR-1 who:
    1. Appoints members or organizations to the ARC, at the Director's sole discretion;

   2. Selects the industry chair(s) from the ARC membership;
   3. Selects the FAA's designated federal official for the ARC;
   4. Receives all ARC recommendations and reports; and
   5. Provides administrative support for the ARC through the Safety Management Design and Analysis Branch (AIR-150).

b. Once appointed, the industry chair(s) will:
   1. Coordinate required committee and subcommittee (if any) meetings in order to meet the ARC's objectives and timelines;
   2. Provide notification to all ARC members of the time and place for each meeting;
   3. Ensure meeting agendas are established and provided to the committee members in a timely manner;
   4. Keep meeting minutes;
   5. Perform other responsibilities as required to ensure the ARC's objectives are met; and
   6. Provide status updates in writing to AIR-1 at 6 months and 12 months from the effective date of this charter.

6. COST AND COMPENSATION. The estimated operating cost (including *pro rata* share of salaries of FAA employees) to the Federal Government for this ARC is approximately $400,000 annually. All travel costs for government employees will be the responsibility of the government employee's organization. Non-government representatives serve without government compensation and bear all costs related to their participation on the committee.

7. PUBLIC PARTICIPATION. ARC meetings are not open to the public. Persons or organizations outside of the ARC who wish to attend a meeting must get approval in advance of the meeting from a committee co-chairperson or designated federal official.

8. AVAILABILITY OF RECORDS. Consistent with the Freedom of Information Act, Title 5, U.S.C., section 522, records, reports, agendas, working papers, and other documents that are made available to or prepared for or by the committee will be available for public inspection and copying at the FAA's Office of the Director, Aircraft Certification Service (AIR-1), 800 Independence Avenue SW, Washington, DC 20591. Fees will be charged for information furnished to the public according to the fee schedule published in Title 49 of the Code of Federal Regulations, part 7.

You can find this charter on the FAA Web Site at: http://www.faa.gov/about/committees/rulemaking/.

9. DISTRIBUTION. This order is distributed to director-level management in the Office of the Associate Administrator for Aviation Safety, the Office of Aviation Policy and Plans, the Office of Rulemaking, and the director- and division-level management in the Aircraft Certification Service.

10. EFFECTIVE DATE AND DURATION. This committee is effective upon issuance of this charter. The committee shall remain in existence for 2 years, unless sooner terminated or

extended by the Administrator.

The effective date of this charter is October 5, 2012.

Michael P. Huerta
Acting Administrator

U.S. Department
of Transportation
**Federal Aviation
Administration**

January 14, 2015

Mr. Walter Desrosier
Part 21 SMS ARC Co-Chair
1400 K Street NW, suite 801
Washington, DC 20005

Dear Mr. Desrosier:

On behalf of the Aircraft Certification Service I would like to thank you for serving as the industry chairperson of the Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee (ARC).

The Federal Aviation Administration (FAA) acknowledges receipt of the ARC report dated October 5, 2014 and would like to extend our gratitude to all those who participated on the committee. The recommendations made by the ARC will be very helpful in assisting the FAA to address certification process improvements recommended by the Aircraft Certification Process Review and Reform (ACPRR) ARC.

We appreciate the thoughtful consideration of how to shift towards a systems approach for product certification including revisiting the recommendations submitted by the Certified Design Organization (DO) ARC in May 2008. We agree with the recommendation to use a "building block" approach for implementing DO. The FAA looks forward to working with industry on the near term concepts of including SMS for design and manufacturing organizations and recognition of voluntary systems development for compliance. We concur with the ARC recommendation to consider future rulemaking to establish regulatory requirements for issuance and oversight of certificated DOs after successful implementation of the necessary building blocks.

Again, thank you for your time, effort, and leadership you devoted to this committee.

Sincerely,

Dorenda D. Baker

Dorenda D. Baker
Director, Aircraft Certification Service
Federal Aviation Administration

U.S. Department
of Transportation
**Federal Aviation
Administration**

January 14, 2015

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Part 21 SMS ARC Co-Chair
1400 K Street NW, suite 801
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Again, thank you for your time, effort, and leadership you devoted to this committee.

Sincerely,

Dorenda D. Baker

Dorenda D. Baker
Director, Aircraft Certification Service
Federal Aviation Administration

A Report from the

Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee to the Federal Aviation Administration

Recommendations on Certification Procedures for Products and Parts

October 5, 2014

Prepared for:

Dorenda D. Baker, Director
Aircraft Certification Service
Federal Aviation Administration
Washington, DC

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LETTER FROM THE ARC CO-CHAIRS

October 5, 2014

Ms. Dorenda Baker
Director
Aircraft Certification Service
Federal Aviation Administration
800 Independence Avenue, SW.
Washington, DC 20591

Dear Ms. Baker,

On behalf of the Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee (ARC), we are pleased to submit the enclosed report, which provides recommendations to improve the overall effectiveness and efficiency of the certification procedures in Title 14, Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products and Parts, by updating regulations and policies to reflect a systems safety approach to product certification and FAA oversight of design organizations (DO).

This report directly addresses the Aircraft Certification Process Review and Reform (ACPRR) recommendation to Congress to review and update part 21and provides detailed considerations of minimum qualification and organizational requirements for design approval applicants and holders including responsibilities and privileges. The ARC also considered other key ACPRR recommendations on the importance of ensuring a comprehensive means for implementing certification process improvements and change management planning to prepare both industry and the FAA workforce for their new and evolving roles and responsibilities in a systems safety approach to certification and oversight.

The ARC's goal was to determine the best way the FAA and industry can effectively fulfill their respective compliance and safety responsibilities while improving the efficiency and robustness of the certification process.

In this report, the ARC provides four high-level recommendations:

- Phased implementation of a systems approach to certification.
  - Promote accountability framework and enhanced applicant showings.
  - Establish minimum requirements for design approval applicant/holder.
  - Establish requirements for voluntary certificated Design Organizations (DO).
- Application of SMS requirements to design and production approval holders.
- Evolution of FAA oversight toward performance based systems safety (SMS) approaches.
- Part 21 miscellaneous cleanup and TSO modernization.

An overview of these high-level recommendations and discussion of the ARC's proposed phased implementation through a building block approach is provided in section 4 of this report. The remaining sections of the report provide detailed discussion on the issues and concepts considered by the ARC and the basis for its findings and high-level recommendations. It also provides "key considerations," which are supporting detail level recommendations necessary for practical implementation, summarized in appendix E.

On behalf of the Part 21/SMS ARC, it has been a privilege to be selected to undertake this important initiative. We are confident the ARC recommendations, when implemented, will result in a safer, more effective, and more efficient certification process for both the FAA and industry. Furthermore, the changes recommended have the potential to facilitate increased international cooperation and efficiencies, strengthening the FAA's global aviation safety leadership and supporting the competitiveness of U.S. products.

The ARC members express our appreciation for this opportunity and offer our support for future activities to consider these recommendations and develop additional clarification, guidance, and policies necessary for implementation.

Sincerely,

Mike Reinert, Co-Chair
Manager, System Performance and
Development Branch, AIR−150
Aircraft Certification Service
Federal Aviation Administration

Walter Desrosier, Co-Chair
Vice President, Engineering & Maintenance
General Aviation Manufacturers
Association (GAMA)

EXECUTIVE SUMMARY

This executive summary and summary of recommendations will provide a high-level overview of the Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee (ARC) activities and recommendations. This report provides the background for the ARC, then describes the current state for aircraft and component certification activities, followed by the ARC's vision for the future direction of the certification process.

The Part 21/SMS ARC's objectives and tasks were to evaluate certain improvements to the effectiveness and efficiency of existing "certification procedures for products and parts," along with incorporating SMS in the design and manufacturing environment. This included considering the effects of certain changes to the existing regulations, such as applicant qualifications, hazard (or safety) reporting, compliance assurance, and continued operational safety assurance systems for all design approval holders (DAH). The intent was to facilitate shifting toward a systems approach for product design approval/certification similar to that used for production approvals, which involves a clear understanding of roles, responsibilities, and privileges. The ARC's goal was to determine the best way the Federal Aviation Administration (FAA) and industry can effectively fulfill their respective compliance and safety responsibilities while improving the efficiency and robustness of the certification process.

The Aircraft Certification Process and Review Reform (ACPRR) ARC report, dated August 13, 2012, responded to section 312, Aircraft certification process review and reform, of the FAA Modernization and Reform Act of 2012 (Public Law 112–95), and provided recommendations to reform, streamline, and reengineer the certification process to meet future challenges. Previous assessments of the certification process found industry development of new aviation products and technologies is expected to continue growing at a pace that exceeds the FAA's ability to support. Of particular interest is the ever-increasing demand for FAA resources in areas other than certification such as continued operational safety of the existing fleet of aircraft, resulting in fewer available resources for aircraft certification in the future. This highlights the need for change to the certification process. The ACPRR's key recommendation is shifting the FAA certification process from a detailed product approach toward a systems safety approach. This report builds on the recommendations of the ACPRR report to Congress in support of an ongoing evolutionary shift to a systems approach to certification and provides high-level recommendations and detailed key considerations for a phased implementation using a building block approach. This enables a natural progression of the maturity and robustness of the current certification process, including industry compliance and FAA oversight processes.

In this report, the ARC provides four high-level recommendations on the following:

1. Phased implementation of a systems approach to certification.
    a. Promote accountability framework and enhanced applicant showings.
    b. Establish minimum requirements for design approval applicant/holder.
    c. Establish requirements for voluntary certificated design organizations (DO).
2. Application of SMS requirements to design and production approval holders.

3. Evolution of FAA oversight toward performance-based systems safety (SMS) approaches.
4. Part 21 miscellaneous cleanup and technical standard order (TSO) modernization.

Each recommendation is discussed in detail within the report, which provides significant supporting information and "key considerations," which are supporting detail level recommendations necessary for practical implementation. Appendix E provides a summary overview of the key considerations that support the high-level recommendations and where they are discussed in the report.

1.0 BACKGROUND

1.1 INTRODUCTION

This report documents the results of the Part 21/Safety Management Systems (SMS) Aviation Rulemaking Committee (ARC), chartered by the Federal Aviation Administration (FAA) on October 15, 2012, to update the certification procedures in Title 14, Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products and Parts, to reflect a systems safety approach to product certification processes and oversight of design organizations (DO). The charter tasked the ARC to evaluate and recommend requirements for design approval applicants, application qualifications, hazards (or safety) reporting, compliance assurance, and continued operational safety (COS) systems for all design approval holders (DAH). The intent was (1) to provide guidance to the FAA on shifting toward a systems safety approach for DAHs similar to the approach used for production approval holder (PAH) requirements, which involves a clear understanding of roles, responsibilities, and privileges, and (2) to determine how the FAA and industry can most effectively fulfill their respective safety and compliance responsibilities.

Appendix A to this report contains a list of ARC members and support staff. Appendix B contains a glossary of terms, and appendix C is a list of acronyms used in the report. A copy of the charter is found in appendix D.

1.2 ARC SCOPE AND STRUCTURE

1.2.1 SCOPE

The scope of the ARC's tasks was to review and provide recommendations to update part 21 certification procedures to reflect a systems safety approach to product certification processes and oversight of DO. The goal was to identify the regulatory requirements for implementing DOs that would be fully accountable for determining compliance with the applicable product regulations using a systems approach that integrated the safety management requirements of the proposed 14 CFR part 5, Safety Management Systems. The part 21 requirements would establish minimum qualifications, performance, and management systems to ensure the DO could accomplish this activity with minimal FAA involvement and oversight. (Refer to section 1.3 below for an overview of the rulemaking process Federal agencies use to create regulations.)

1.2.2 ARC STRUCTURE

To accomplish its goals, the ARC formed four working groups to identify applicable regulatory requirements: the Design Organization Working Group (and Technical Standard Order Subteam), the Safety Management Systems Working Group, the Oversight Working Group, and the Cost-Benefit Analysis Working Group. The ARC created a charter for each working group to identify objectives, and each group produced a summary report containing the results of its deliberations and a set of final recommendations. The working group and subteam reports are included in their original form as appendixes F, G, H, I, and J to this report.

1.2.3 Organization of This Report

The body of this report consists of an executive summary and 11 numbered sections. Section 1 provides an introduction to the ARC's taskings and organization. Section 2 summarizes the current state of the certification processes, and section 3 introduces the ARC's proposed future state. A high-level summary of each of the four major recommendations is found in section 4. Key elements of the future state are explored in section 5 (regarding SMS), section 6 (regarding the DO model), and section 7 (regarding alternatives to DO for small businesses). The next two sections detail means by which the FAA and industry can achieve the desired future state: section 8 explains the ARC's recommended changes to part 21, and section 9 sets out the building block approach to transitioning from a delegated process to a system safety process for certification. Section 10 summarizes cost information related to the current and proposed certification processes. Dissenting or minority opinions from ARC members not included in the applicable sections of the report can be found in section 11. The report also includes 16 appendixes.

1.3 Rulemaking Process

The following section is an overview of the rulemaking process. The end of this section includes references to provide a more in-depth study of the rulemaking process.

Federal regulations are created through a process known as rulemaking. Regulations are issued by Federal agencies, boards, or commissions, and explain how the agency intends to carry out a law. By law, Federal agencies must consult the public when creating, modifying, or deleting rules in the CFR. Once an agency decides a regulation should be added, changed, or deleted, it typically publishes a proposed rule in the Federal Register to ask the public for comments.

After the agency considers public feedback and makes changes where appropriate, it then publishes a final rule in the Federal Register with a specific date for when the rule will become effective and enforceable. When the agency issues a final rule for comment, it must describe and respond to the public comments it received.

Refer to section 8 of this report for the ARC's recommendations on regulatory changes to part 21. Further information about the rulemaking process can be found at the following online sources:

- Electronic Code of Federal Regulations (eCFR): http://www.ecfr.gov/
- A Guide to the Rulemaking Process, Prepared by the Office of the Federal Register: http://www.federalregister.gov/uploads/2011/01/the_rulemaking_process.pdf
- The Rulemaking Process (U.S. Department of Transportation): http://www.dot.gov/regulations/rulemaking-process

1.4 Previous Reviews and Recommendations

The FAA Modernization and Reform Act of 2012 (Public Law 112–95) required the FAA Administrator, in consultation with the aviation industry, to conduct an assessment of the aircraft certification and approval process and to make recommendations to streamline and reengineer to improve overall effectiveness and efficiency. The final report submitted to Congress included a review of previous reports conducted by an FAA/industry ARC that recommended changes to the certification process.

These reports were conducted by independent expert bodies such as the U.S. Aerospace Commission and National Research Council, as well as oversight agencies such as the U.S. Government Accountability Office (GAO) and the U.S Department of Transportation Office of the Inspector General (OIG). Some of these reports focused on specific FAA programs such as organization designation authorization (ODA) and risk-based resource targeting (RBRT) tools, and provided recommendations to improve implementation and effectiveness of FAA program management and safety oversight. Other reports assessed the rapidly changing aviation environment (increased growth in industry activity combined with the accelerated development of new technology and products) and provided recommendations for reengineering the FAA certification processes to meet future challenges and continue to improve safety levels.

Certification Process Reform Streamlining and Reengineering

The Aircraft Certification Process and Review Reform (ACPRR) ARC report (often referred to as the “312 report”) dated August 13, 2012, was a response to section 312, Aircraft certification process review and reform, of the FAA Modernization and Reform Act, and summarized key recommendations for certification process improvements from previous reports. The ARC identified multiple instances where recommendations from previous reports converged and overlapped. Several independent assessments of the certification process found that industry development of new aviation products and technologies is expected to continue growing at a pace that exceeds the FAA’s ability to support. All of the reports provided recommendations to reform, streamline, and reengineer the certification process to meet future challenges. The common theme among these recommendations is shifting the FAA certification process from a detailed product approach toward a systems safety approach. This Part 21/SMS ARC report builds on the ACPRR report to Congress in support of an ongoing evolutionary shift to a systems approach to certification, and provides high-level recommendations and detailed key considerations for a phased implementation using a building block approach.

Certified Design Organization ARC

The FAA Certified Design Organization (CDO) ARC submitted a final report to the FAA in May 2008 with recommendations for rulemaking, policies, and guidance to serve as the foundation for the establishment of FAA certification and oversight of design organizations (DO). The Part 21/SMS ARC notes that some of the information in sections 2 and 3 of this report was taken from the CDO ARC report because it remains relevant in describing some of the conditions driving the desire for an approved/certified DO.

2.0 CURRENT STATE

2.1 FAA and Industry Share the Responsibility for Current Safety Success

The flying public currently enjoys an unprecedented level of safety as a direct result of the FAA and industry's collaborative certification, maintenance, and operational approaches. By all measures, aircraft and aircraft operations have never been safer. Manufacturers, operators, repair stations, and the FAA have improved design, modernized operations, improved infrastructure, and delivered on a mandate for safe air travel.

This collective work by government and industry has resulted in a 5-fold reduction in air carrier accidents, reducing the rate of accidents that result in passenger fatalities to about one in every 14 million commercial flights. This has been accomplished, in part, with advances in technology, the use of structured data and analysis, and improved processes for the design certification, production, maintenance, and operation of aviation products. Notably, many of the actions to achieve this record safety level were developed and implemented as a result of voluntary actions by industry.

A fundamental aspect of the current certification process (the "detailed product approach") is that FAA resources (FAA engineers, inspectors, designated engineering representatives (DER), or ODA unit members (UM)) must be involved in an applicant's critical path activities to make discrete compliance findings with all U.S. aviation regulations applicable to the project. To determine opportunities to minimize critical path exposure, the ARC reviewed the requirement for FAA/DER/Designated Airworthiness Representative (DAR), or ODA UMs to find compliance and the delegation process for potential improvements. This section identifies some of the issues associated with the current certification process that need attention if the FAA and industry were to shift from a delegation process to a DO process.

2.2 Delegation

The current process for issuing an aircraft, engine, or propeller design certification or approving a change to type design is authorized under Title 49, United States Code (49 U.S.C.) § 44702(d), Issuance of Certificates. The FAA has increasingly recognized industry's expertise and resources in creating its system of individual and organizational delegations. Civil aviation expansion has far outpaced the FAA's growth in resources, and to leverage its resources, the FAA often relies on designees or delegated organizations to make discrete findings of compliance with regulatory requirements on its behalf.

The following outlines the history of the FAA's delegation system:

- 1940s: DER, designated manufacturing inspection representative (DMIR), designated pilot examiner (DPE) individual designees.
- 1950s: Design organization approval (DOA) organizational delegations for small airplanes, propellers, and engines.
- 1958: Federal Aviation Act of 1958 (Public Law 85–726) reaffirms delegation.

- 1960s: Designation alternation station (DAS) organizational delegation for repair stations.
- 1970s: Special Federal Aviation Regulation (SFAR) 36, Development of Major Repair Data, authorizations for operators.
- 1980s: DAR individual designees.
- 1990s: Organizational Designated Airworthiness Representative (ODAR) organizational delegations.
- 2006: ODA organizational delegations for all products and organizations; replaces DOA, DAS, ODAR, and SFAR 36.

The FAA has the authority to decide which aspects of a project require direct involvement, which aspects it should delegate, and to whom those aspects should be delegated. The FAA has tailored its delegation programs to ensure it retains responsibility for direct oversight of safety-critical areas.

For decades the aviation statutes and regulations have contained the provisions for delegation to both individuals and companies, but have also recognized that the FAA may rely on industry resources and expertise for compliance activities without delegation. Industry has assumed an enhanced role in making compliance showings that the FAA relies upon without making discrete findings in areas (such as primary category aircraft certification) that permit reduced FAA involvement before the issuance of a type certificate (TC) and technical standard order authorization (TSOA) design approvals.

The current U.S. certification processes require applicants to show compliance with all applicable airworthiness requirements, then relies on FAA resources, company DERs, and ODA UMs to review and verify the applicant showing to find compliance. For every applicant action, there is a corresponding need for an FAA reaction. This "show" and "find" process is repeated for nearly every discrete individual airworthiness requirement. Consequently, this certification process can be time consuming for larger and more complex projects.

Moving to a more effective and efficient certification process through a systems approach to safety, leveraging both the capability of applicant (with past experience) and the use of risk management techniques within the FAA, would benefit the overall timeliness of certification.

A systems approach that allows the FAA to accept the company statement of compliance through enhanced showings will allow FAA resources to focus on more safety-related issues would save the FAA and industry time and money.

This is an issue that both industry and the FAA must address. Industry members must ensure they have processes in place and personnel with the experience necessary to determine compliance with minimal FAA involvement. Industry members must also develop their processes to allow less reliance on their DERs and ODA UMs to both show and find compliance, particularly for low-risk requirements that can be approved by a company statement of compliance in accordance with § 21.20, Compliance with applicable requirements. This will require that the company fully understand and accept the FAA accountability framework. The

FAA must review its decisions for being involved in a project if the applicant has the capability to perform the compliance determination. Unless valid reasons exist to withhold complete delegation, a project should be delegated. If delegations are withheld, the FAA and applicant must develop a procedure to agree on how the applicant can perform the determination without FAA involvement.

As the U.S. aviation industry expands (in terms of both increased production and introduction of new products and technologies), more effective and efficient approaches to certification and related findings of compliance is needed so industry can more effectively and efficiently plan and execute the certification of new products with improved safety and utility.

2.3 Current Oversight Process

The FAA and applicant have a dual responsibility leading to the issuance of a certificate. Industry has the responsibility of full compliance and the FAA has the responsibility to make a finding of compliance before issuing any certificate. The current oversight process can be broken out into two different classifications: design certification oversight and production certification oversight. This section gives a high-level overview of the oversight process for both design and production.

Today's system for design certification is based on a "showing" (that is, a showing of compliance) by the applicant and a "finding" by the FAA. For every action by the applicant, there is an equal action by the authority on a project-by-project basis. An Aircraft Certification Office (ACO), Manufacturing Inspection District Office (MIDO), Flight Standards District Office (FSDO) and/or Aircraft Evaluation Group (AEG) office conducts design certification oversight through several methods.

With the introduction of ODA, the FAA instituted organizational management teams (OMT) for every ODA. FAA Order 8100.15, Organization Delegation Authorization Procedures, captures the OMT operations and requirements. An OMT's fundamental purpose is to oversee the ODA holder, which includes the ODA unit. In certain ODA applications, the FAA created "customized" OMTs for companies with large and/or complex ODAs. In general, these OMTs use dedicated resources to oversee the volume, complexity, and integration of ODA operations.

This structure is designed to combine the resources of current FAA offices (such as ACOs, MIDOs, and FSDOs). The centralized nature of these OMT structures enables increased commonality for ODA oversight. The dedicated resources reduce priority ODA support from competing with other FAA priorities.

In addition to design certification, the FAA is required to inspect aircraft during manufacture. Certificate management is the FAA's method for meeting this requirement, and auditing is its key component. The purpose of an audit is to verify a PAH has established and continues to follow approved procedures in the production of products, articles, and parts that conform to their approved type design and are in an airworthy condition for safe operation.

Certificate management of a production approval consists of four processes:

- **Principal inspector (PI) audit:** An ongoing progressive review of the PAH's quality system over a given period of time.
- **Supplier audit (SA):** An audit of the PAH's supplier control system, generally conducted at the supplier's facility.
- **Quality system audit (QSA):** A periodic, complete review of a PAH's approved quality system by FAA personnel.
- **Product audit:** Using a product or article produced by the PAH to prove the PAH is following its approved procedures/processes and their effectiveness. Product audits are performed during PI audits, QSAs, and SAs.

Certificate management of a PAH is a planned activity based on risk. The PI responsible for the PAH will enter required information concerning the PAH into the RBRT tool. The RBRT assessment tool is used to assign risk to a PAH according to the likelihood that it will produce nonconforming products, articles, or parts, and consequential results associated with introducing those products, articles, or parts into the system. RBRT assessments and associated procedures provide a consistent and justifiable basis for effective deployment of FAA resources when performing certificate management. Each directorate must annually assess PAHs using RBRT assessments. The RBRT assessment of each applicable facility is based on organizational and technical indicators that demonstrate a facility's potential for producing nonconforming products, articles, or parts. The RBRT assessment results in assigning a facility one of the following risk levels:

1. **High:** Having a facility with the greatest potential to produce nonconforming products, articles, or parts.
2. **Medium (Medium Low and Medium High):** Having a facility with moderate potential to produce nonconforming products, articles, or parts.
3. **Low:** Having a facility with low potential to produce nonconforming products, articles, or parts.

Audit data resulting from PAH certificate management activities is stored in the Certificate Management Information System (CMIS). CMIS data is used to detect shifts in performance and statistically significant trends within the manufacturing industry, by directorate, production approval type, or other categories as supported by the data available within CMIS. CMIS data may also be used to study various aspects of QSA performance as needed.

A key difference between design and production oversight is that design oversight is still more of a product-based oversight. Production oversight has moved to recognizing an organization and performing oversight based on risk.

2.4 Demand for FAA Resources

The FAA must support several planned or implemented activities with the potential to further reduce FAA support for certification activity, including—

- **Increased globalization.** Companies around the world are constantly looking for opportunities to conduct innovative aircraft design and production. This changes the way the FAA is involved in projects and adds to the need for resources that can address those needs. This can potentially reduce the FAA's aircraft certification budget and personnel available for other certification activity.
- **Safety management systems.** Safety management is an FAA-supported mandate from the International Civil Aviation Organization (ICAO). Safety management may not affect design significantly but could affect the continued airworthiness process and require additional personnel and resources that could affect the budget available to support certification.
- Ne**xt Generation Air Transportation System (NextGen).** The NextGen project, although not directly involved in certification, affects it by requiring certification of new equipment that must be installed to operate in the system. The implementation of this system will lead to a significant demand for certification services.
- **Unmanned Aircraft Systems (UAS).** UAS technology is on the cusp of explosive growth, requiring the FAA to allocate resources to support safe and successful integration of UAS into U.S. airspace.
- **Environmental considerations (such as noise, emissions/carbon dioxide, halon, lead, and chemicals).** There is a continuing demand from the U.S. Environmental Protection Agency (EPA) and public, to further restrict noise, emissions, chemicals, and other materials from the atmosphere. This requires additional FAA resources and could potentially affect the FAA's budget for certification activity.
- **Military and public use aircraft.** There are increasingly requirements to support military aircraft such as the McDonnell Douglas KC–10 and public use aircraft for the Department of the Interior, U.S. Forest Service, and others.

2.5 Economic Impact of Aviation Industry

The civil air transport industry plays a crucial role in fostering trade and making any location worldwide easily and quickly accessible. U.S. industry and consumers depend on the vital services of air transportation, which continue to maintain and stimulate the U.S. economy. Even with the extreme fluctuations in the economy and government sequestration, the aviation industry continues to readjust itself and regain stability.

- In 2009, air carriers operating in U.S. airspace transported 793 million passengers over 1,039.3 billion revenue passenger miles (RPM).
- More than 53 billion revenue ton-miles (RTM) of scheduled freight passed through U.S. airports in 2009.

- The U.S. civil aviation manufacturing industry continues to be the top U.S. net exporter. According to 2009 data from the U.S. International Trade Commission (USITC), the U.S. civil aviation manufacturing industry supported a positive trade balance of over $75 billion.
- The 2011 FAA Aerospace Forecast expects average annual growth rates of 2.7 percent per year through 2034 for U.S. air carriers.

Despite these achievements, the U.S. aerospace industry may be facing some of its greatest challenges in decades. While weathering numerous hardships during 2013, the industry produced relatively flat results compared with 2012. An overall slight decrease in sales is forecasted, reaching $220.1 billion for 2013—down from $222 billion in 2012—with only civil aircraft sales showing growth. Figure 1 below, from the Aerospace Industries Association (AIA) Annual Report, depicts annual aerospace industry sales from 1998 through 2014.

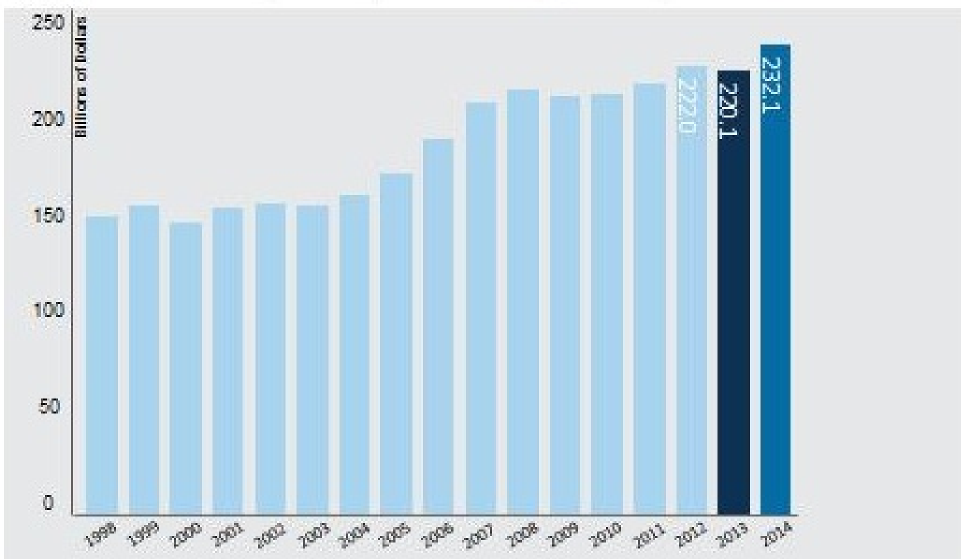

Figure 1. Aerospace Industry Sales

Data has proven that civil aviation is on the rise, and even through difficult transitions, continues to increase. However, the FAA's ability to support this continuous growth at its current capacity is a concern. According to the Bureau of Transportation Statistics (BTS), employment projections show an increase in aviation transportation employees by 0.7 percent annually and, conversely, a decline of 1.6 percent in government employment through the year 2022. Additionally, the FAA, and the Office of Aviation Safety (AVS) in particular, has maintained a relatively flat increase in hiring because of a slow and steady hiring rate as well as attrition. Figure 2 illustrates this gap.

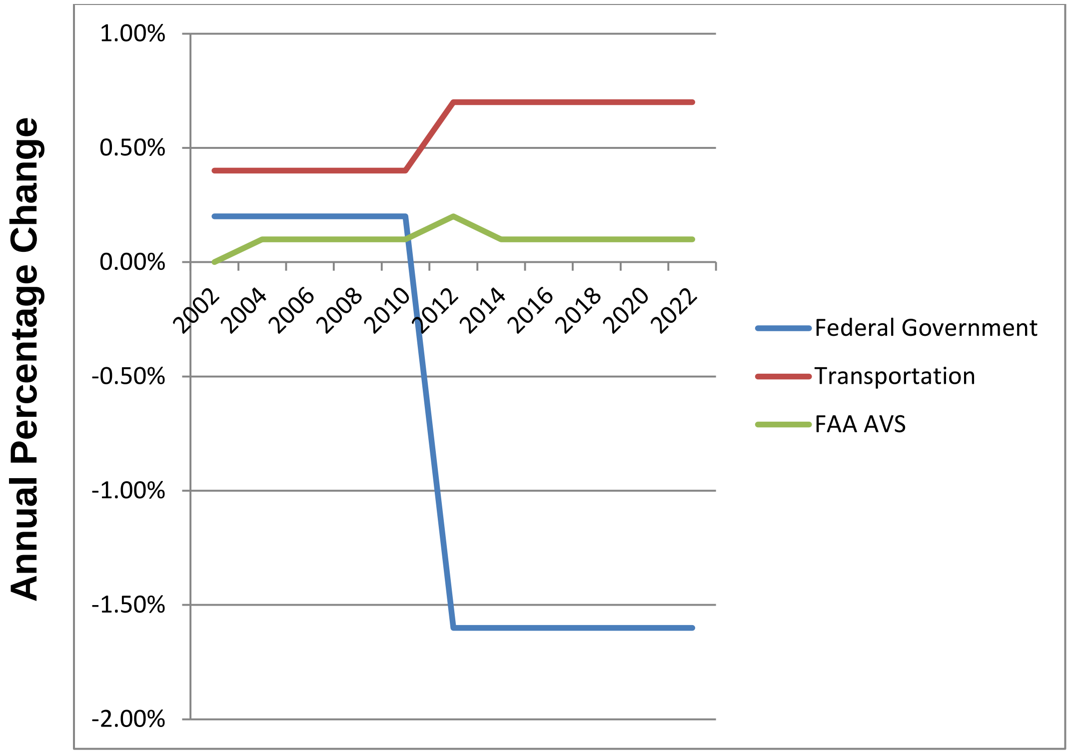

Figure 2. Employment Projections

If the anticipated industry growth continues by 0.7 percent per year through 2022 and the FAA employment rate remains level, the rate at which the FAA is able to support critical activities becomes increasingly more difficult. This significant gap will translate to lost industry revenue, stifling of innovation and entrepreneurs, a possible decline in air travel, and possible future safety-impacting occurrences. Civil aviation is moving faster than the government can keep up with, and if this trend continues, the direct and indirect impacts could be substantial. The longer a company is waiting for the FAA to proceed with certification activities, the longer product time to market will be.

Mitigation strategies have been implemented for certification activity to assist with the increasing trend of industry growth. However, systems such as sequencing and designee programs are no longer mitigating the existing gap appropriately, as evidenced by sequencing wait times and FAA employees' shifting areas of focus. The United States has reached a time where significant change is needed. This change can be made through an adjustment of the FAA's certification system, a topic considered in the next section of this report.

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3.0 FUTURE STATE

This section examines the future challenges in U.S. aviation and the ways in which the FAA and industry can effectively face these challenges. Sections 5, 6, and 7 of this report detail three key elements of the ARC's desired future state of a systems approach to certification and oversight: SMS, DO, and minimum organizational requirements for design approval applicants and holders.

3.1 CASE FOR CHANGE

3.1.1 SAFETY THROUGH FUTURE COLLECTIVE ACTIONS OF FAA AND INDUSTRY

The continued growth of aviation will lead to an aviation system of the future with more general aviation aircraft and significantly more commercial aircraft flying more operations. New and different aircraft designs will also emerge at an increasing rate. Cost pressures have increasingly led to new business models for producing and selling aircraft and for the use of aftermarket parts in service and maintenance operations.

The FAA's current efforts to (1) rewrite part 23, Airworthiness Standards: Normal, Utility, Acrobatic, and Commuter Category Airplanes; (2) develop standard means of compliance to the regulations; and (3) find ways to implement new safety improvements in older airplanes represent a new approach to collective actions between the FAA and industry that could lead to additional collaboration. The European Aviation Safety Agency (EASA), Transport Canada Civil Aviation (TCCA), National Civil Aviation Agency of Brazil (ANAC), Civil Aviation Administration of China (CAAC), and the Civil Aviation Authority of New Zealand are also involved in this activity, representing a major change in the approach to collaborative effort among the FAA, industry, and major certification authorities.

3.1.2 THE CHALLENGE TO MEET PUBLIC DEMANDS FOR INCREASED SAFETY

The FAA and industry's joint challenge for the future is to continue the unprecedented safety improvements of the last decade. The level of safety the public has come to expect will be challenged by the FAA's ability to respond to the effects of new technology, new regulations, acute global competition, and global engineering and manufacturing.

With the FAA Aircraft Certification Service's (AIR) budget nearly flat, the increasing amount of time AIR spends on continued airworthiness and other high priority activities leads to less time available to support certification activity. At the same time, industry is attempting to increase certification activity and needs more support or an alternative approach to certification. The lack of sufficient FAA and designee resources and clearly defined means of compliance proposed by industry and accepted by the FAA exacerbates industry's inability to efficiently certify and market products that could help further improve safety.

Because history has shown the FAA's growth rate to be less than the growth rate of industry, the FAA must continue to seek solutions to improve safety while optimizing the use of its resources. Significant changes must be made to the certification process if the U.S. aviation industry is to continue to be a world leader in the production of aircraft products and maintain or improve safety. New aircraft sales and service support contribute significantly to the balance of trade. The loss of these economic factors because of the failure to improve the certification process would greatly harm the U.S. economy.

3.1.3 Opportunities for Additional Safety Improvements

Several studies, reports, and initiatives have been developed and implemented to "streamline" the certification process, shifting from reliance on FAA resources (FAA engineers, DERs, DMIRs, DARs, or ODA UMs) to an increased use of robust, predictable industry processes. The ACPRR ARC report (refer to section 1.4 above) summarized a need to "shift the FAA certification process from a detailed product approach toward a systems safety approach." This systems safety approach would use processes developed by the company or jointly by the FAA and industry as a means of determining compliance.

These documented industry systems and procedures to determine compliance with appropriate verification/assurance enable the FAA to propose this new shift in the certification process. This shift would also allow the FAA and industry to satisfy ICAO's SMS implementation mandate.

3.1.4 Bilateral Agreement SMS Considerations for Products and Articles Certification

The desired future state for SMS is that importing (validating) authorities will rely on the exporting (domestic) authority's overall system for aeronautical product design, certification, and production, including SMS implementation, in accordance with ICAO principles and existing bilateral agreements. Specifically, the importing (validating) authority would not—

- Evaluate or re-approve an organization's SMS to be able to accept/validate that organization's aeronautical products.
- Impose its domestic SMS requirements in addition to the exporting (domestic) authority's SMS requirements, which would result in the organization needing to adapt its SMS to multiple authority requirements and hold multiple SMS approvals.
- Impose its domestic SMS requirements on an organization even if the exporting (domestic) authority has not yet formally accepted/approved an organization's SMS at the time of product acceptance by the importing (validating) authority.

The Safety Management International Collaboration Group (SM ICG) (refer to appendix K to this report) is working with ICAO to embed these principles for contracting states' SMS development and safety programs. As a result, the FAA should continue to pursue the above principles when developing modified bilateral and validation agreements.

3.1.5 Why ODA Is Not Enough—Shifting to a Systems Approach to Certification

The FAA adopted the ODA program expanding organizational delegation as a means to provide more effective certification services to the aviation industry. As stated in the final rule preamble, the level of industry certification project activity and needs continue to grow at a rate exceeding that of FAA resources, and expansion of the available authorized functions will reduce the time and cost for these certification activities. This is a shift toward a systems approach to certification and oversight through authorization of industry organizations with the appropriate capabilities and processes to make compliance findings on behalf of the FAA so it may better focus its resources on oversight and safety areas.

The basis for a systems approach to certification is increased responsibility and capability of applicants for compliance activities, which the FAA can recognize and rely upon to support a shift from discrete product-level show/find activities toward systems safety oversight. The maximum opportunity to achieve the potential benefits and efficiency of a systems approach to certification and oversight requires the applicant/DAH and FAA engineers to understand and fully embrace the concept of accountability framework (refer to section 4.1.2 of this report).

However, ODA programs are delegation, which means the FAA remains responsible for the discrete compliance activities. ODA certification programs depend on the traditional "show/find" certification process whereby the applicant is responsible to "show compliance" and the FAA through its own resources or its designees (such as ODA unit member) must "find compliance" for each individual discrete requirement. Although the FAA's oversight of the ODA organization facilitates increased delegation, the roles and responsibilities of industry and the FAA are mixed because delegation is reliance on industry resources to act on behalf of the FAA. Likewise, industry compliance activities rely on the FAA/ODA review and verification of its showing. In addition, the use of delegation is completely discretionary for the FAA, which means that on any given project or area of a project the FAA can decide to be directly involved at any level and even retain any discrete findings that it chooses.

FAA delegation to industry individuals and organizations is also challenged by significant public and political perceptions and misunderstandings. Following an aviation safety issue or incident, there are typically many concerns raised and challenges that question the level of delegation the FAA exercised in certification of the product. The FAA's discretion to fully utilize delegation and have a high level of direct involvement in certification projects can swing like a pendulum, which poses significant challenges in establishing an efficient certification process that is effective and predictable.

Therefore, simply optimizing ODA is not enough—an update to part 21 certification procedures to approve/certify design organizations that can make compliance determinations that the FAA can rely upon is necessary to achieve the full potential of a systems safety approach for effective and efficient certification processes. FAA approval or certification of DOs provides significant opportunity for improvements in safety, safety culture, and the overall effectiveness and efficiency of aircraft certification processes through an evolutionary shift to a full systems safety approach to certification and FAA oversight.

3.2 VISION FOR THE FUTURE

The ARC envisions a future in which the FAA continues its leadership in advancing efficient certification and effective safety risk management (SRM). Ideally, the certification workload would be managed by a risk-based system using approved processes that places responsibility and accountability on industry in designing and manufacturing products in compliance with all applicable requirements with minimal direct FAA involvement. This new certification system would be more robust than the delegation system currently in place, and would be based on accountability and risk using a systems approach to determine and oversee compliance. This system would significantly help the United States maintain its outstanding safety rating and protect competitiveness in an increasingly global aircraft manufacturing market. Without significant changes in the certification process, the U.S. industry will not be able to grow at the rate needed to keep up with the demands for new products while remaining competitive in the global market and meeting new mandates created by NextGen and other required programs.

Listed below are five primary attributes of the future certification system that would provide significant benefits to the FAA and industry.

1. Compliance assurance system for industry compliance determination;
2. A systems approach to FAA oversight;
3. Greater industry control of project schedules;
4. Better leveraging of FAA and industry resources, enabling the growth that the market demands; and
5. Industry compliance determination best practices.

Each of these attributes contains significant change, but also significant benefits that would contribute to a balanced certification system and allow for increased project capacity and continued safety enhancements. These five attributes are briefly described below.

3.2.1 COMPLIANCE ASSURANCE SYSTEM FOR INDUSTRY SHOWINGS

A compliance assurance system (CAS) in which the FAA can confidently accept industry compliance determinations without an additional finding of compliance will depend heavily on defined processes that are continually reviewed and updated to ensure all required activities are conducted in a consistent and acceptable manner. In contrast, the current process for finding compliance depends on a one-for-one show/find process. This process is frequently inconsistent and has a large number of variables because it lacks clearly defined and accepted means of compliance and personnel on both sides of the show/find equation have different levels of experience and interpret requirements differently. If the system has clearly defined processes that the applicant consistently follows, the FAA will be able to evaluate the health of the organization and develop trust in the system. This process also places more accountability on applicant management to ensure the processes are properly maintained and followed. The current process can be likened to a production system that attempts to inspect quality into a product rather than build it in.

3.2.2 Systems Approach to FAA Oversight

Taking a systems approach to industry compliance allows the FAA to also take a systems approach to oversight. In the desired future state, the current oversight process would transition from the traditional one-for-one show/find process to oversight of predetermined company processes. The FAA would perform oversight by reviewing an organization's self-assessment activities and auditing the processes. The FAA would not normally audit the results, unless a process was found to be deficient; if so, the FAA could review the results, or any other part of the process, to determine whether the results were unsatisfactory and whether any safety issues should be corrected. This approach reduces the amount of resources the FAA must allocate toward oversight and will enable it to allocate resources in an area of greater need.

3.2.3 Greater Industry Control of Project Schedules

Currently, the industry is subject to the FAA's availability to initiate certification projects. With the transition to a compliance assurance procedure (CAP), the industry will have full control of each project schedule and will move the FAA off the project critical path. This benefit will be seen through reduced product development time and cost, as well as potentially increased revenues by quicker product time to market and allocation of resources to areas other than FAA detailed project-level involvement.

3.2.4 Better Leveraging of FAA and Industry Resources

A systems approach allows for better leveraging of FAA and industry resources. Industry would be able to use resources that would normally be allocated to FAA detailed level of project involvement and product audits in areas of greater need such as project development and research and development (R&D). This enables a company to reduce its product time to market, have more control of project schedule, and eliminate sequencing or FAA resource and response wait times with a higher level confidence than for a product being developed in the current environment.

The FAA will experience similar benefits. By implementing a systems approach, the FAA can reduce the amount of resources allocated to support the find compliance process and product audits, and focus instead on the health of the organization. Additionally, with the increased demand of civil aviation, the FAA will be able to provide support at its current capacity with less concern of being able to keep up with industry demand.

3.2.5 Industry Compliance Determination Best Practices

Compliance by process is a main contributor to the overall performance-based system. This process depends on using FAA-accepted industry best practices for determining compliance. These best practices can be any of the following:

1. Industry standards such as SAE International (SAE), RTCA, Inc. (RTCA), or ASTM International (ASTM);
2. Company-developed and maintained compliance determination processes;
3. FAA advisory circulars (AC), policy, etc.;

4. A combination of the above when accepted by the FAA; or
5. Other FAA-accepted compliance determination processes.

These industry best practices are frequently referred to as a “compliance library.” Most companies can review existing compliance reports and select compliance determinations that are considered acceptable and easily create a standard for that regulation. These practices will take time to establish, but will result in a system that when properly constructed allows repeated, consistent compliance determination that is accepted by the FAA. Because the library defines how compliance will be determined for a particular regulation, many determinations can be accomplished by engineers with less experience, freeing the senior engineers to do more critical work. Having an FAA-accepted compliance library will increase the FAA’s confidence in the system and eliminate the need for find compliance inspections conducted through delegation.

3.3 Performance-Based Oversight (PBO) Recommendations

The recommended future oversight model is fundamentally composed of assessment and surveillance. The ARC envisions in the future the FAA will require minimum organization capabilities to justify application. Those capabilities and expanded capabilities will be determined by an FAA oversight assessment methodology. Similarly, the FAA will define capability requirements to become a DO. The same FAA assessment approach will be used to determine whether a company meets the DO qualifications. As that DO company develops additional capabilities that are further assessed by the FAA, it may gain additional privileges. In between the application, DO certification, and expanded privileges, the future FAA oversight will be surveillance of the company’s performance.

The future oversight model concept includes oversight for design/manufacturing organizations, product/article, and post-certification using COS processes. The three areas introduce levels of capability (organization), levels of project involvement (product/article), and levels of surveillance (post-certification). The model envisions a single FAA oversight presence for the three key areas:

- Organizational: Transition from traditional show/find compliance to an organizational PBO model.
- Products and Articles: Transition from the FAA’s traditional role of direct project involvement to a performance-based project oversight model. FAA participation will be limited to LOPI.
- Post-Certification Using COS Processes: Transition from traditional reactionary model to a systemic (process-based) surveillance model.

The future FAA oversight system will be based on two principles: PBO and compliance-based oversight (CBO). Each oversight principle has advantages and disadvantages, and collectively they balance the safety performance goals. PBO has greater advantages than CBO. PBO focuses FAA resources on areas of higher risk in the aviation system and moves the FAA from a total dependence on compliance findings, audits, and inspections to a more effective approach of monitoring safety and compliance performance data from the aviation industry. CBO is at point of manufacture/integration rather than storefront, while PBO can be virtual. Increases in compliance, conformity, and safety performance will adjust the traditional CBO activity and frequency.

Performance data has target goals that are mutually agreed to by the company and the FAA (vitals show the health of the company's compliance, conformity, and safety). A company maintains its system to move in the direction of acceptable/better performance. Developing performance indicators would enable selection of the indicators best suited to establish the safety and compliance health of a company. The types of indicators used could be added, deleted, or adjusted based on acceptable performance trends. The FAA could also identify minimum types of risk-based performance data the FAA should monitor.

The ARC recommends a dedicated FAA and industry effort to develop guidance for determining performance indicators that are mutually acceptable before implementing the new oversight model. Consideration for the effort would include review of an existing documentation such as the AVS Strategy and Framework to Manage Safety Performance in AVS document, dated June 30, 2013 (refer to appendix D to the Oversight Working Group Report, included as appendix H to this report). In addition, the development of the performance level indicators should consider the EASA approach, which intends to assign a performance level to a company based on performance parameters from its surveillance of the company's organization as well as its involvement in projects and activities. This is captured in the EASA Embodiment of LOI and SMS Requirements into Part 21 document (refer to appendix E to the Oversight Working Group Report).

4.0 HIGH-LEVEL RECOMMENDATIONS & IMPLEMENTATION

The Part 21/SMS ARC's objectives and tasks were to evaluate certain improvements to the effectiveness and efficiency of existing "certification procedures for products and parts," along with incorporating SMS in the design and manufacturing environment. This included considering the effects of certain changes to the existing regulations, such as applicant qualifications, hazard (or safety) reporting, compliance assurance, and COS assurance systems for all DAHs. The intent was to facilitate shifting toward a systems approach for product design approval/certification similar to that used for production approvals, which involves a clear understanding of roles, responsibilities, and privileges. The ARC's goal was to determine the best way the FAA and industry can effectively fulfill their respective compliance and safety responsibilities while improving the efficiency and robustness of the certification process.

In this report, the ARC provides four high-level recommendations on the following:

1. Phased implementation of a systems approach to certification.
   a. Promote accountability framework and enhanced applicant showings.
   b. Establish minimum requirements for design approval applicant/holder.
   c. Establish requirements for voluntary certificated DOs.
2. Application of SMS requirements to design and production approval holders.
3. Evolution of FAA oversight toward performance-based systems safety (SMS) approaches.
4. Part 21 miscellaneous cleanup and technical standard order (TSO) modernization.

Appendix E identifies all of the key considerations that support each of these four high-level recommendations and where they may be found in the report.

4.1 SYSTEMS APPROACH TO CERTIFICATION

The ACPRR ARC conducted an assessment of the aircraft certification and approval process, and the FAA's final report to Congress makes recommendations to streamline and reengineer to improve overall effectiveness and efficiency. A key recommendation is shifting the FAA certification process from a detailed product approach toward a systems safety approach.

Effective implementation of the shift from the current certification process and ODA procedures and the FAA's internal SMS for risk-based decisions on oversight and direct level of involvement in certification activity to a systems approach to certification leverages the FAA's limited resources and improves the efficiency of certification process. However, a reengineering update to part 21 certification procedures is necessary to achieve the full potential of a systems safety approach for effective and efficient certification processes. The ARC finds that following the systems approach to the certification method outlined in this report is a natural progression of the maturity and capability of current industry and FAA processes.

FAA approval or certification of DOs provides significant opportunity for improvements in safety, safety culture, and the overall effectiveness and efficiency of aircraft certification processes through an evolutionary shift to a systems safety approach. This is consistent with how the FAA provides safety oversight of aircraft production, air carrier operations, and repair stations. In addition, this approach to aircraft certification is used in Europe, Canada, and Brazil. The ARC strongly supports initiatives to continue shifting the aircraft certification and FAA oversight process toward a systems approach including the establishment of new regulatory requirements for design approval applicants/holders, SMS, and approved or certified DOs.

In support of an ongoing evolutionary shift to a systems approach to certification and the broad range of project activities, the ARC has structured its recommendations into a phased implementation using a building block approach.

4.1.1 Phased Implementation Using a Building Block Approach

Table 1 below provides a high-level view of the three phases the ARC anticipates in implementing the identified report recommendations. The three phases consist of "Today," "Transitional," and "Transformational," which stretch across a 7+ year timeframe to reach the goal of having certified DOs. There are individual actions and recommendations from different sections of this report within each phase for both industry and the FAA. This table should not be viewed as including all of the final, definitive requirements but as a high-level proposal to achieve the desired goal of a systems approach to certification and oversight through maturity of industry organizational and compliance capabilities to an approved DO (that is, the building block approach).

Table 1. Three-Phase Implementation of Systems Approach to Certification

<table>
<tr><th>Today
Near Term (0-3 Years)</th><th>Transitional
Intermediate Term (3-7 Years)</th><th>Transformational
Long Term (7+ Years)</th></tr>
<tr>
<td>Optimize ODA and organizational oversight.
Systems approach to certification—voluntary.
Enhance policy and understanding of accountability framework.
Promote enhanced showings (showing only, no discrete findings).</td>
<td>Develop and promulgate new Part 21 regulations:
Minimum organizational requirements for all design approval applicants and holders.
SMS requirements for certain organizations.
Compliance Assurance Procedures (CAP).
Compliance libraries.
Continue to mature oversight methods as the FAA transitions to a more systems safety-based oversight (SMS).</td>
<td>Develop and promulgate new Part 21 regulations for voluntary DO—a certificated organization with compliance verification process.
Feedback loop to ensure processes are continuously monitored and updated.
Reduction in designees.</td>
</tr>
</table>

The ARC has recognized that neither industry nor the FAA is ready to go directly to a mandatory DO implementation or to define a specific future date where we think robustness of industry compliance processes and FAA oversight will be ready. The phased implementation is a methodical, although slower, transition that allows both industry and the FAA to mature into a robust systems-based approach to safety. Upon completion of the phased building block approach, an applicant would be expected to have sufficient processes in place to meet the requirements of an approved DO. This allows the FAA and industry to properly shift their cultures and business structures without extreme cost while gradually obtaining benefits. With successful implementation of these building blocks, the ARC supports a future rulemaking to consider mandatory implementation of DO.

4.1.2 Systems Approach: Today—Near Term (0-3 Years)

The near-term activities focus primarily on improving the implementation of current certification processes and developing policies and guidance to promote a better understanding of systems approaches to certification and oversight and voluntary implementation/use in certain areas. A major focus in the near term needs to be a better understanding by both industry and FAA personnel of the accountability framework on which much of the remainder of the activities will depend.

Optimize ODA and Organizational Oversight

The FAA should continue to manage ODA initiatives as a priority, including the monitoring of field performance to ensure consistent implementation and intended benefits for both industry and the FAA. ODA streamlining and certification efficiency is characterized by "full utilization," which can be defined as ODA management of any function that is not inherently governmental.

Optimizing ODA will begin with the ODA holder developing defined processes it can use to satisfy the ODA and certification requirements. As these processes are developed and validated in accordance with an FAA-approved procedures manual, the ODA holder will be granted additional approvals to perform the applicable tasks with minimal direct involvement and will rely more on the processes to ensure the ODA holder is performing the tasks in a satisfactory manner.

These processes must cover all aspects of an ODA holder's responsibilities. This would typically include all administrative requirements as well as maintaining the appropriate design documents, training, and personnel records; developing a compliance library and COS procedures, etc.

There should be a continuous effort on the part of both the ODA holder and the FAA to review all ODA limitations and identify areas where improvements can be made to reduce FAA direct involvement.

Maximizing the full capacity of ODA will further reduce the FAA's certification workload. This will ensure alignment with the objectives to improve efficiency, reduce cost, and redirect FAA resources to enable development of new products and technologies and establish a strong foundation for building blocks toward DO.

Systems Approach to Certification—Voluntary

The ARC finds that FAA certification of DOs is a natural progression of the maturity and capability of organizational delegation that provides a significant opportunity for improvements in safety, safety culture, and the overall effectiveness and efficiency of aircraft certification processes.

One of the biggest challenges related to the systems approach to certification is the maturity and robustness of processes and the cultural shift that must occur with both industry and the FAA. Accomplishing this cultural shift will require education, patience, diligence, and perseverance on both sides. Using a phased approach is the most realistic method of achieving a transition to a systems approach to certification and oversight. The basis for a systems approach to certification is increased responsibility and capability of applicants for compliance activities, which the FAA can recognize and rely upon to support a shift from discrete product-level show/find activities toward systems safety oversight. Several examples of voluntary approaches between industry organizations and the FAA reflect a systems approach to certification on specific tasks. This is based on the concept of the accountability framework and applicant enhanced showings.

Accountability Framework

To optimize a systems approach, it is critical that the applicant/DAH, along with the ODA holder and FAA ACO, understand and fully embrace the concept of the accountability framework. The underlying premise of the accountability framework is that applicants and approval holders have full responsibility (legal and regulatory) for compliance with all applicable requirements (refer to 14 CFR). The FAA Administrator has the authority under the statutes to exercise discretion in promulgating airworthiness regulations and standards in the interest of safety, and defining by regulations and directives how the FAA will oversee compliance by those it regulates. Amendment 92 to §§ 21.20 and 21.97, effective April 16, 2011, provides the regulatory basis for the company statement of compliance, and AC 21–51, Applicant's Showing of Compliance and Certifying Statement of Compliance, provides clear guidance on the intent of the accountability framework.

The practical implementation of the accountability framework is for the FAA to exercise its discretion on the level of involvement necessary to make a finding that the applicant has shown compliance with all the applicable requirements before issuing a design approval. In the current show/find process, the FAA is involved in nearly 100 percent of all discrete compliance activities but this is not required. The FAA may rely on an applicant's showing and not make a discrete finding based on demonstrated capability or accepted processes. Increased reliance and acceptance of applicant showings and the ability for the FAA to focus its resources primarily in risk-based areas will require both additional training on the technical aspects of robust processes and a cultural shift in responsibilities.

Enhanced Showings

This phased approach begins moving toward a more uniform and consistent approach to those activities the applicant must perform. Among those processes would be FAA and industry agreed-upon standards for performing such tasks as burn testing, an FAA-approved compliance library, and a process for receiving and processing field reports to ensure the continued airworthiness of products. It is anticipated that the compliance library could be an individual library for each applicant or a consensus standard developed by industry and the FAA that is available for anyone to use. The benefit of a consensus-based means of compliance is that it takes advantage of input from numerous sources, including other CAAs, to ensure all aspects of an issue are covered, and it can reduce the number of different means of compliance the FAA would have to approve. This would significantly reduce the need for direct FAA involvement for most projects and would allow the applicant more flexibility to meet their schedules. Once the standard procedures are developed and an applicant documents compliance to those procedures, the FAA involvement would depend on the LOPI deemed necessary by the FAA based on the risk. It should be noted that there will be overlap from one area to the next in some of the objectives.

Table 2 below depicts the requirements for a low, medium, or high risk project to determine the FAA LOPI privilege. The objective is to decrease the LOPI as the capability of the applicant increases.

Table 2. Near-Term Systems Approach to Certification

Project Risk Level	Requirements to Earn LOPI Privilege	Begin Implementing Today
High	The safety assurance feedback loop has been achieved when the ability to ensure COS tracking and compliance verification has been accomplished through a systems approach to safety.	Creates a feedback loop (or safety assurance function) that allows high-risk projects to be reduced to medium or low risk.
Medium	Approved Compliance Assurance Procedures (CAP). Example: CAP for flammability.	
Low	Documented and agreed-upon means of compliance. Self-audit program.	

Recommendation 1a—Systems Approach to Certification – Voluntary Initiatives: The ARC recommends that the FAA issue policy and guidance to promote the understanding of the accountability framework as a basis for a systems approach to certification and facilitate voluntary approaches to implementation through FAA recognition and acceptance of applicant enhanced showings. (Refer to section 10.2 of this report.)

4.1.3 Systems Approach: Transitional—Intermediate Term (3-7 Years)

The intermediate "Transitional" phase will focus on new part 21 requirements to clarify applicant responsibilities and continue maturing applicant compliance processes. This includes new requirements for applicants to show a minimum level of understanding of certification processes to make application to the FAA as well as the application of SMS requirements into the certification and COS processes for certain organizations. Throughout this phase, applicant CAPs and FAA oversight will continue to mature in robustness and capability.

New Minimum Organizational Requirements for All Design Approval Applicants and Holders

One of the effects of shifting from a detailed product approach to a systems approach to certification is the increased responsibility on the applicant to know and understand the regulations, certification process, and applicable airworthiness requirements before starting a project. The current part 21 requirements do not require the applicant to have any knowledge or capability, so often much of the work falls on the FAA to educate applicants on certification processes and airworthiness requirements and to ensure the applicant carries out their responsibility to show compliance. For applicants that do not have experience or understanding of the certification requirements and processes, this introduces a significant number of unknowns that result in projects that can require significant back-and-forth with the FAA and can take a substantial amount of time beyond the intended schedule and budget. There is also a significant impact on the FAA due to increased workload and a high level of involvement in detailed project activities that often result in incomplete certification projects. This has a much broader impact across the industry as inefficient use of FAA resources detracts from other safety activities and certification projects.

The ARC proposes changes to part 21 to more clearly define the minimum regulatory requirements for all design approval applicants and holders to ensure they understand the responsibilities of an applicant and to explain to the FAA how they intend to carry them out. The ARC's recommendation for minimum applicant/holder requirements is discussed in detail in section 9 of this report.

> **Recommendation 1b—Systems Approach to Certification – Minimum Applicant/Holder Requirements:** The ARC recommends establishing minimum requirements for design approval applicant/holder qualification and responsibilities to ensure they fully understand the type certification process and how they intend to carry them out.

New SMS Requirements

The ARC recommends applying most of the requirements of the proposed part 5 to certain design and production approval holder organizations and incorporating these elements into certification and COS processes. The ARC's SMS recommendation is discussed in detail in section 4.2 below.

CAPs and Compliance Libraries

The evolution to a systems approach requires increased responsibility and capability of applicant processes and compliance activities consistent with the accountability framework. To support efficient certification processes and the ability for increased FAA recognition of applicant enhanced showings, the ARC recommends the development of policy/guidance to formally establish compliance libraries and a CAP. Any applicant can establish a compliance library that reflects those methods acceptable to the FAA and with which the applicant has demonstrated experience. This allows for efficient acceptance of the same methods of compliance for similar projects in the future. Organizations will implement SMS and CAPs that provide robust verification and monitoring of safety and compliance activities within their safety assurance functions. In conjunction with appropriate oversight, this can recognized and relied on by the FAA as enhanced showings without need for discrete compliance findings.

Continue to Mature Oversight Methods in the Transition to a More Systems Safety-Based Oversight

The ARC recommends that the FAA continue to mature performance-based oversight methods throughout this phase and that the FAA define reporting requirements. This will provide an opportunity to test and evaluate feedback processes that provide a clear picture of FAA and industry activity and will assist in identifying areas that may need assistance, or different reporting methods or data. The ARC's oversight recommendation is discussed in detail in section 4.3 below.

4.1.4 Systems Approach: Transformational—Long Term (7+ Years)

The transformational period will be critical in terms of completing the transition to approved DOs. It will depend highly on how successful the previous phases were in meeting their objectives.

New DO Requirements

Recommendation 1c—Systems Approach to Certification – DO Requirements: The ARC recommends establishing regulatory requirements for the issuance and oversight of voluntary certificated DOs, including the necessary compliance assurance, safety management, and controls to make all compliance determinations through applicant showing and verification processes. Through FAA DO certificate management oversight and direct project involvement in defined risk-based areas, the FAA may rely on the DO compliance determinations to make its finding for the issuance of a design approval. This report builds on the recommendations submitted to the FAA by the CDO ARC in May 2008. The ARC recommends a building block approach to implementing DO, which includes establishing a clear accountability framework, transitioning the FAA's oversight of design activities to a centralized systematic model, optimizing use of ODA, and implementing new organizational and SMS requirements. With successful implementation of these building blocks and voluntary DO, the ARC supports future rulemaking to consider mandatory DO.

Feedback Loop

The ARC recommends that feedback loops be created that will provide information on the activities throughout the transition to ensure the transition is moving in the direction that supports reaching DO status during the third phase. Following the transition to DO, there will still need to be feedback loops to ensure all of the processes are functioning as intended and to assist in spotting issues that one or more DOs may be having that may need to be addressed either individually or as a group. However, the feedback loops used during the transition may not continue into the mature DO stage or may be modified to provide different types of information or at different frequencies.

Reduction in Designees

The ARC recognizes the need for designees and ODA UMs will be reduced when the transition to DO occurs. However, it is expected that the designees will continue to function in much the same role as they do today for much of the certification work. Their technical expertise will still be needed to help maintain the compliance libraries and determine compliance on which the company statement of compliance can rely.

4.2 Safety Management Systems Requirements

The ARC's vision for the future of the FAA certification process depends on a systems-based approach by both industry and the FAA. The goal of this approach is to gain efficiencies and maintain effectiveness while also increasing the safety of the aviation system as a whole. Thus the ARC envisions SMS to be an integral part of an organization's processes for type certification compliance and post-TC COS processes.

An SMS includes an organization-wide safety policy, formal methods for identifying hazards, controlling and continually assessing risk, and promoting a safety culture. When systematically applied, an SMS provides a set of decisionmaking tools that certificate holders can use to improve safety. SMS requires a proactive approach to discovering and addressing hazards before they exhibit safety consequences. SMS also includes processes to assess potential organizational and process changes to ensure a compliant conformed product or article and the proper functioning of the COS processes, which allow management to address a safety issue before a noncompliant or unsafe condition results. SMS is not a substitute for compliance with FAA regulations or FAA oversight activities.

The ARC's SMS Working Group analyzed current requirements and planned future requirements in the proposed part 5, and developed a concept of operations (CONOPS) describing the practical application of part 5 for design and manufacturing (D&M) organizations. Consistent with ICAO guidance, the ARC recommendations allow a phased approach to implementation, with a manageable series of steps to follow including allocation of resources, effectively managing the workload associated with implementation, and providing for a realistic implementation of an effective SMS (avoiding a "cosmetic compliance"). This phased approach is described in more detail in sections 5.1.5 and 5.1.6 of this report.

Recommendation 2—SMS Requirements: The ARC recommends establishing regulatory requirements for implementing SMS consistent with the proposed part 5 for design and production approval organizations. This new requirement should apply to organizations that design or manufacture type-certificated products (under a TC or production certificate) and those that design or manufacture articles (under a TSO or parts manufacturer approval (PMA)) or make changes to products (under a supplemental type certificate (STC)) that could directly prevent continued safe flight and landing if they fail.

For additional details on the ARC's SMS evaluation and recommendations, refer to section 5 of this report.

4.3 Evolution of Oversight

Establishment of a systems approach to certification requires a different approach to FAA oversight of an applicant or DAH. Using FAA-approved standards for determining compliance will require the FAA to develop and implement processes for ensuring the applicant is following their approved processes rather than looking at discrete findings of compliance except as necessary to support the procedures-based oversight. In turn, industry must develop robust processes that demonstrate compliance and can be used as part of an FAA-approved compliance library. The oversight process will also ensure the appropriate SMS requirements are included in the applicant's processes. Additionally, an applicant's quality management system (QMS) should ensure a continuous self-evaluation and improvement process is in place to identify processes that need to be revised and the corrective action process to address those issues.

The development of this new approach to oversight will be best managed using a centralized FAA oversight system to provide consistent and progressive assessment and surveillance processes leading to performance-based standards.

Establishing a central FAA oversight organization will—

- Achieve standard surveillance practices.
- Centralize policy responsibility ensuring consistency in interpretations.
- Allow the ACO to focus on safety-critical functions.
- Provide "third-party objectivity," as the office does not work programs with the DO.
- Provide a single source/repository for the oversight data, which will drive the risk-based modeling controls.
- Manage skill development practices for the surveillance staff.
- Allow for a highly trained staff in system surveillance.
- Provide a single source for oversight of corrective actions.

Recommendation 3—Evolution of FAA Oversight Toward Performance-Based Systems Safety (SMS) Approaches: The ARC recommends development of a performance-based single surveillance oversight approach that aligns with proposed changes to design and production organizational requirements and a systems approach to certification. The three key oversight areas are: (1) Organizational—transition from traditional show/find compliance to organizational PBO model; (2) Product and Articles—transition from the FAA's traditional role of direct project involvement to a LOPI approach focused on performing governmental functions and enhanced showing capabilities; (3) Post-Certification (COS)—transition from a traditional reactionary approach to a systemic (process-based) surveillance model. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data that will drive the risk-based modeling controls, and allow for a highly trained staff in system surveillance, skill management, and a single source for corrective actions. As companies continue to evolve to a systems safety-based certification and organizational oversight, a centralized FAA oversight system will provide consistent and progressive assessment and surveillance processes leading to the performance-based standard.

The detailed recommendations for this process are found in section 3.3, section 9, and appendix H of this report.

The ARC developed proposed practices for FAA oversight that correlate with recommended D&M organizational changes. This enables a shift to performance-based oversight where the FAA can effectively allocate resources based on D&M system risk management performance, and moves the FAA from a total dependence on discrete compliance findings, audits, and inspections.

Figure 3 illustrates the stepping stone to oversight as envisioned by the ARC and is designed to align with the table 1 above.

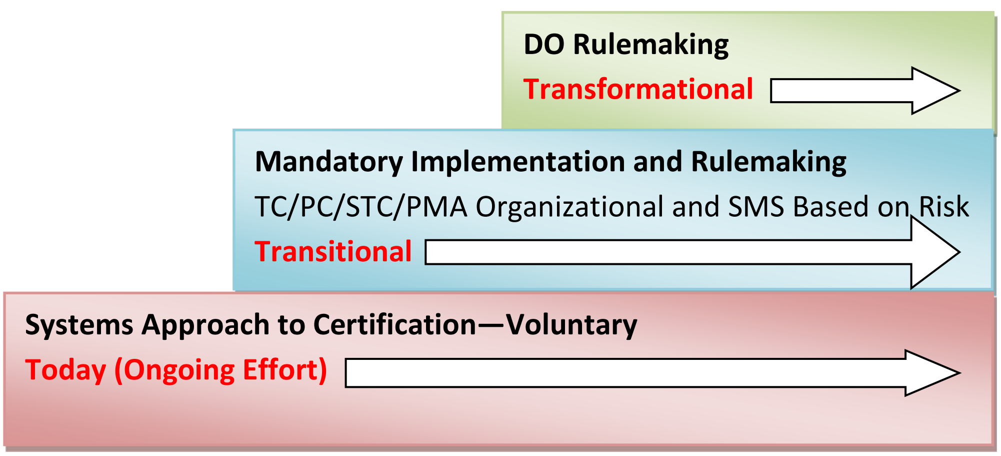

Figure 3. Evolution of Oversight

4.4 PART 21 MISCELLANEOUS CLEANUP AND TSO MODERNIZATION

The Part 21 Cleanup section was developed based on the broad nature of this ARC. There were many items to be addressed within part 21 that may have been deemed insignificant, or that could not be grouped with one of the other three primary recommendations. However, the ARC felt these items were significant enough to address and should not go unaccounted for. The part 21 cleanup items can be grouped into three subject areas:

1. Recommendations to simply clean up issues that would eliminate confusion and inability to comply in the current regulation, if addressed.
2. Response to recognition of part 21 related recommendations from the Part 23 Reorganization ARC to reduce costs related to certification.
3. Changes to § 21.3 reporting, which also aligns with SMS and part 183, Representatives of the Administrator, § 183.63.

The details of these recommendations can be found in section 9 of this report.

The ARC's TSO Subteam recommends a number of changes to modernize the TSO process that require changes to part 21. However, some of these recommendations can be addressed by policy changes and do not require part 21 rule changes. These proposals are discussed in detail in sections 9.1.3 and 9.2 of this report. The ARC believes those TSO modernization changes that do not require rule changes could be accomplished in the first of the three phases.

Recommendation 4—Part 21 Cleanup and TSO Modernization: The ARC recommends FAA consideration of several proposed changes and updates to various part 21 regulations, which primarily reflect clarifications to eliminate confusion, modernization to reflect current practices, and updates to align with other recommendations in this report for a systems approach to certification.

5.0 SMS RECOMMENDATIONS AND REQUIREMENTS

5.1 SMS IMPLEMENTATION

5.1.1 SMS RECOMMENDATIONS

The ARC's vision for the future of the FAA certification process depends on a systems-based approach by both industry and the FAA. The goal of this approach is to gain efficiencies and maintain effectiveness while also increasing the safety of the aviation system as a whole.

An SMS includes an organization-wide safety policy, formal methods for identifying hazards, controlling and continually assessing risk, and promoting a safety culture. When systematically applied, an SMS provides a set of decisionmaking tools that certificate holders can use to improve safety. SMS requires a proactive approach to discovering and addressing hazards before they exhibit safety consequences. SMS also includes processes that seek to assess organizational changes to allow management to address a noncompliant condition before an unsafe condition results. SMS is not a substitute for compliance with FAA regulations or FAA oversight activities.

The ARC's SMS Working Group performed a gap assessment of the current part 21 requirements to the proposed part 5 requirements (refer to appendix G to this report). The working group determined part 21 only partially addresses the requirements of the proposed part 5, primarily through meeting the airworthiness standards and quality system requirement. Therefore, gaps in safety management exist that must be closed by the application of SMS.

In addition, ICAO Annex 19, Safety Management, mandates the implementation of an SMS for organizations responsible for design and/or manufacture of aircraft. The United States must adopt a system meeting the ICAO standards as a member state.

In consideration of the above, the ARC recommends SMS be applied to D&M organizations. Refer to the National Air Traffic Controllers Association's (NATCA) dissenting opinion of section 5.1.1 in section 12 of this report.

The ARC has determined the SMS requirements in the proposed part 5, with consideration given to D&M sector comments for recommended changes contained in the docket, are appropriate for D&M organizations. In addition, the ARC evaluated the proposed § 5.27, Coordination of emergency response planning, and determined it is not necessary for D&M organizations. <u>Therefore, the ARC recommends the FAA modify part 21 to make part 5, excluding § 5.27, the SMS requirements for organizations meeting the SMS applicability threshold.</u>

The ARC recommends the proposed part 5 be referred to by the appropriate part 21 regulations because it was determined to be applicable (with only minor deviation), minimizes the regulatory revisions required to implement, ensures harmonization with FAA and ICAO SMS requirements, and allows for efficient oversight by the FAA.

5.1.2 SMS Applicability

ICAO Annex 19 only requires SMS for organizations that design or produce products (aircraft, engines, and propellers). That requirement does not include DAHs for STCs, PMAs, or TSOs. Several ways to apply SMS requirements to D&M organizations were considered:

- Organizations that design or manufacture products (that is, aircraft, engines, or propellers);
- All D&M organizations that hold a design approval (that is, a TC, STC, PMA, or TSO) or hold a production certificate to manufacture products or articles; and
- Certain D&M organizations based on safety risk.

The ARC considered the scope of applicability for SMS and determined it should be based on safety risk. To that end, applying SMS to only the product-level D&M organizations does not adequately address safety risk as it does not apply to many aspects of COS, and an SMS requirement for all D&M organizations would be too broad, including organizations with minimal impact to increased safety risk. A risk-based approach provides a fair solution among small and large businesses and among various business structures.

Based on the SMS Working Group's considerations and recommendation, the ARC makes the following recommendation for SMS applicability to D&M organizations.

<u>The ARC recommends the FAA and industry develop guidance for an SMS applicability threshold requiring an SMS for organizations that—</u>

- <u>Design or manufacture products (that is, aircraft, engines, or propellers);</u>
- <u>Design or manufacture articles (TSO, PMA) whose failure could directly prevent continued safe flight and landing; or</u>
- <u>Make design changes to a product through an STC, failure of which could directly prevent continued safe flight and landing.</u>

Note that this recommendation is not intended to discourage voluntary implementation of SMS for organizations producing articles with criticality falling below the SMS applicability threshold.

> **Recommendation 2—SMS Requirements:** The ARC recommends establishing regulatory requirements for implementing SMS consistent with the proposed part 5 for design and production approval organizations. This new requirement should apply to organizations that design or manufacture type-certificated products (under a TC or production certificate) and those that design or manufacture articles (under a TSO or PMA) or make changes to products (under an STC) that could directly prevent continued safe flight and landing if they fail.

5.1.3 SMS Application to D&M Organizations Without a Certificate

Other regulatory authorities have applied SMS to the aviation industry by linking SMS with an "operating certificate" (such as a maintenance organization approval, operator certificate, or production approval) that allows the organization to conduct specific activities/operations. The SMS is a condition of initial certificate issuance and ongoing certificate maintenance. A discrete SMS approval is not issued; instead, the "operating certificate" is issued when the applicant/holder demonstrates the organization meets all certificate requirements, including those for SMS. In this case, deficiencies in the SMS can lead to the regulator refusing initial certificate issuance, or taking certificate action such as fines or limited certificate privileges.

Application of an SMS to the U.S. aeronautical product design industry is challenging, as no "operating certificate" exists similar to other aviation industry sectors. The main organizational approval (ODA) is a "delegation" from the FAA, and is not an "operating" certificate. The main certificates issued by the FAA are specific product design approvals (for example, TCs, STCs, TSOs, or PMAs) issued to a holder. The design approval confers no "operating" privileges to the holder, other than the ability to assign a production organization to produce the design under an FAA certificate or approval.

To apply the SMS requirements to non-certificated organizations, the SMS requirement should be applied through part 21 to design approval applicants and DAHs as follows:

- Part 21 TCs and STCs. If the design to be approved/held meets the SMS applicability threshold, the applicant/holder should have an SMS per part 5.
- Part 21, subpart K—PMA. If the article meets the SMS applicability threshold, the applicant/holder should have an SMS per part 5.
- Part 21, subpart O—TSO. If the article meets the SMS applicability threshold, the applicant/holder should have an SMS per part 5.

Regarding production organizations, it would be consistent to have any organization producing a part/product that requires an SMS from a design approval perspective (as outlined above) to also have an SMS as follows:

- Part 21 Production (PC for TCs and STCs). If the product to be produced meets the SMS applicability threshold, the applicant/holder should have an SMS per part 5.

5.1.4 SMS Acceptance/Oversight

The FAA should develop an approval document (letter or certificate) to indicate FAA acceptance of the organization's SMS and any associated limitations and conditions. In addition, the FAA should establish methods to address deficiencies in the organization's SMS, because FAA certificate action will not be effective for an organization without an FAA certificate. The traditional means of FAA compliance and enforcement procedures can be updated to clarify how to apply to non-certificated organizations to ensure compliance with SMS implementation requirements.

5.1.5 SMS With Different Design and Production Organizations/Different Countries

Given the evolving nature of the D&M industry, DAH organizations with different production organizations, and even production organizations in different countries (and therefore under different State of Design/State of Manufacture authorities), are not uncommon. From an SMS perspective, this means the potential for two SMS systems in different companies and potentially under different national authorities. In these cases, there should be appropriate coordination between the two organizations' SMS systems and their regulators (if in different countries). The ARC recommends the FAA work with other authorities and SMS teams to review requirements and establish guidance as required.

5.1.6 SMS Implementation

SMS implementation strategy for D&M organizations should maintain alignment with the ICAO Safety Management Manual (SMM). The document allows a phased approach to implementation, with a manageable series of steps to follow, including allocation of resources, effectively managing the workload associated with implementation, and providing for a realistic implementation of an effective SMS (avoiding a "cosmetic compliance").[1]

There are four levels to SMS implementation:[2]

- **Level 1: Planning and Organization.** This consists of orientation, defined safety policy, gap analysis (preliminary and detailed), an SMS training plan, and an implementation plan.
- **Level 2: Reactive Processes, Basic Risk Management.** The organization develops and implements a basic SRM process. The organization is engaged for further SMS development.
- **Level 3: Proactive Processes, Looking Ahead—A Fully Functioning SMS.** This consists of applying the SRM to the initial design of systems, processes, organizations, and products.
- **Level 4: Continuous Improvement, Continued Assurance.** This level is achieved when all SMS processes have been implemented and their performance has been verified.

5.1.7 Effective SMS Requirement Dates for D&M Organizations

The timeline for initial SMS implementation for D&M organizations meeting the SMS working group's applicability threshold would be similar to that for the current proposed § 5.1, Applicability. Modification of the appropriate sections of part 21 would point to the SMS requirement of the proposed part 5. The ARC recommends § 5.1 refer to the period of time following the *approval* of an implementation plan, rather than the *effective date* of the final rule, as the deadline for an accepted SMS. This would allow sufficient time to work with the FAA on revising the submitted implementation plan and to develop and enact proper processes.

[1] FAA: SMS Implementation Guide, Rev 3
[2] D&M SMS Pilot Project Guide, Rev C

For organizations that have already implemented an SMS, evidence of a suitable SMS could be submitted to the FAA within the implementation plan submittal deadline. The suitable evidence would consist of details such as a detailed gap analysis, previous voluntary implementation plan, and records from all levels of the active SMS that demonstrate meeting the requirements. If deficiencies are found, a streamlined implementation plan would be submitted to address those deficiencies within the mandated timeline to have an accepted SMS. Otherwise, if found acceptable, the SMS would be accepted immediately.

5.1.7.1 Existing DAHs/PAHs Meeting the SMS Applicability Threshold

Existing D&M organizations holding a design or production approval should submit an implementation plan within 6 months of the rule's effective date, and have a full SMS within 3 years of an approved implementation plan.

For new applications by an existing D&M holding a design or production approval, the requirement to have an SMS should still be dictated by the above requirements.

5.1.7.2 New Applicants for DAHs/PAHs Meeting the SMS Applicability Threshold[3]

New applicants for a design or production approval would be held to the same timelines as current D&M organizations. However, the implementation plan should be submitted at the time of application and must be approved by the FAA before issuance of a design approval, production approval, or PMA. The full SMS would be required within 3 years of the implementation plan approval. A requirement to have a fully functioning SMS on initial design approval, production approval, or PMA issuance may be unrealistic or cost-prohibitive due to resources required within a short timeframe. Because the timeline required to have a fully implemented SMS is the same as that required for current D&M organizations at the final rule issuance, allowing new D&M organizations to enter the market with the same grace period afforded to the existing D&M organizations retains fair treatment of new organizations. This process also requires the applicant to show full understanding of the COS and safety requirements (that is, an understanding of certain aspects and responsibilities of part 21 requirements) before a design approval, production approval, or PMA can be issued.

[3] That is, currently not holding a design or production approval.

5.1.7.3 Proposed Regulatory Text for SMS Implementation

The following provides the ARC's recommended regulatory text for the implementation of SMS upon design and production approval holders.

The changes to § 21.135, Organization, are intended to satisfy the requirements for an SMS process for production certificate holders.

§ 21.135 Organization

Each applicant for or holder of a production certificate must—

(a) Provide the FAA with a document describing how its organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

(b) Within 3 years after the FAA approval of the implementation plan for design and manufacturing, each applicant for or holder of production certificate for a product or change to a product whose failure could directly prevent continued safe flight and landing must have a safety management system that meets the requirements of part 5 of this chapter (except § 5.27) and is acceptable to the Administrator. The applicant for or holder of a production certificate required to have a safety management system must—

(1) Submit an implementation plan to the FAA Administrator for review no later than [date 6 months after the effective date of the final rule for existing production certificate holders, or with the application for a new production certificate].

(2) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of part 5 of this chapter.

The changes to § 21.305, Organization, are intended to satisfy the requirements for an SMS process for PMA certificate holders.

§ 21.305 Organization

(a) Each applicant for or holder of a PMA must provide the FAA with a document describing how its organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

(b) Within 3 years after the FAA approval of the implementation plan for design and manufacturing, each applicant for or holder of a PMA whose failure could directly prevent continued safe flight and landing must have a safety management system that meets the requirements of part 5 of this chapter (except § 5.27) and is acceptable to the Administrator. The applicant for or holder of a PMA required to have a safety management system must—

(1) Submit an implementation plan to the FAA Administrator for review no later than [date 6 months after the effective date of the final rule for existing PMA certificate holders, or with the application for a new PMA].

(2) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of part 5 of this chapter.

The changes to § 21.605, Organization, are intended to satisfy the requirements for an SMS process for TSO certificate holders.

§ 21.605 Organization

(a) Each applicant for or holder of a TSO must provide the FAA with a document describing how its organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

(b) Within 3 years after the FAA approval of the implementation plan for design and manufacturing, each applicant for or holder of a TSO whose failure could directly prevent continued safe flight and landing must have a safety management system that meets the requirements of part 5 of this chapter (except § 5.27) and is acceptable to the Administrator. The applicant for or holder of a TSO required to have a safety management system must—

(1) Submit an implementation plan to the FAA Administrator for review no later than [date 6 months after the effective date of the final rule for existing TSO certificate holders, or with the application for a new TSO certificate holder].

(2) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of part 5 of this chapter.

The following text would be included as part of any new regulation for minimum design approval applicant and holder regulatory requirement to satisfy the requirements for an SMS process for design approval holders.

(e) Within 3 years after the FAA approval of the implementation plan for design and manufacturing, each applicant for, or holder of, a type certificate or for a product or change to a product whose failure could directly prevent continued safe flight and landing must have a safety management system that meets the requirements of part 5 of this chapter (except § 5.27) and is acceptable

to the Administrator. The applicant for or holder of a type certificate required to have a safety management system must—

(1) Submit an implementation plan to the FAA Administrator for review no later than [date 6 months after the effective date of the final rule for existing design approval holders, or with the application for a new design approval].

(2) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of part 5 of this chapter.

5.1.7.4 New Applicants for DAH/PAHs Meeting the SMS Applicability Threshold After 3 Years of Rule Effective Date

Once 3 years has passed since the rule's effective date, a full approved/accepted SMS would be a requirement for the applicant at the time of application. The 3-year phase-in period for the SMS requirement would allow sufficient time for new applicants to prepare before proceeding with an application.

5.1.7.5 Voluntary Implementation for Current and New D&M Organizations

Voluntary submittals of implementation plans or evidence of an existing active SMS can be made at any time. The FAA resources would be prioritized to those D&M organizations requiring an SMS based on the applicability threshold; therefore, those D&M organizations with the highest risk would be being evaluated first. Subsequent prioritizations could be based on FAA RBRT criteria if resource restraints prevent immediate FAA review.

5.2 OTHER PARTY SMS ACCREDITATION

5.2.1 SUMMARY

The international scope of ICAO Annex 19 suggests SMS requirements can be uniquely defined on the country/state level. This creates a concern within industry because of the potential of having to comply with a complex array of SMS requirements. The ARC believes developing an "other" party recognition or accreditation could solve this problem. The proposal presented here is to adopt a model similar to the current aviation standards associated with QMS (via the International Aerospace Quality Group (IAQG)) to apply to SMS for D&M organizations.

5.2.2 DEFINITIONS

AS9100/AS9110. International standards that include ISO 9001, Quality Management System, requirements and specifies additional requirements for a QMS for the aerospace industry.

International Organization for Standardization (ISO) 9001. A quality systems model for quality assurance in design, development, production, installation, and servicing.

5.2.3 Organizations

IAQG—International Aerospace Quality Group. "The IAQG Council sets the policy, purpose, and objectives of the organization and drives initiatives to meet the goals and objectives of the organization. There are 26 Council Voting Members; 10 from the Americas, 10 from Europe, and 6 from Asia-Pacific."[4]

AAQG—Americas Aerospace Quality Group. "The AAQG is a cooperative organization within the aerospace industry in the Americas (including North, Central, and South Americas). Its processes are established in a set of agreed, documented, operational procedures."[5]

5.2.4 "Other Party"—IAQG Definition

"The Other Party Scheme is based on—

- The use of identical or equivalent international, sector, and national standards based on the 9104/1/2/3 trilogy of standards;
- An industry oversight system at international, sector and national levels to ensure that scheme's requirements are fulfilled; and
- Auditors authenticated against identical requirements."[6]

5.2.5 "Other Party" Management Team Standards

9104–1 Requirements for Aerospace QMS are—

- Certification/Registrations Programs, and
- Globally harmonized standard defining the certification/accreditation process.

9104–2 Requirements for Oversight of Aerospace QMS Registration/Certification Programs

- Globally harmonized standard defining the surveillance and oversight processes.

9104–3 Requirements for Aerospace Auditor Competency and Training Courses

- Globally harmonized standard defining the auditor qualification and auditor training processes.

5.2.6 "Other Party" SMS

Requirements for SMS:

- Based on ICAO Annex 19.

Oversight of SMS:

- Based on SMS ICG Evaluation Tool.

[4] http://www.sae.org/iaqg/organization/council.htm.
[5] http://www.sae.org/aaqg/.
[6] http://www.sae.org/iaqg/organization/opmt.htm.

Auditor Competency and Training Courses:

- Analogous to IAQG.

The proposed plan is to work initially with the AAQG toward a new set of standards (AS91xx–1/2/3) based on the above to leverage existing local and international groups.

The primary advantage of this approach is the ability to begin implementing this activity immediately. It also serves as one of the bricks in the "building blocks" approach detailed in section 10 of this report. This timely approach also provides a means for D&M companies that are voluntarily implementing SMS aligned with ICAO Annex 19 intent to get validated without waiting on proposed regulations (part 21/part 5) that face cost-benefit challenges.

5.3 Additional SMS Recommendations

The SMS Working Group, comprised of industry and FAA subject matter experts, developed SMS regulatory material and a basis for preamble, policy, and guidance material as provided in this report. However, the working group determined additional work is necessary to produce detailed guidance material for the practical implementation of SMS requirements to part 21 design and production approval holder organizations and processes. The ARC tasked the working group to develop a framework for additional guidance, which will be provided as an addendum to the SMS Working Group Report (included as appendix G to this report). The ARC recommends that this guidance material be fully developed by the subject matter experts that comprised the SMS Working Group before the issuance of an SMS notice of proposed rulemaking (NPRM), so it is available for concurrent review and comment.

Specific guidance that requires further development includes—

- How safety objectives are established;
- Evaluating the performance of an organization's SMS;
- Development of an "operational" definition of a hazard throughout the life cycle of a product;
- Acceptable criteria for the effectiveness of safety risk controls at a system level;
- A process the D&M organization implements to meet § 5.55(b), Safety risk assessment and control, and the extent to which the FAA is engaged; and
- Flexibility in applying SMS to the D&M organization.

Notwithstanding the gap assessment (refer to section 4.1 of appendix G to this report) that identifies regulatory gaps between part 21 and part 5, the D&M community has established business practices that accomplish, to varying degrees, the intent of SRM and safety assurance as part of its design, certification, production, and continued airworthiness efforts (although not using the SMS terminology). However, much of what has been written about SRM and safety assurance has been from an operational perspective (for example, air carrier flight operations or airport air traffic operations), and limited documentation/guidance exists for how these SMS elements relate or are equivalent to what D&M organizations do as part of their compliance to the current airworthiness regulations and design and certification procedures.

To ensure the intent of SRM and safety assurance is applied to D&M organizations in the most effective and efficient manner, the ARC recommends the interpretations and explanations provided herein be included in any preamble, policy, or guidance material. Also, depending on the future state of delegation and approved or certificated organizations, regulation, policy and guidance should allow an organization to use the same processes and procedures to satisfy the intent of the equivalent regulations. This approach would minimize the economic burden to industry while maximizing the enhancement to aviation safety.

The ARC has developed an SMS CONOPS describing the intent of the part 5 SMS framework (safety policy, SRM, safety assurance, and safety promotion) for D&M organizations as it applies to each life cycle phase (design and certification, production and airworthiness certification, and continued airworthiness) of a product or article. <u>The ARC recommends the CONOPS form the basis for the development of preamble, policy, and guidance material for D&M organizations. The ARC also recommends that, as described in the CONOPS, existing processes and procedures should be considered as meeting the intent of part 5.</u>

The following SMS recommendation was not directly tied to the ARC charter or its taskings, but supports the § 21.3, Reporting of failures, malfunctions, and defects, requirements and proposed changes discussed in section 8.2 of this report.

<u>The ARC recommends the FAA develop an approach to make fleet data already provided to the FAA (hours, flights, reported failures, malfunctions, and defects and service difficulty reports) readily available to D&M organizations, in support of executing SRM (§ 5.71, Safety performance monitoring and measurement).</u>

6.0 DESIGN ORGANIZATION MODEL AND FRAMEWORK

A DO must have systems in place that ensure the FAA may rely on any and all statements of compliance when it issues a certificate. That activity must occur under established minimum requirements of a DO.

An integrated and systematic approach to compliance and safety therefore encompasses several elements, including an organization, CAS, and SMS. Successful execution of these elements should enable the continued growth of a compliance and safety culture within the DO. Although the DO should satisfy each of the elements of the systems discussed below, the elements may be arranged or grouped differently or encompassed within organizational systems with different names to accomplish the intended purpose.

The DO must be able to establish and show that the organization—

- Possesses the required competence to determine that the certificate holder's designs meet all applicable airworthiness standards within the scope of the DO certificate.
- Has procedures for assuring compliance to the airworthiness standards.
- Maintains the essential process controls to deliver repeatable and sustainable compliance.

Recommendation 1c—Systems Approach to Certification – DO Requirements: The ARC recommends establishing regulatory requirements for the issuance and oversight of voluntary certificated DOs, including the necessary compliance assurance, safety management, and controls to make all compliance determinations through applicant showing and verification processes. Through FAA certificate management oversight and direct project involvement in defined risk-based areas, the FAA may rely on the DO compliance determinations to make its finding for the issuance of a design approval. This report builds on the recommendations submitted to the FAA by the CDO ARC in May 2008. The ARC recommends a building block approach to implementing DO, which includes establishing a clear accountability framework, transitioning the FAA's oversight of design activities to a centralized systematic model, optimizing use of ODA, and implementing new organizational and SMS requirements. With successful implementation of these building blocks and voluntary DO, the ARC supports future rulemaking to consider mandatory DO.

The DO Working Group Report contains a number of detailed recommendations proposed when the ARC envisioned the DO to be mandatory. Because these recommendations only apply to a mandatory DO and the ARC is now recommending the DO be voluntary, these working group recommendations have not all been brought forward into this final ARC report. However, the intent of the building block approach is to eventually get to a DO during the "Transformational" phase, at which time the detailed information provided in the working group report becomes relevant and should be reviewed.

Additionally, the ARC recommends that proposed regulations, preamble language, and guidance material should be discussed as a follow-on activity to mature the information provided in this report.

6.1 DO and Organization Control Systems (OCS)

The ARC does not recommend that a particular organizational structure be required; however, certain functional roles, aspects, and elements must be defined in the FAA-approved DO procedures manual. Each holder of a DO certificate must have a procedures manual that defines the procedures and processes to be used (that is, OCS) that meets the requirements specifically required by the DO regulation to be in the procedures manual.

The holder of a DO certificate must follow the procedures in the manual. The manual must be in the English language and retrievable in a form acceptable to the FAA.

The DO procedures manual contains the DO's procedures for meeting its regulatory requirements. The manual must address all relevant DO requirements.

The DO procedures manual processes and procedures must be sufficient for the FAA to determine that regulatory compliance is properly addressed. The manual is intended to be a top-level document that will guide the development of lower-level processes and work instructions that the DO can develop and change as it finds necessary (that is, without the need for FAA approval) to meet the top-level requirements and objectives. If the FAA determines the procedures manual lacks the detail necessary to ensure regulatory compliance, it will request a change to the manual. The DO is obligated to respond to the FAA's request within an agreed-upon timeframe. The ARC recommends further discussion on the necessary level of detail for inclusion in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual.

The procedures manual must be consistent with all issued FAA regulations and guidance related to the proper function of a DO.

The DO procedures manual may be in any format proposed by the DO and acceptable to the Administrator. There is no expectation that each DO procedures manual would be formatted the same.

The following are the organizational and OCS requirements:

1. Identified DO Executive. The DO Executive is accountable for all activities covered within the scope of the DO certificate. This executive must be identified by name and position within the company. The DO Executive may also act as the primary point of contact (POC) for the DO. The DO procedures manual must contain an explanation of the reporting relationships between the DO Executive and senior company management, as well as the organizational relationships within the DO.

Identified DO point(s) of contact. The DO POC is the person(s) within the DO with whom the FAA will communicate. A formal list of POCs must be maintained by the DO. The DO POC must be familiar with the DO processes and the applicable FAA regulations consistent with the scope of the DO certificate. The DO POC must also have unencumbered, but not necessarily direct, access to the DO Executive. Additionally, defined procedures for communication between the DO and the FAA, including agreement on expectations and expediency, will be stated.

Each DO certificate holder will have qualified staff, as appropriate to DO privileges and obligations. The DO is responsible for ensuring the staff in technical departments has the experience, training, and authority to be able to discharge their allocated responsibilities, and that these, together with the accommodation, facilities, and equipment, are adequate to enable the staff to achieve the airworthiness objectives for the product. Refer to the NATCA dissenting opinion in section 12 of this report.

A process for verification of personnel qualifications. The scope of personnel is intended to focus on those people who hold accountability for maintaining the organizational oversight of the DO and those people with prime accountability for the design management system (DMS), compliance certification system (CCS), and SMS. Personnel qualification includes essential competencies, experience, and training.

A process for verification of systemic performance of duties. This includes procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved procedures manual, DMS, CCS and SMS. The procedures must include reporting of internal audit results to the manager responsible for implementing corrective and preventative actions.

A process for retaining records that are required to be produced. This includes the identification of records that must be retained, the method and means of storage and retrieval, control and access privilege, and retention period. These records typically comprise DO procedures manual approvals (including changes to the manual), design approval records, design change approvals, internal audit records, and CCS records.

A process for identifying which certification projects require an application for establishing details of the project list, and how often this information should be provided to the FAA. (Refer to section 6.4 of this report)

A process for notifying the FAA if circumstances prevent the DO from meeting DO obligations.

The process, timetable, and authority for obtaining and agreeing on changes to the DO procedures manual, DMS, CAS, and SMS.

6.2 Compliance Assurance System

The DO applicant must demonstrate that it has established and is able to maintain a regulatory CAS for—

- The control and management of the design approval(s),
- Design changes of products and articles covered by the scope of the certificate, and
- Any production activities associated with those design approvals.

The CAS should result in assurance that the compliance determinations are correct and consistent with what would result from an independent skilled review of compliance.

The DO applicant’s regulatory CAS must contain a means to provide assurance that the design and design changes of the applicant’s products and articles comply with the applicable airworthiness standards. This is presented in this report as being accomplished through a DMS and CCS.

After the issuance of the DO certificate, any changes to the CAS materially affecting compliance with the certification basis or airworthiness standards must be submitted to the FAA for approval before implementation. The DO must identify to the FAA how the proposed changes to the CAS will result in continued compliance after implementation.

Assurance of compliance with the airworthiness standards, including the performance of suppliers, is of critical importance to the success of DO. No FAA designees are used by the DO. Therefore, the quality of the DO’s processes for determinations of compliance and process adherence, and the robustness of the CAS are the basis for enabling the FAA to rely on the DO’s statement of compliance when making its finding.

The DO CAS is composed of two elements:

1. **Design Management System.** The DMS is the system by which a DO creates and maintains product design data. DMS requirements are—
   - A process for creating and maintaining configuration and control of design data. Establishing a structured and controlled system for the development of design data, the control of changes to the data, and the assurance that the descriptive design data is current and approved is fundamental to this process.
   - A process for retaining, retrieving, protecting, and maintaining design descriptive and substantiating data. This process should also include any agreements between the DO and FAA regarding availability of data, access to the data, and any electronic system requirements required to view the data.
   - A process for engineering supplier control that defines how design activities performed externally to the DO are controlled, validated, and assured. This also includes inter-DO relationships (refer to section 6.5.4 of this report).
   - A process for creating eligible data that can be used for showing compliance when applied to a particular certification activity.
   - A process for receiving and processing safety data related to approved designs.

     Note: “Safety” data is meant to pertain to information relevant to identification of product safety hazards, risk analysis, and mitigation, as appropriate.
   - A process for applying relevant “safety” data to the DMS for purposes of continuous improvement.

Compliance Certification System. The CCS is the system by which a DO ensures product compliance (showing of and verification of, as appropriate) to the applicable airworthiness standards. The CCS requirements are—

- o A process for identifying and/or establishing regulatory certification basis. This process includes an assessment of the product's intended usage and determination of the applicable airworthiness standards. The establishment of a product's certification basis may be a pre-decisional FAA approval based on the agreed processes defined within the DO procedures manual.
- o A process for identifying regulatory changes that affect the design system. The DO must have an active means of monitoring regulatory changes that affect the product(s) for which the organization is responsible and evaluating the need for implementing changes or taking other actions. This includes any activities resulting from the issuance of an airworthiness directive (AD) against a DAH's product. A defined system that shows compliance to the applicable airworthiness standards under § 21.20(a), and how verification of compliance will be conducted including any process for assuring independence and objectivity. The "show" responsibility is identical to that already prescribed under § 21.20(a). However, in the DO model, the "show" and "verification" functions are intended to be accomplished within the DO.
- o A process for using memorandums of cooperation (MOC) that are acceptable to the FAA, including, as appropriate, a process for verification and validation of analytical tools and a process for managing testing and inspection required to support each showing of compliance. This would include conformity inspections used to support showings of compliance. It is expected that this process will delineate between showings within well-established MOCs and procedural distinctions when addressing a MOC that is new or novel.
- o A process for declaring to the Administrator that a design is in compliance with the applicable airworthiness standards at the time the design approval is requested. This documentation fulfills the requirement under § 21.20(b).
- o A process for reporting other approvals such as design changes, changes to Instructions for Continued Airworthiness (ICA), and approval of repair data.
- o A process for receiving, processing, and implementing corrective action regarding "compliance" data related to approved designs. If during the course of regular business or as the result of a finding during any internal or externally conducted audit a noncompliance to the approved procedures or airworthiness standard is identified, the mechanism for evaluating the risk of the noncompliance and identification of any corrective actions must be defined.

DO Show and Verify Compliance Certification Functions. The CCS processes must include a showing of compliance by the DO to each applicable airworthiness standard. The following principles provide guidance in this regard:

- Show and verify functions are part of the CCS.
- The show function is a demonstration of compliance to an airworthiness standard (that is, 14 CFR parts 23, 25, 27, 29, 33, and 35) and is composed of substantiating data,

statements, and/or other acceptable methods of demonstration (for example, acceptable MOC).

- The verify function is an independent check, or equivalent, of the show function.
- The show and verify functions are distinct functions or activities, where appropriate. The degree of independence between the individuals performing the show and verify functions or activities should be established in the DO procedures manual.

A DO determination of compliance is a showing with an independent verification function unless the DO procedures manual identifies a specific area where a verification is not required or where the procedures manual identifies a process that allows the DO to assess risk to make decisions on whether a verification step is required.

- The showing of compliance requirement remains identical to that which exists in the current regulatory system. There is no intent to establish a changed requirement for showing of compliance for a DO.

Tools Used for Performing Compliance Activities. Where the system is dependent on the use of a tool for performing some of the processes and methods, means must be provided to ensure—

- The tool performs its required function,
- The tool and its output are being controlled under a configuration management program,
- The tool is periodically verified for its applicability regarding the processes and methods for which it is intended to apply, and
- A record is kept of the use of the tool to accomplish the compliance activity.

6.3 Safety Management System

The SMS requirements for a DO are to be provided in a separate report by the ARC's SMS Working Group.

The ARC anticipates the SMS to be the system for actively monitoring product safety, identifying and managing risks to product safety, and promoting a strong safety culture throughout the organization, which would likely consist of—

- Safety policy and objectives including management commitment, responsibilities, accountabilities, key safety personnel, and coordination of emergency response planning;
- Safety risk management including hazard identification, and risk assessment and mitigation;
- Safety assurance through performance monitoring, measurement, change management, and continuous improvement; and
- Safety promotion through training, education, and communication.

6.4 DO Project Applications and Activity Reporting

The ARC believes the DO certificate holder may complete many projects without notifying the FAA, because the DO will be making all determinations of compliance in accordance with its FAA-approved procedures manual. There are other projects the FAA must be immediately aware of, as they require the FAA to validate the existing type certification basis or establish a new one.

Part 21 already specifies when an application must be made to the FAA. This includes applications for TC, STC, and PMA. The existing required applications could be used to discriminate between those projects that required FAA notification and those that did not. If the project would require an application under part 21, the FAA must be notified when the project is initiated. Such projects would be any new design approval, amended TCs requiring a new model designation, new STCs, and any project that would be expected to have a revised type certification basis under § 21.101, Designation of applicable regulations. Any change that does not rise to this level will be handled by the DO under its approved procedures manual.

The details of the project list, how often it should be provided to the FAA, and how the FAA should be notified of projects requiring an application are some of the matters that should be discussed with the FAA and included in the procedures manual.

6.5 DO Relationships and Supplier Control

6.5.1 General Requirements

A design approval applicant or DAH has sole responsibility for proper control of all its suppliers, whether they are suppliers of engineering services, manufacturing of pre-production parts, special process, or any other part of its compliance responsibilities. Should there be any deficiency or noncompliance on the part of a supplier, even if it is a supplier of compliance determinations, products, parts, or appliances, the FAA holds the applicant or holder of the design certificate responsible to correct the deficiency. This longstanding principle remains for the DAH even if the DAH is also the holder of a DO certificate.

The DO must qualify its engineering suppliers, provide oversight, and define the process by which suppliers function within the DO system. This means a DO may authorize suppliers to make determinations of compliance only after the DO has evaluated the supplier's system and determined that the supplier is qualified to act in that capacity for the DO. This does not mean suppliers must adopt the DO's system of processes, but it does mean the DO must determine the system of processes to be used by the suppliers are acceptable and meet the DO's requirements.

To fulfill its supplier management responsibilities, a DO must have as part of its system a process by which it will determine the appropriate level of oversight required for its suppliers. The DO should consider such things as—

- The criticality of the design,
- Its experience with the supplier,
- The supplier's standing as an FAA-approved DO or as a holder of other FAA design approvals or delegations,

- Additional compliance determinations to be made during integration testing of the design, and
- Any other appropriate factors.

The ARC recommends DO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities, in a manner similar to what is currently done by manufacturing facilities and airlines under the Coordinating Agency for Supplier Evaluation (C.A.S.E.), http://www.caseinc.org/. As an example, several companies buying avionics components from a single supplier may cooperate in the surveillance of that supplier by allowing one of the companies to conduct the audit and the other companies to use the results as if they conducted the audit themselves. To gain the credit for such pooling of audit requirements, it is essential that the supplier processes be consistent across all companies, or that the company auditing the supplier assess all the requirements of those companies wishing to share the benefits of the single-party audit.

In selecting suppliers, the DO must consider that, for both engineering and production suppliers, there must be means for the FAA to gain access to the facility for the purposes of DO oversight.

6.5.2 Oversight of Foreign Suppliers

Oversight of foreign suppliers is required whether or not a bilateral agreement exists between the FAA and the country in which a foreign supplier is located. A DO may authorize foreign suppliers to make determinations of compliance only after the DO has evaluated the suppliers' systems and determined they are qualified to act in that capacity under the DO processes.

To fulfill its supplier management responsibilities, a DO may also propose, as part of its quality system, a foreign supplier oversight process for its design services supplier, just as companies currently do for parts suppliers under AC 21–1B, Production Certificates. This process could be based on using an approved organization as a supplier to its DO, for example, a contract with an EASA DOA holder in good standing. In doing so, it must be recognized that the foreign civil aviation authority (CAA) may not be performing any oversight of that activity if it does not lead to an approval under the CAA. If representatives of an EASA DOA, for example, are authorized by the DO to make compliance determinations, those determinations must be acceptable and meet the DO's requirements.

The DO remains fully responsible for all compliance determinations made by the foreign suppler holding an organizational approval from its cognizant CAA, just as it is for all other compliance determinations. However, in its supplier oversight function, the DO may take credit for the surveillance of the supplier by its CAA. That credit would result in a reduced need for oversight by the DO, and the foreign supplier oversight process should be defined within the supplier surveillance portion of the DO procedures manual. The DO, for example, could review periodic reports from audits performed by the supplier CAA or establish some other means of tracking supplier performance. The DO should consider the criticality of the design, experience with the supplier, and other factors in determining the degree of oversight necessary, as it does with all supplier oversight. The DO oversight methodology applied to foreign suppliers having capabilities recognized by their respective CAA would be evaluated as part of the FAA's oversight function. Additionally, the DO supplier oversight process could include a qualified third-party organization (such as Bureau Veritas).

6.5.3 The Need for Specialty Service Providers

For the design and production companies in the aviation system, the FAA has been moving away from a system of approvals based on the use of individual designees, and toward organizational delegations based on demonstrated and approved processes within a company. This is especially true for those seeking or holding original design approval certificates. The DO concept further propagates this trend.

At the same time, many companies in the aviation community are becoming very specialized in their ability to perform unique technical services. In certain highly technical areas, the number of qualified organizations that can perform specialized services has been reduced to a critical few. The designers and producers of approved products and articles rely on these specialty services to supplement their capabilities. The 2008 CDO ARC Report recognized a need to create a new process wherein these specialty companies are recognized for their capability, and that capability can be used to supplement DO (and ODA) compliance activities, as well as those of other applicants. The 2008 CDO ARC chose to call these companies "Specialty Service Providers" (SSP).

The ARC recommends the FAA give priority to developing a means for recognizing an accreditation system for these SSPs. This concept could encompass technical specialties ranging from the more complicated (such as flammability, dynamic seats, icing, electromagnetic interference, and high-intensity radiated fields) to the more routine specialties (such as materials testing, nondestructive inspection processes, and environmental testing of components). These are only a few examples of the scope of activities that could be included under this concept.

The ARC recommends that industry develop this concept with the direct participation of the FAA because of the variety of issues that must be addressed and the need to create industry consensus standards.

- The SSP could perform compliance with industry consensus standards acceptable to the FAA and DO as evidence of compliance with specific airworthiness standards, resulting in a determination of compliance.
- The possibility of third-party approval and oversight of SSPs should be considered.
- The data developed by SSPs must be directly useable by all applicants without further verification of the data's integrity.
- The FAA should pursue international acceptance of the SSP system.
- Although SSPs may have individuals who are designees of the Administrator, such individuals do not exercise delegation in the course of a DO project as a SSP.
- Persons using SSPs must do so under their supplier control system. The amount of supplier oversight conducted by the user of these services can take into consideration the accreditation of these SSPs.

- The continued compliance responsibility of applicants who use SSPs is not reduced by the fact that the SSPs are recognized by the FAA for their expertise. The TC, PMA, or part approval holders still have the total responsibility for initial and continued compliance of the design approvals they hold, and the resolution of all COS issues.
- The ARC recognizes that there are different methods that may be used to implement the SSP concept, and that the concept is not necessarily tied to implementation of the DO. <u>Regardless of the method of implementation, the ARC recommends the FAA give priority to developing a means for recognizing an accreditation system for SSPs (for example, Nadcap or similar) and the system be made available to the aviation community.</u>

6.5.4 Inter-DO Relationships and Responsibilities as Design Partners

Inter-DO relationships will be controlled by a supplier interface document (refer to section 6.8 of this report). This interface document will allow the supplier DO to use its own procedures and processes within its scope of authority as a DO. The applicant DO will identify how supplied data (and potentially determinations of compliance) will be assessed for integration and applicability to the product.

6.5.5 Agent Design Organization (ADO)

The ARC discussed the creation and recognition of a DO that has been contracted to act on behalf of a design approval applicant. The ARC refers to such a DO as an ADO. An ADO may or may not hold a design approval and must meet the minimum DO requirements specified within this report. The ADO provides an avenue for an interested design approval applicant to use the professional DO services that the applicant either does not have or does not have the financial ability to create. The use of an ADO promotes consistency in design activity (safety enhancement), an accountable DO (responsibility), and may reduce the necessary aviation system assessment and oversight resources. The ARC believes the ADO role fills a critical need in the DO model where a full DO would be more than was needed and would have an adverse impact on an applicant's ability to create needed designs or design changes, particularly regarding small business applications.

The following text from EASA 21.A.2 describes a similar application of the ADO concept:

> "Undertaking by another person than the applicant for, or holder of, a certificate. The actions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part, or appliance under this section may be undertaken on its behalf by any other natural or legal person, provided the holder of, or applicant for, that certificate can show that it has made an agreement with the other person such as to ensure the holder's obligations are and will be properly discharged.

Refer to section 7.2 of this report for more information about ADOs.

6.6 Business Structure Variation

The ARC recognized that additional business structures may exist where a DO is part of a business structure in which companies are not in a traditional supplier relationship. An example of such a business structure is a consortium, where each company is an equal business partner and is not considered a supplier to the other. In some cases one business partner is U.S.-based while the other is foreign-based. Also the consortium company may or may not be U.S.-based. As such, neither company has complete oversight, in the supplier sense, of the other company. Each business partner wants recognition of their respective DO in a certification project. Such is the situation, in any business structure, where one company does not have full supplier oversight responsibilities over another company.

Industry currently has such business structures with U.S.-based companies and foreign-based companies. As the aviation business continues to grow globally, industry members foresee continued growth of these business structures to mitigate associated business risks and leverage various strengths of different companies.

The ARC discussed the notion that when the consortium company is foreign-based, a U.S.-based DO should be able to manage the integration responsibilities for the FAA portion of a certification project, including the project statement of compliance to the applicable airworthiness standards, knowing that the U.S.-based DO may not possess or have access to all project descriptive and/or substantiating data. This is a result of the need to protect proprietary methods and information within each respective company. Completion of all required determinations of compliance must be documented to support the project statement of compliance.

The ARC also discussed that a consortium may consist of two U.S.-based DOs. Industry recognizes there is one applicant and certificate holder for each TC; that has historically been the consortium company. The FAA has worked with consortium companies to execute shared-responsibility agreements between the members, which are acceptable to the FAA. That has allowed each consortium member to autonomously execute its role independent of the other consortium members, including findings of compliance under FAA delegation, thus protecting its proprietary data. A similar FAA-accepted working agreement could describe how those autonomously performed design and compliance determination processes under DOs are integrated into a single type design, TC, and continued airworthiness process.

The ARC believes further discussion is needed between the FAA and industry to develop how this would be accomplished. Therefore, the ARC recommends further development of how such business structures will be accommodated under the proposed DO framework. Input from industry, especially those who currently have consortium programs, should be further considered.

6.7 Scope, Limitations, and Privileges of DO Certificates

There are many variations in design and production organizations and their products throughout the aviation system. They range from organizations dealing with a full line of products, like transport airplanes, high-tech general aviation aircraft, helicopters, and high-bypass engines, to PMA holders with a more narrow focus. In some cases, FAA compliance approvals for the activities of these organizations are made either directly by FAA resources, or by using individual or organizational delegation approvals from the FAA. Repair stations may have ODA authorizations or their own company designees, or may contract with consultant designees to perform design approval functions. This describes only a few of the organizations that make a business of engaging in design and production certification activities.

In addition to the FAA's ability to implement SMS, the safety benefits of a more complete corporate focus on compliance and safety can further permeate the industry if these organizations are required to obtain DO certificates. For this reason, the criteria for obtaining and holding a DO certificate must be such that they can be tailored to the size and functions of the specific DO certificate holder.

A total "culture of compliance" must exist within each DO company, but how that culture is established will likely differ for each DO certificate holder. The key is to define criteria against which all potential DO certificate holders will be measured, but recognize that there will be variables in how the criteria are met based on different types and sizes of companies and associated regulatory obligations.

6.7.1 FAA Limitations on the DO Certificate

A DO certificate may cover type certification activities, supplemental type certification activities, and PMA issuance activities, as well as production approval activities. For a particular DO, the FAA may limit the scope of activities that might be accomplished by that DO.

Type Certificates. For type certification activities, it would be rare that a certificate holder would be able to perform all the responsibilities necessary to demonstrate compliance for all products that are eligible to receive a TC. For this reason, the FAA may restrict a DO certificate to only products covered by a specific part of the airworthiness/design requirements, such as 14 CFR part 23 (small airplanes), part 25 (large airplanes), part 27 (small rotorcraft), part 29 (large rotorcraft), part 31 (balloons), part 33 (engines), or part 35 (propellers).

The FAA may further limit the scope of DO certificate activities within a given regulatory part. For instance, a manufacturer might only have the experience necessary to properly comply with DO requirements for small transport airplanes under part 25 airplanes, but not large transport airplanes; or for reciprocating engines under part 33, but not large turbofan engines. The FAA may use other parameters it determines to be necessary to further limit the scope of a DO certificate. The intent is to allow the widest scope of certificate for which the applicant has been able to demonstrate its capability to comply with the relevant design and airworthiness requirements.

Supplemental Type Certificates. In the case of STCs, the scope would also likely be defined in more narrow terms. For example, the scope might be limited by the products that a particular air carrier operates, or by technical discipline and subpart (part 23 structures, for instance), or by the complexity of the product (large turbofan engines, for instance), or by other generic parameters the FAA determines to be appropriate.

PMAs. In the case of PMAs, the scope would likely be tailored to each certificate holder.

Determining the Appropriate Scope of a DO. When determining an appropriate scope for a DO certificate, the FAA must ensure the certificate holder has, and will continue to maintain, the capability to meet all the requirements of the subpart within the scope of its certificate.

As part of this determination, the FAA may consider providing multiple DO certificates in unusual situations for applicants with substantially decentralized organizations, or who have a wide range of products or capabilities. When evaluating whether a single certificate or multiple certificates is most appropriate, the FAA would consider the organizational structure of the applicant, interactions of remote or co-located design and production facilities, and the use of common processes and procedures.

The scope of any DO certificate will be clearly defined so that all persons, including other CAAs, will understand the scope of authority for FAA-approved data granted under that certificate.

Transfer of a DO Certificate. A DO certificate holder cannot transfer the DO certificate.

6.7.2 Scope of DO Certificate Privileges Must Be "Functionally Complete"

The DO certificate privileges must be functionally complete, which means they must cover all activities that would have to be undertaken to fully complete a design approval project within the scope of the DO's authority. The DO holder's competence and capabilities must also be functionally complete to certify compliance with the applicable airworthiness safety standards within the scope of its authority. Those include—

- All certification activities leading to the issuance of an original or amended design approval, including design, airworthiness, manufacturing, and maintenance and operations activities as they relate to a design approval. This includes engineering inspection, analysis, and tests; flight tests; ICA; and aircraft flight manuals.
- All determinations of compliance, including those that involve a subjective evaluation.
- Continued airworthiness activities, including changes to those approved designs for product improvements or safety enhancements, such as those contained in service bulletins, or repair data.
- Manufacturing and airworthiness activities, such as the pre-production manufacturing of parts, components, and subassemblies; and conformity of test articles and products, and their airworthiness certification for flight test.
- The development and testing of designs and processes for possible inclusion in future approved designs (that is, "eligible data").
- Any other activities leading to the development of data necessary for the FAA to determine compliance with the requirements issued by those countries from which validation is sought and with which the FAA has a bilateral airworthiness agreement covering that compliance activity.

6.7.3 Form of a DO Certificate

The ARC reviewed and discussed examples of EASA DOA certificates and terms of approval in assessing application to DOs. <u>The ARC recommends a certificate structure similar in nature to the EASA DOA certificate and terms of approval for an FAA DO certificate.</u> This would provide consistency between FAA and CAA certificates.

Refer to appendix L to this report for an example of an EASA DO certificate.

6.7.4 Transfer of Design Approvals under DO

A TC/STC issued after the effective date of regulation (for example, under the DO framework) is transferable provided the following requirements are met:

1. The transferor of the TC/STC makes a statement, in writing, to the FAA that they are providing all descriptive data and providing, or making available, all substantiating data to the transferee. This statement must describe the conditions under which the substantiating data is made available to the transferee if the data will not be provided (that is, contractual agreement).

A TC/STC issued before the effective date of regulation is transferable provided the descriptive data and substantiating data the transferor has, or has access to, is provided to the transferee. The ARC recognized that existing TC/STC holders may or may not have the descriptive data and/or substantiating data and imposing a regulatory restriction on the transfer would negatively impact the asset value.

<u>The ARC recommends non-DO design approval transfer requirements be provided by a separate follow-on activity to the ARC.</u>

Note: Because of the unique combined design and production nature of a PMA, PMA is not eligible for transfer.

6.7.5 The Generation of "Eligible Data"

Under a DO certificate, compliance is an intended by-product of an FAA-approved DO system properly functioning under its procedures manual, which includes a formal internal audit and oversight process. For the compliance determination for a particular part or component to be complete, it is essential that a certification basis be established for the product on which it is to be installed or for the article itself. Another essential element is that a type or article design be fully defined so that the interaction of products, parts, and components may be assessed. This interaction may establish additional certification needs.

It is common for the normal engineering and production system of a company to develop products, parts, components, and processes for future use in certification programs. In the case of a DO certificate holder, if that development is accomplished under the approved DO system, that development could be eligible for inclusion in subsequent designs, except for the establishment of a product final certification basis and complete product or article definition. It would be inappropriate to consider such development activity as meeting the standards for complete compliance determination because those two elements would be missing. It is appropriate, however, to give credit for any compliance activities accomplished under a DO. The ARC refers to this as "eligible data."

“Eligible” data is data developed under the processes of an approved DO system, given a specified, but not necessarily final, certification basis and product type or article design.

To use “eligible” data, the DO holder must assess the data’s compliance against the final type certification basis of the product or article and final type or article design, respectively, in which it is to be used. It would not be necessary to repeat the compliance activities, provided those activities were appropriate for the final product or article and its certification basis.

The creation of “eligible” data is a concept that is intended for use internal to the DO. No approval or compliance determination can be conferred on the data if the data is provided for use outside the DO.

6.7.6 VOLUNTARY DISCLOSURE PRIVILEGES

The FAA has several active voluntary disclosure programs for air carriers, PAHs, and organizations that have an ODA, among others. These programs are designed to encourage the reporting of product and process deficiencies so they can be corrected before unsafe conditions occur. The programs also apply to discovered deviations from FAA-approved procedures manuals and inadvertent regulatory violations. If the deficiencies or noncompliance activities reported were not intentional or criminal in nature, the FAA will refrain from using the disclosures as the basis for any civil penalty, as long as the certificate holder takes swift action to correct the deficiencies discovered.

As stated on the FAA’s Voluntary Safety Programs Branch Web site—

> “ ... the FAA believes that aviation safety is well served by providing incentives for certificate holders to correct their own instances of noncompliance and to invest more resources in efforts to preclude their recurrence. The FAA’s policy of forgoing civil penalty actions when a certificate holder meets the requirements of this program, is designed to encourage compliance with the FAA’s regulations, foster safe operating practices, and promote the development of internal evaluation programs.”[7]

Although the DO is a new type of certificate, the ARC concludes that the information presented above remains equally applicable for a DO, and the FAA voluntary disclosure policy should be extended to DO certificate holders. Activities under a production approval are already covered by FAA voluntary disclosure policy.

The FAA voluntary disclosure reporting program is presented in AC 00–58B, Voluntary Disclosure Reporting Program. Under section 1, Purpose, there is an important exception that must be recognized. The AC states, in part—

> “The procedures and practices outlined in this AC <u>cannot</u> be applied to those persons who are required to report failures, malfunctions, and defects under 14 CFR part 21, § 21.3, and who do not make those reports in the timeframe required by the regulation.”

[7] http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/afs/afs200/branches/afs280/descriptions/

This exception to the program is in recognition of a determination made by the FAA that, because there is a regulatory requirement to report under § 21.3, the voluntary disclosure of a failure to report cannot relieve the certificate holder from any enforcement that might be based on that failure to report. This exception still appears to be appropriate for a DO certificate holder under the same defined.

6.7.7 Manufacturing and Production Functions Under DO

There are two types of manufacturing and production functions that should be addressed regarding a DO and a production organization:

- Those pre-production manufacturing functions associated with obtaining a design approval, and
- Those associated with a production approval (that is, post-design approval production).

The intention is to allow a DO to use its existing FAA-approved production system during pre-production manufacturing functions associated with obtaining a design approval. If the organization, within the scope of its design authority, chooses to use its approved production quality system, it must use the DO procedures manual processes for any of the following:

- Conformity inspection,
- Determining conformity of parts and test articles,
- Determining conformity of test setup, and
- Determining conformity of installations.

For DOs performing pre-production manufacturing as part of their scope of activities, in addition to the above, the DO procedures manual must also contain procedures for—

- Controlling documents and data associated with pre-production manufacturing;
- Ensuring each supplier furnished product, part, or appliance conforms to its design;
- Controlling manufacturing processes to ensure conformity to its design;
- Conducting inspections and tests;
- Ensuring calibration and control of all inspection, measuring, and test equipment;
- Documenting the inspection and test status of products, parts, and appliances supplied or manufactured to the design;
- Ensuring discarded articles are rendered unusable;
- Implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the design or noncompliance with the approved DO procedures manual;
- Preventing damage and deterioration of each product, part, and appliance during handling, storage, preservation, packaging, and delivery;

- Identifying, storing, protecting, retrieving, and retaining quality records; and
- Planning, conducting, and documenting internal audits to ensure compliance with the approved DO procedures manual.

For post-design approval production, the production approval requirements remain the same.

The DO processes would also support the FAA's issuance of special airworthiness certificates in the experimental category for the purpose of R&D or show compliance.

Although the ARC intended to further discuss the manufacturing and production functions to include the combined design and production organizations (that is, one certificate comprising design and production), it was limited to the pre-production concepts noted above because of schedule constraints. Further discussion would be required to recommend additional privileges that may be available for a combined Design Production Organization (DPO).

6.7.8 Flight Standards Functions

Section 21.17(a)(1) requires an applicant for a TC to show that its product meets "the applicable requirements of this subchapter that are in effect on the date of application for that certificate." Part 21 resides in 14 CFR chapter 1, subchapter C, Aircraft. This subchapter covers parts 21 through 59, which includes the type certification airworthiness standards found in parts 23 through 35. The operating rules applicable to these same type certificated aircraft are found in subchapters F and G, which include parts 91 through 135.

Although a TC may legally be awarded without the product complying with appropriate operating requirements, the practice has been to provide an initial operational evaluation of aircraft during the type certification program. That operational evaluation is carried out by the Flight Standards AEG that has the responsibility for the particular product being type certificated. The AEG performs or coordinates the following activities associated with the type certification of products, which are discussed in FAA Order 8900.1, Flight Standards Information Management System (FSIMS):

- ICA—Review and find acceptable the maintenance aspects of the ICA which are required under § 21.50, Instructions for continued airworthiness and manufacturer's maintenance manuals having airworthiness limitations sections, and §XX.1529, Instructions for Continued Airworthiness, in the respective aircraft certification standards.
- Flight Operations Evaluation Board (FOEB)—Develop and revise the master minimum equipment list (MMEL).
- Flight Standardization Board (FSB)—Determine the requirements for pilot type ratings, develop minimum training recommendations, and ensure initial flight crewmember competency.
- Maintenance Review Board (MRB)—Establish the minimum maintenance and inspection requirements for transport category aircraft, engines, propellers, and auxiliary power units. Participate in industry steering committee meetings to review the Maintenance Steering Group (MSG)–3 analyses.
- Participate in Type Certification Board and Flight Manual Review Board activities.

During type certification, all determinations of compliance to the airworthiness requirements in parts 23 through 35 are made by the DO certificate holder, with appropriate FAA oversight. <u>Because compliance with the ICA requirement in §§ XX.1529, 31.82, 33.4, and 35.4 are to be determined by the DO certificate holder, the ARC recommends the maintenance aspects of those requirements also be determined by the DO</u>. The DO procedures manual would need to contain appropriate procedures that ensure the maintenance aspects of the ICA are properly addressed, and consistent with § 21.50 and FAA Flight Standards' regulatory guidance.

The ARC believes the formulation and execution of the FOEB, FSB, and MRB should continue as Flight Standards AEG functions, with support from the DO certificate holder. All determinations of compliance to airworthiness standards associated with those boards would be made by the DO certificate holder consistent with its procedures manual. Some additional responsibilities associated with the operation of those boards might be assigned to a DO certificate holder, under Flight Standards policy, after experience is gained. This would necessitate a revision to the DO procedures manual.

AEG participation in Type Certification Board and Flight Manual Review Board activities would continue to the degree that AIR participates in those functions. For new TCs and amended TCs requiring a model change there would be a review by the Type Certification Board, but it is expected that most major changes would be conducted under DO procedures and would not require board review. This is because the type boards are identified in an FAA Order and the DO certificate holder is free to propose its own procedures instead of those identified in existing FAA Orders.

For a DO, a Flight Manual Review Board would not have the sole responsibility for determining compliance with the flight manual, which would reside with the DO certificate holder. Any operational regulations and associated flight standards guidance regarding flight manuals would be complied with through processes and procedures defined in the DO procedures manual.

6.7.9 Noise, Fuel Venting, and Exhaust Emissions

Although Congress has granted the FAA full statutory authority over the airworthiness certification of civil aviation products in the United States, the EPA guides FAA requirements regarding noise, fuel venting, and exhaust emissions (14 CFR part 34, Fuel Venting and Exhaust Emission Requirements for Turbine Engine Powered Airplanes, and part 36, Noise Standards: Aircraft Type and Airworthiness Certification).

Under the current system, FAA Order 1050.1E, Environmental Impacts: Policies and Procedures, sets policies and procedures and assigns responsibilities for ensuring the FAA complies with environmental procedures as required by the National Environmental Policy Act under the direction of the Council on Environmental Quality. The order contains examples of actions that normally require an environmental assessment, including noise and emission requirements.

In addition, the Noise Control Act of 1972 requires the FAA to make findings, notwithstanding any delegation to companies, other private persons, CAAs, or any procedures for type certificating foreign-manufactured aircraft. The FAA's Office of Environment and Energy (AEE) delegates the authority to make these types of findings to the appropriate

FAA certification directorate, depending on the type of aircraft involved. That directorate may not re-delegate the authority and the FAA must base its finding on actual examination of each type design. Individual delegations have been granted by the FAA but they are only for recommending approval, not finding compliance.

Although the ARC recognizes the distinction between the airworthiness requirements of 14 CFR and the noise, fuel venting, and emissions requirements, it believes a DO could be found to have the necessary capabilities and expertise to make compliance determinations regarding the environmental requirements contained in parts 34 and 36. Specific noise, fuel venting, and emissions processes would be developed within the DO compliance, safety, and quality systems to ensure proper compliance determinations. This is in keeping with the principle of a DO making 100 percent of the compliance determinations.

The ARC recommends the FAA propose to the EPA that the process-based approach to compliance, as established by DO program principles, is far more robust than the normal delegation process and is sufficient to ensure compliance with the environmental aspects of parts 34 and 36. The ARC believes this to be consistent with the recommendations set forth by the FAA in response to section 312 of the FAA Modernization and Reform Act of 2012, which recommend "expanding delegation capability to include support for all certification airworthiness standards when appropriate, particularly low-risk or routine activities such [as] those related to noise and emissions tests and ICA." Refer to NATCA's dissenting opinion to section 6.7.9 in section 10 of this report.

6.7.10 Establishing a Certification Basis

An applicant for a design approval may propose a certification basis to the FAA, and the FAA can establish the certification basis. Regarding design changes under a DO, the FAA could establish a certification basis within the limited boundaries set forth in the DO approved procedures manual. This is considered an FAA pre-decisional approval process provided to the DO. Projects that fall within the approved boundaries would be performed under the domain of the DO without additional FAA input. Industry has identified such pre-decisional approval as critical to the success of DOs.

6.7.11 Changed Product Rule

The derivative type certification requirements, which apply to TCs and STCs, specify the need for the FAA to make a determination of the appropriateness of the original type certification basis. This is sometimes referred to as the "changed product rule requirements." As a general rule, those projects would be subject to FAA LOPI, and it is expected that a DO would notify the FAA when it undertakes such projects.

As the FAA gains more confidence in specific DO certificate holders, it may be willing to rely on specific DO approved processes to assist the FAA in making its determinations under the changed product rule.

6.8 DO Approval of Data

The DO privileges associated with approval of data discussed below are made in consideration of a 14 CFR part 21 accountability framework policy initiative, which the FAA has indicated it is currently pursuing for FAA-managed certification projects. The FAA has advised that it will formalize the policy in FAA Order 8110.4D, Type Certification, and future changes to FAA Order 8110.37, Designated Engineering Representative (DER) Handbook, and FAA Order 8100.15. The new policy will clarify that discrete substantiating or descriptive data generated in support of part 21 certification projects do not need to be discretely "approved." Although the ARC accepts the FAA's intent to return to the basic foundations of part 21, the ARC believes this specific change alters an accepted practice that has been established over several decades within FAA policy. However, if the FAA continues to pursue this new policy, the ARC strongly believes that whether a project is managed by the FAA with designees or by a DO, the status of any data, regardless of the part 21 process that produced it, should be the same. Should the FAA not pursue this policy change, the FAA must ensure the DO regulation includes the privilege of making discrete compliance determinations that result in data that is (or is equivalent to) FAA-approved, and that the data is internationally recognized within the scope of bilateral agreements. Refer to section 12 of this report for a dissenting opinion on approval of data.

Data Supporting a Design Approval Under Part 21

Current practice has facilitated FAA approval of discrete substantiating data as well as discrete descriptive data that ultimately makes up the type design. However, part 21 contains no requirement for approval of this discrete data separate from issuing the TC (refer to § 21.41, Type certificate, where the TC is defined to include the type design, any operating limitations, the certificate data sheet, the certification basis, and any other conditions or limitations). The substantiating data is the documentation related to the applicant's showing, while the descriptive data defines the type design that should be determined "compliant" to the regulations and ultimately approved when the FAA issues a design approval. The ARC agrees with the FAA that making this clear would eliminate the perceived value and pedigree many currently attach to data and the assumption that the reason data has value is because the FAA has labeled it "FAA-approved."

Getting back to the basics of part 21 is relevant to all discrete data showings and will become even more relevant as the FAA begins to implement risk-based decisionmaking and when it chooses not to be involved in certain aspects of a certification project. In such cases, requiring the FAA to provide a status for discrete data "showings" would not be logical when it has chosen not to be involved in making a discrete finding of compliance. Doing so wrongly implies that all data should be statused by the FAA, which implies some level of FAA involvement, even when the FAA has already determined not to be involved in a given aspect of a certification program.

The ARC acknowledges that regardless of how any data was used in the past, it remains the applicant's responsibility to show compliance even when such data is used to support subsequent part 21 projects. The ARC understands the FAA intends to clarify this in future type certification policy to further reinforce the accountability framework concepts related to design certification. This should include revisions to FAA Forms 8110–3 and 8110–9 to distinguish between when the form is being used for a part 21 project and when it is supporting a maintenance or other operational requirement under part 43, Maintenance, Preventative Maintenance, Rebuilding and Alternation, associated with an existing design approval.

Although not the case for part 43 maintenance actions, and unlike current practice, the data produced for the purposes of showing compliance under part 21 needs no label or pedigree designating it as "approved" by the FAA. Instead, the descriptive and substantiating data will only be designated as "found to have shown compliance to the airworthiness standards by the FAA" or "determined compliant to the airworthiness standards by a DO." In either case, only when the FAA issues its design approval will it make the single finding required by part 21, and in so doing approve the descriptive data that defines the complete type design.

Data Supporting Major Design Changes Under Part 21

Part 21 currently contains provisions for FAA approval of both major and minor design changes. In promulgating the DO regulation, once a type design is held by a DO, the DO must have the privilege to make all necessary determinations of compliance associated with any change and also approve the descriptive data by incorporating the change into its type design. Although existing statutory law (49 U.S.C. § 44702) allows only the FAA to issue a certificate, there is no restriction preventing the FAA from allowing a DO to make changes to an existing TC as a privilege of its DO certificate (that is, DO is not a delegation). In exercising this privilege, the DO will approve the descriptive data associated with any design change once it incorporates the change in accordance with its approved procedures. This privilege should be given regarding any type of design approval held by a DO, including PMAs (which are not addressed in 49 U.S.C.). This privilege should also be given to a DO that is contracted to act as an agent of the applicant to manage its type design. In a supplier role, a DO may provide determinations of compliance that support a design change; however, as a supplier a DO cannot approve design changes because it is not the custodian of the type design.

In promulgating this privilege, the existing part 21 regulations regarding major changes should be changed. For major changes, the current regulations require that 1) an application be made, 2) the regulations under § 21.101 be considered, and 3) the "person" obtain either an STC or an amendment to the TC. There is no alternative process that allows this to happen without the FAA. Today, only the FAA or its designee can address the certification basis or issue an amended TC or STC. Therefore, the approval of the major change is currently an FAA activity. In the case of § 21.101, the function is inherently governmental and will require the FAA to be involved. However, the ARC foresees that the FAA could facilitate its involvement through a "pre-decisional" process that is part of the DO procedures manual. The DO could follow such a process to ensure the FAA is properly engaged on certification basis decisions that are outside what is allowed by the pre-decisional process. In this way the DO is not held up and forced to wait on the FAA for the majority of its project activity.

Data Supporting Part 43 Maintenance or Any Operational Requirement

Although DO determinations of compliance associated with seeking a design approval or supporting a minor or major change do not need to result in discretely approved data, a DO must have the authority to make determinations of compliance that result in the creation of approved data when required to support part 43 maintenance or any operational requirement associated with an existing type design. In such cases, the data may or may not be part of the approved type design. For example, when a DAH issues a service bulletin or service letter, the data is conveyed as a change to the type design. However, a holder (or even the FAA) can provide data to support a unique repair or alteration for an individual owner/operator, an action which does not result in a change to the type design.

The ARC contends that the "approved data" required by part 65, Certification: Airmen Other Than Flight Crewmembers, for use in part 43 is the approved descriptive data and any other technical data required to perform the maintenance. (This includes any drawings, material specifications, process specifications, procedures, and other data describing an approved repair or alteration). The ARC contends that part 43 does not require direct FAA approval of any substantiating data used to show compliance. Thus, the DO's authority to approve data in support of part 43 maintenance applies only to the descriptive data (that is, not the substantiating data) associated with the design approvals it holds. This means that, at its discretion and without any action by the FAA, the DO may create "approved data" to support repairs and alterations by third-party owner/operators for design approvals held by the DO (or regarding any other design approval for which the DO is authorized to provide data for maintenance under its scope of authority).

The ARC sees three possible regulatory options for the FAA to consider in addressing DO "approved data" to support major changes and to support maintenance:

Option 1: The DO has authority to create "FAA-approved data." This option assumes the DO will be authorized to create FAA-approved data in a manner that does not include delegation. In the FAA's current system, all type design data approved by the FAA for use in the global aviation system has been referred to as "FAA-approved." This option continues with that approach.

For decades § 21.95, Approval of minor changes in type design, has allowed minor changes to a type design to be "approved under a method acceptable to the Administrator before submitting to the Administrator any substantiating or descriptive data." Additionally, in 14 CFR part 1, the term "approved" is defined as "approved by the Administrator, unless used with reference to another person." Because § 21.95 makes no reference to another person, the regulation allows for the creation of FAA-approved data without the data being submitted to the FAA or reviewed by the FAA. The FAA-approved data is created when the TC holder executes the "method acceptable to the Administrator."

Although § 21.95 applies only to minor changes to a TC, the ARC believes this existing approach can be applied to major type design changes determined to be compliant by a DO (that is, DO creation of FAA-approved data before any substantiating or descriptive data is submitted to the FAA). The DO regulatory requirements, along with the processes and procedures contained in an FAA-approved DO procedures manual, must be sufficiently thorough for the FAA to approve the data resulting from it before being submitted to the FAA. As with minor type design changes, the FAA may review any "compliance determinations" and supporting data after the DO determines it is compliant.

Under this concept, a DO is not approving data on behalf of the FAA, because a DO is not a delegation. Once the FAA-approved DO process for making a compliance determination has been properly executed, the descriptive data are FAA-approved.

Option 2: The DO has authority to create "DO-approved data" equivalent to "FAA-approved data." This option would facilitate recognition of DO-approved data. It would require a change to 14 CFR part 1, where the term "approved" is defined as "approved by the Administrator, unless used with reference to another person." The regulation should be changed to include other entities entrusted by the Administrator to approve. Under this option, the ARC would recommend the definition be revised to "approved by the Administrator or under the authority of a certificate granted by the administrator, unless used with reference to another person." In granting this privilege to each DO, it is essential that the FAA affirm to its international airworthiness partners that such DO data is equivalent to being "FAA-approved."

Option 3: Create a different term for "DO-approved data." This would require a change to parts 65, 121, 135, and 145, instead of part 43 to make it clear that it can be used.

Although it may seem easy to simply permit certificate holders to issue "approved" data, this function would actually be far more difficult to reconcile with current regulatory practice than it appears at first glance. The FAA Chief Counsel's Office has already met with the ARC to explain that the word "approved" is currently defined to encompass inherently governmental tasks, and the office has expressed reservations at permitting a certificate holder to issue approved data. The word "approved" is also a difficult word to redefine in this situation because it is used in a variety of different contexts in the FAA regulations to reflect things that are approved by the Administrator, and this use imposes certain constraints on the ability to make changes in the use of the term.

Options 1 and 2 are trying to affect a very specific use of the term "approved" (a subset of the ways that it is used): the use of the term in the context of data on which maintenance providers may rely in the case of major repairs and major alterations. Rather than trying to craft language that does not adversely affect the other uses of the term "approved," it might be preferable to adopt a different adjective to describe the data that is appropriate for use to support major repairs and major alterations. To effect this change, one could define a new term ("purple data" and "eligible data" have been used as placeholders, but any adjective not already in use in the regulations could be acceptable). The data included under the definition of this adjective would include both FAA-approved data and DO-approved data (it should be defined in § 1.1 of the regulations to have global impact on all FAA parts of the regulations). The requirements for approved data currently found in parts 65, 121, 135, and 145 could then be updated.

Some positive aspects of this proposed change would include (1) accomplishing the goal of permitting DOs to issue data on which the maintenance community could rely in a manner that is nearly identical to current practice, except with limited FAA involvement (limited to FAA-chosen LOPI), (2) being consistent with existing statutory authority, (3) limiting the possibility of unintended consequences (impact on other uses in the regulations of the term "approved"), and (4) avoiding potential delegation to the public of inherently governmental functions. The negative aspect of this proposal would be the potential need to update international executive agreements (like the maintenance-acceptance provisions of the bilateral agreement with Canada) to reflect the new terminology; however, this impact would likely also apply to expanded use of the term “approved,” because the inherent definition of a term on which the bilateral agreements rely would be changing, which may cause trading partners to want to revisit the affected bilateral agreements.

Although any of the above three options would be acceptable to industry, the FAA indicated that option 3 is likely the most viable option for supporting part 43 maintenance without the use of delegation (an action achieved in the past through recognition of SFAR 36 organizations). The FAA expressed concern regarding whether it was statutorily possible to grant DOs the privilege of approving major changes to the design approvals under part 21, as industry prefers. Current FAA thinking is that some form of delegation would be required. FAA members of the ARC’s DO Working Group acknowledge that, to work within the DO construct, any delegation would essentially be performing an administrative function in making its statutorily required finding. In this role, the delegation would perform the following administrative actions before certificate issuance or approving a type design change:

- Verify the FAA’s planned project LOPI is complete without open issues.
- Verify the statement of compliance was issued by a DO representative authorized to make the statement.
- Ensure there is no knowledge of any noncompliance or unsafe condition conveyed by FAA or DO personnel involved in the project. (Note: This is intended to be a yes-or-no answer without conducting research.)

In summary, three key privileges have been identified that a DO must be granted regarding how it documents its compliance decisions and dispositions data. In all cases, the data would require no further “showing” on the applicability and acceptance of its intended use.

1. New Part 21 Design Approvals. Make determinations of compliance related to the design approvals the DO is seeking to hold under part 21, and similarly make them as either a supplier to another DO or as an agent contracted to manage a certification project for an applicant seeking a design approval, when authorized through a formal interface agreement.
2. Part 21 Type Design Changes. Make determinations of compliance related to both major and minor changes to the design approvals the DO holds under part 21, or for those it has been contracted as an agent for another holder evidenced by a formal interface agreement, and to also approve those type design changes. (Note: In a supplier role, a DO does not approve design changes because it is not the custodian of the type design.)
3. Maintenance and Operations. Create and distribute “approved data” to support part 43 maintenance or any operational requirement associated with a design approval the DO holds, and similarly regarding third-party design approvals (that is, not held by the DO), but where the data approval is executed within the DO’s FAA-authorized scope of authority.

6.8.1 Service Bulletins and a Standardized form for DO Transmittal of Approved Data

When issued, service bulletins constitute a change in type design by the holder and convey the necessary "approved data" to implement the change by owner/operators under part 43. The ARC recommends DO-issued service bulletins or other types of service data should be a means for DOs to provide "approved data" for general use, and a new or revised form is needed for domestic and international recognition of "approved data" created under the DO concept. The new or revised form should contain the same basic information as FAA Forms 8110–3 and 8100–9 regarding compliance data and the approval's purpose.

The form should be titled to recognize the source of the data approval and should be traceable to the originator. In addition, there should be no provisions for recommending approval of data. Thus, "approved" is the only statement that can be made about the data. The form should also address the date the determination of compliance was made and the date the form was signed.

The ARC believes allowing FAA designees and DOs to use the same form is the preferred option. This would help reinforce the equivalency of the data when executed by a DO. The FAA should also consider whether electronic formats would be acceptable for transmitting this type of information to owner/operators.

6.8.2 DO Use of Previously Approved Data

The concept of previously approved "substantiating" or "descriptive" data implies the data has an established pedigree with an FAA approval that makes the data more valuable than data without such a pedigree. However, no inference can be made regarding the applicability of such data to another design approval project unless a determination of compliance has been made by the DO. This does not mean the DO should regenerated, recalculated, or retested the data, but no relief regarding the part 21 showing is implied regarding the new project based on how it was used in the past. The DO will still have to assess the data to determine its applicability to the new project and to make a determination of compliance to the certification basis of the new certification project.

In addition, when a DO incorporates a type certificated or TSO component into its type design, it is only required to show the product's type design, including the installation of that component, is compliant. There is no requirement for the installer to "look behind" the design or compliance status (for example, TSOA status) of the component itself. A similar approach can be taken with STCs and PMA parts when they are installed by owner/operators. However, if a DO desires to make an STC or PMA part directly a part of the type design on which it is being installed, the DO should obtain, or have access to, both the substantiating and descriptive data associated with the STC to make its determination of compliance. Drawing this distinction in no way prevents a TC holder from installing an STC in its production line, but in such cases the STC is not a part of the DO's type design, but rather a change to that design, installed at the time it is manufactured, but held by another entity.

6.8.3 Use of the FAA's Delegation System

One of the basic principles developed for DOs is that the FAA makes no discrete findings of compliance. DOs are issued a DO certificate because they have a demonstrated engineering capability and commitment to compliance. This enables the FAA, using its discretionary authority, not to direct its resources to making numerous discrete compliance findings. Instead, it can rely on the DO's statement of compliance in making its overall compliance finding when issuing a TC or other design approval.

Because the FAA is making no discrete compliance findings, there is no basis for allowing the use of engineering designees, either within the DO itself or at its partners/suppliers. Designees are authorized only to perform tasks the FAA itself would otherwise perform. Because the FAA is not making any discrete findings of compliance under the DO concept, there is nothing to delegate. Thus, the advantage to industry of being able to make all determinations of compliance is that the DO is not dependent on the existing delegation system.

This does not mean DOs cannot use individuals and companies that also hold FAA delegations, but those designees would be acting solely as a design supplier resource to the DO and any compliance determinations made by such suppliers must be conducted under a system determined acceptable by the DO. DOs are not acting as representatives of the Administrator.

6.8.4 DO Recognition and Use of Design Suppliers With FAA Credentials (Including Other DOs)

A DO may take the status of an FAA designee or another DO into consideration when determining the appropriate method and level of supplier oversight it should perform. That oversight must be defined within the DO supplier procedures and must include both the qualification of that supplier and periodic oversight. In conducting its oversight of the supplier, the "project DO" may include as one of its considerations the fact that the supplier is a designee of the FAA, but it must recognize that the FAA will not be conducting oversight on any non-delegation activity. If the supplier is another DO, the FAA will perform oversight of the "supplier DO," but this does not relieve the project DO of performing oversight.

Regardless of a particular supplier's FAA credentials, the project DO must, under its CAS and SMS processes, assess and find acceptable the compliance and safety risk associated with its degree of reliance on this type of supplier. The project DO must also be satisfied that these organizations or individuals are performing as expected, and must be aware of any FAA corrective action related to their performance. The project DO could achieve this awareness by contractually requiring the designee or supplier DO to provide records of any FAA corrective action, such as designee counseling letters or audit records.

A formal supplier interface agreement must exist between a project DO and every supplier DO providing it with determinations of compliance. The interface document should address the scope of what the supplier DO may accomplish for the project DO. The document may authorize the supplier DO to follow its existing DO procedures when making determinations of compliance associated with the project DO's certification plan. The presence of a supplier interface document does not relieve the project DO from showing compliance responsibility as an applicant.

7.0 OTHER PROCESSES FOR SMALL BUSINESSES

The goal of recommending change to part 21 is to streamline certification so the FAA and industry are able to maintain or improve the current level of safety while keeping up with industry growth and ensuring small business are not adversely affected. To encourage small business and innovation, the ARC identified three options to obtain similar responsibilities and certification process efficiencies for any applicant that chooses not to pursue a DO with privileges or, in the long term, falls below the DO applicability threshold:

- Accredited organization (AO),
- Agent design organization (ADO), and
- Modified current model.

The ARC proposed these alternatives in response to the concern that moving most organizations to a DO could introduce costs that would be detrimental to many small businesses. These options would pose less of a burden to small businesses, and each is designed to reduce the FAA's daily involvement in low-risk activities while still maintaining or improving aviation safety. Because of the ARC's inability to focus primarily on those companies falling below the DO applicability threshold, these options have been explored as a preliminary effort. Further research and definition are required for each option following the conclusion of this ARC.

7.1 ACCREDITED ORGANIZATION

An AO would be authorized to determine compliance to specific regulations for the articles or the work the organization performs. The accreditation would be performed by an FAA-approved organization that provided an accreditation process acceptable to the FAA.

The AO approach would seek to achieve many of the same objectives as the DO/SMS approach, but with a goal of making such achievements cost effective for smaller business while maintaining or improving safety. This would be an optional program, with a goal of voluntary adoption by industry.

To parallel or harmonize with the international mandate for SMS principles, the AO would implement COS principles or SMS principles. COS principles incorporate many but not all principles of SMS, and many companies below the DO applicability threshold are already familiar with, or have already implemented, COS.

Those companies seeking to export products to SMS-requiring ICAO countries may elect to implement appropriate additional SMS requirements; however, adoption of SMS requirements would not be mandatory for those implementing an AO.

Adoption of certain established COS/SMS principles would be required for accreditation to a voluntary industry standard. The AO approach would be a voluntary industry accreditation program similar to AC 00–56, Voluntary Industry Distributor Accreditation Program, for distributors. Under such an approach, one or more industry representatives (for example, SAE) would develop industry accreditation standards articulating the necessary requirements for an AO system, including implementation of COS/SMS principles. Those "below-the-threshold" companies successfully accredited to such standards would be identified in an FAA tool indicating compliance. The objective of such an accreditation program is to encourage voluntary participation by industry, and for customers to make inclusion in such a program a prerequisite to doing business. As accreditation to the standard becomes an accepted norm, more companies will seek to implement COS/SMS principles under the AO model.

The AO approach may also provide companies that meet the required accreditation standard with the opportunity to use an approved "compliance library." The compliance library could be one the AO develops on its own and has FAA approval, or one developed as part of a consensus standard approved by the FAA. If a consensus standard were to be used, the AO would use only those standards included on a list approved for the AO by the FAA. The compliance library would enable a "below-the-threshold" company to take advantage of the reliability indicated by accreditation to self-start projects fitting in its compliance library. This would permit the AO to take advantage of the benefits of avoiding the FAA sequencing/project prioritization queue to more quickly initiate projects, with the end result of bringing end-products to market more quickly. Projects not within an AO's compliance library would still be subject to FAA sequencing/project prioritization. The compliance library could be expanded to demonstrate more competencies that would permit the AO to avoid the FAA queue for additional projects.

The AO approach will also provide for a reduced LOPI. The extent to which the LOPI is reduced or increased will depend on the proposed project's complexity. Complex projects will involve more a significant LOPI from the FAA in terms of systems oversight and findings, though not rising to the level of the one-for-one show/find process of the current model. Projects becoming less complex will allow for correspondingly reduced LOPI (and in some cases almost zero LOPI), reflecting their level of complexity and effect on safety, and preserving FAA resources.

7.2 AGENT DESIGN ORGANIZATION

An ADO is a person or organization that could perform certification and COS activities on behalf of an applicant through a contractual arrangement. This would be similar to the current consultant ODA.

ADO is a concept that needs further discussion and understanding by both the FAA and industry. Persons or organizations qualifying as ADOs would have responsibilities similar to those of the AO approach.

ADOs would provide cost-effective options for small companies, STC applicants, and small PMA applicants that do not have resources to implement an AO approach, or that have limited needs for FAA resources because of limited applications.

An ADO may provide services to comply with the § 21.3 requirements and COS monitoring on behalf of holder of a TC (including amended or supplemental TCs), a PMA, or a TSOA, or the licensee of a TC. This enables small companies to comply with the § 21.3 and COS requirements without the maintaining the required resources on their own. This concept needs further exploration and the ADO approach would not be applicable until DOs become available.

7.3 MODIFIED CURRENT MODEL—ENHANCED SHOWING

This process would be open to all applicants and would probably be most used by small applicants with limited resources. This process would require projects to enter the FAA's resource prioritization process and depend on the availability of FAA engineers or DERs to assist the applicant, but could be subject to potentially significant delays because of FAA engineer or DER availability.

The modified current model approach reflects the use of designees by small businesses, including PMA companies and STC applicants. Although the process has not been changed, the model is "modified" in the sense that the FAA anticipates a reduction in the number of DERs available to provide services to these small applicants. With a transition of organizations toward ODA and future DO concept, DERs will be reduced by approximately two-thirds of current numbers by attrition, non-renewal of privileges, and limitations of new DER privileges. RBRT and/or project prioritization will still apply, causing certain applicants to be substantially delayed in the FAA queue based on the perceived value and safety considerations of their application, while giving preference to those applicants whose projects are deemed to have a greater impact on safety.

Criteria for applicant-only showing will be developed by means of a standard (for example, ISO or SAE) for low-risk projects. Specific criteria for applicant-only showing would include the article being considered low risk, meeting criteria of the compliance library, and the ability to issue a § 21.20 statement. If the standard is adopted, applicants will gain privileges.
A compliance library would be developed and accessible in a repeatable manner, allowing the applicant to initiate low-risk projects independent of the FAA. However, for the applicant to take advantage of the privileges, all criteria must be met. If an applicant deviates from the defined criteria, there will be stipulations potentially involving the FAA or a DER. Additionally, the company would have a system in place to meet the specific criteria and have a process with proper oversight and/or checks in the system. The system would have reporting requirements back to the authority regarding self-disclosures and a corrective action program regarding noncompliances. This system would then provide for additional privileges under applicant-only showing program.

The modified current model will encourage those companies that can afford to implement a DO or an AO to do so, to avoid being subject to sequencing with the FAA. Smaller businesses unable to establish an AO or DO will still have access to the FAA but may be subject to delays in FAA compliance findings in areas of FAA involvement such as flight testing, software, human factors, noise, test witnessing, and inherently governmental functions, like exemptions. The FAA must balance the certification needs of applicants producing future products for the National Airspace System with the need to maintain an ever-growing COS responsibility within that airspace. Most FAA resources are currently focused on lower risk projects because of the sheer number of such projects initiated each year. Transitioning small business and lower risk activities to this type of system has the potential to affect the product time to market for the individual companies, allowing the FAA to focus resources in areas of greater risk. The FAA has been successful in the use of abbreviations of this model such as memorandums of understandings between the FAA and applicant.

8.0 MINIMUM DESIGN AND PRODUCTION APPROVAL APPLICANT/HOLDER REQUIREMENTS

8.1 Minimum Design Approval Applicant/Holder Requirements in Support of SMS and Oversight Objectives

8.1.1 Background

The objective of the ARC is to improve the overall effectiveness and efficiency of part 21 certification procedures by updating regulations and policies to reflect a systems safety approach to product certification and FAA oversight of DOs. The ARC considered minimum qualification and organizational requirements for all design approval applicants and holders as a systems approach requires the ability to recognize and establish FAA oversight for the responsibilities and privileges of design approval applicant/holder organizations.

The concept of establishing new minimum design approval applicant/holder requirements is consistent with the ARC's recommendation to establish new SMS requirements for organizations that design or manufacture type-certificated products (under a TC or PC) and those that design or manufacture articles (under a TSO or PMA) or make changes to products (under an STC) that could directly prevent continued safe flight and landing if they fail. SMS is a structured approach to safety that relies on qualified personnel and documented processes and actions requiring some type of minimum organization. Current regulations for design approval eligibility (§ 21.17) allow any person to make application for design approval and do not provide for any minimum qualification.

In addition, minimum qualifications for applicants is necessary to ensure they fully understand the type certification process and their roles and responsibilities so as to ensure effective and efficient certification programs and ongoing continued airworthiness, which allow the FAA's limited resources to focus on safety and value-added activities.

The challenge the ARC faces is to develop a minimum qualification for an applicant without discouraging innovation or disenfranchising small businesses, while at the same time improving the certification efficiency and quality assurance.

To this end, the ARC reviewed the typical small business activities with TSO application and production as well as PMA application and production. From this review, the ARC determined a two-step process was necessary so initial applicants are not discouraged, or overly burdened by new regulatory requirements, from bringing new products into aviation while at the same time ensuring they understand the safety standards applicable to their intended products.

As a result, the ARC developed a progressive approach beginning with an "applicants" minimum understanding of the regulations and compliance process followed by a producer's requirement for a quality system appropriate to the products being produced. The minimum applicant standards are intended to be demonstrated either by the applicant's personal knowledge and/or experience or by contracting with a consultant with the requisite knowledge and experience.

Once the initial application and demonstration of certification is completed and production is ready to begin, the applicant should upgrade their system to include a quality system similar to the quality system requirements of the TSOA and PMA appropriate to their intended product.

> **Recommendation 1b—Systems Approach to Certification – Minimum Applicant/Holder Requirements:** The ARC recommends establishing minimum requirements for design approval applicant/holder qualification and responsibilities to ensure they fully understand the type certification process and how they intend to carry them out.

8.1.2 RECOMMENDED REGULATORY TEXT FOR MINIMUM REQUIREMENTS

A subteam of ARC members that represent small businesses and TSO, PMA, and STC applicants and holders developed a proposed new part 21 requirement establishing minimum standards for all design approval applicants and holders, referred to as "§ 21.nnn." These proposed regulatory requirements for all design approval applicants are similar to requirements currently in place for TSO and PMA applicants/holders:

§ 21.305 [605] Organization.

Each applicant for or holder of a PMA[TSO authorization] must provide the FAA with a document describing how its [the applicant's] organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

§ 21.316 [616] Responsibility of holder.

Each holder of a PMA [TSO authorization] must—

(a) Amend the document required by § 21.305 [605] as necessary to reflect changes in the organization and provide these amendments to the FAA. [...]

§ *21.nnn Minimum standards for design approval applicants and holders.*

(a) No person may apply for a design approval unless that person submits to the FAA—

(1) The following organizational information:

(i) The identity of an accountable manager.[8]

(ii) The identity of a primary point of contact during the approval process.

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[8] For the purposes of this requirement, the accountable manager means the person designated by an applicant or design approval holder who is responsible for and has the authority over all design approval operations that are conducted under part 21, including ensuring that design approval holder personnel follow the regulations and serving as the primary contact with the FAA. (Refer to the glossary in appendix C of this document.)

(iii) The reporting relationship between the point of contact and the accountable manager, if they are different.

(iv) How the accountable manager fits within the company's reporting and budget structure.

(2) A document describing how the applicant intends to show compliance with all applicable requirements for the issuance of the design approval.

(b) No person may hold a design approval unless that person submits to the FAA—

(1) The following organizational information:

(i) The name and address of the design approval holder;

(ii) The identity of an accountable manager;

(iii) The identity of a primary point of contact;

(iv) The reporting relationship between the point of contact and the accountable manager, if they are different.

(2) A document describing how the design approval holder intends to comply with all applicable requirements including —

(i) Process for controlling descriptive and substantiating data and subsequent changes to that descriptive and substantiating data to ensure that only current, correct, and approved data is used in production;

(ii) Process for complying with the reporting requirements of this Part.

(iii) Process to make available the instructions of continued airworthiness and changes thereto pursuant to § 21.50.

(c) A design approval holder must submit to the FAA each change to any process required by this section.[9]

The proposed § 21.nnn is intended to assist those new applicants who do not have prior experience certifying aircraft or other products better understand what is required before they submit an application for a design approval. This can help them potentially reduce their costs and frustration with the complex nature of the certification process. Most established companies will already have processes in place to address all of these requirements.

8.1.3 Corresponding Changes to Related Regulations

The FAA provided the ARC with initial proposals for "part 21 cleanup," which includes different approaches and concepts to establish minimum requirements for design approval applicants/holders. Although considered, the ARC decided to propose new § 21.nnn regulatory text to provide a complete understanding of the objectives and intent. However, the ARC

[9] The ARC notes that during the pre-application consultation phase, it would expect that the potential applicant might not yet meet the applicant requirements, but the potential applicant would be able to identify point of contact and would have some idea of how it plans to demonstrate compliance.

recognizes there are several existing part 21 regulatory requirements affected that will need to be changed to either incorporate these concepts or ensure consistency with new requirements. The following table reflects proposed changes in the original FAA cleanup document and is provided for reference as the ARC's proposed § 21.nnn may also require consideration of corresponding changes to these related regulatory paragraphs.

Table 3. Recommended Changes to Part 21 Regulatory Requirements

Existing Regulation	FAA Cleanup Proposed Change	FAA Explanation
§ 21.13 Eligibility. Any interested person may apply for a type certificate.	§ 21.13 Eligibility. *a) Prior to application, applicants for type certificate must propose an acceptable system/process for establishing compliance.* *b) Any interested person may apply for a type certificate. The FAA may decline the application if the submittal is incomplete or the project has no U.S. interest.*	Require applicants for TCs to propose acceptable system/process for establishing compliance prior to application.
§21.15 Application for a type certificate (a) An application for a type certificate is made on a form and in a manner prescribed by the FAA and is submitted to the appropriate aircraft certification office. (b) An application for an aircraft type certificate must be accompanied by a three-view drawing of that aircraft and available preliminary basic data. (c) An application for an aircraft engine type certificate must be accompanied by a description of the engine design features, the engine operating characteristics, and the proposed engine operating limitations.	**§21.15 Application for a type certificate** (a)*** *(b) An applicant for an aircraft type certificate must submit with the application:* *1) a detailed description of the design features* *2) a detailed engineering graphic representation of the aircraft with multiple views* *3) any available preliminary basic data.* *4) proposed certification basis and other data (e.g., preliminary means of compliance).*	Need to require more information initially from the applicant, ensuring early understanding of certification process and schedules before application.
§ 21.21 Issue of type certificate: normal, utility, acrobatic, commuter, and transport category aircraft; manned free balloons; special classes of aircraft; aircraft engines; propellers. An applicant is entitled to a type certificate for an aircraft in the normal, utility, acrobatic,	**§ 21.21 Issue of type certificate: normal, utility, acrobatic, commuter, and transport category aircraft; manned free balloons; special classes of aircraft; aircraft engines; propellers.**	To require a standard high level of certitude by applicants (i.e. the applicant cannot just be a leasing company, front company, etc.). Align with EASA (e.g.,

Existing Regulation	FAA Cleanup Proposed Change	FAA Explanation
commuter, or transport category, or for a manned free balloon, special class of aircraft, or an aircraft engine or propeller, if— (a) The product qualifies under §21.27; or (b) The applicant submits the type design, test reports, and computations necessary to show that the product to be certificated meets the applicable airworthiness, aircraft noise, fuel venting, and exhaust emission requirements of this subchapter and any special conditions prescribed by the FAA, and the FAA finds— (1) Upon examination of the type design, and after completing all tests and inspections, that the type design and the product meet the applicable noise, fuel venting, and emissions requirements of this subchapter, and further finds that they meet the applicable airworthiness requirements of this subchapter or that any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and (2) For an aircraft, that no feature or characteristic makes it unsafe for the category in which certification is requested.	*** *** (a) the applicant has established and maintained an engineering system and processes to establish compliance with airworthiness standards and part 21 requirements. (b) The applicant qualifies under 21.43. (text shown is manufacturing link)	procedures manual, milestones, staff and their authority, applicable requirements for a project plus MOC, etc.)
§ 21.47 Transferability. (a) A holder of a type certificate may transfer it or make it available to other persons by licensing agreements. (b) For a type certificate transfer in which the State of Design will remain the same, each transferor must, before such a transfer, notify in writing the appropriate aircraft certification office. This notification must include the applicable type certificate number, the name and address of the transferee, and the anticipated date of the transfer. (c) For a type certificate transfer in which the State of Design is changing, a type certificate may only be transferred to or from a person subject to the authority of another State of Design if the United States has an agreement with that State of Design for the acceptance of the affected product for export and import. Each transferor must notify the appropriate aircraft certification office before such a transfer in a form and manner acceptable to the	§ 21.47 Transferability. *** *** *(e) FAA will agree/approve transfer and reissue of Type Certificate/Supplemental Type Certificate (TC/STC) after review of new potential holder's qualifications and capabilities as a certificate applicant and holder.* *(f) The transferor of a type or supplemental type certificate must provide to the transferee all type design and substantiation data related to the certificate.* *(g) The licensor of a type or supplemental type certificate must provide to the licensee all of the type design and*	Need to ensure continuing airworthiness and design holders reporting responsibilities will be continued. Better aligns with EASA regulations that require transfer of both TC and substantiation data. This would provide enforceability on the selling or licensing party.

Existing Regulation	FAA Cleanup Proposed Change	FAA Explanation
FAA. This notification must include the applicable type certificate number; the name, address, and country of residence of the transferee; and the anticipated date of the transfer. (d) Before executing or terminating a licensing agreement that makes a type certificate available to another person, the type certificate holder must notify in writing the appropriate aircraft certification office. This notification must include the type certificate number addressed by the licensing agreement, the name and address of the licensee, the extent of authority granted the licensee, and the anticipated date of the agreement.	<u>*substantiation data necessary for the licensee to fulfill its obligations under this subchapter.*</u>	
§21.XX Design Approval Holder Responsibilities	**Add new section – Specifies or references Design Approval holder responsibilities.**	To reference responsibilities of a design approval holder in central location. Similar to current 14 CFR 21.146 for Production Approval holders. Require holder to submit address changes to maintain currency and for notification purposes.

8.2 Changes to § 21.3 Reporting to Reflect SMS

8.2.1 Background

Section 21.3 was originally proposed in March 1969 and codified later in 1970. The list of reportable items in § 21.3(c), as promulgated in 1970, was very similar to Civil Aviation Regulation (CAR) 40.508, Mechanical Reliability Reports, which required air carriers to submit mechanical reliability reports. CAR 40.508 was last changed in March 1962. Section 21.3(c) has remained unchanged for close to 45 years. Airplane design, the aviation transportation system, and understanding of how accidents occur have changed dramatically in those years. The proposed changes to § 21.3, namely the addition of a new §§ 21.3(d) and 21.3(e), aim to improve reporting of failures, malfunctions, and defects so it correlates to the current aviation system. Because these new regulations are process-based they will enable reporting requirements to be adapted to future reporting needs.

The purpose of the proposal as expressed in the original proposal for § 21.3 was to provide the FAA with the earliest possible notification of failures, malfunctions, or defects so the FAA may take appropriate mandatory action, such as issuing an AD. AC 21–9B, Manufacturers Reporting of Failures, Malfunctions, or Defects, further implies that compliance with § 21.3 will provide the earliest possible notification to the FAA of a potentially unsafe condition and will ensure appropriate corrective action by the manufacturer.

An update of § 21.3 is also needed to align reporting requirements and processes with existing COS systems in place at many D&M organizations. These changes will also facilitate the FAA in meeting its responsibility to ensure D&M organizations are managing risk acceptably. Lastly, the proposed changes to § 21.3 will increase harmonization with other regulatory authorities' reporting requirements.

One of the ARC's objectives was to develop these changes while minimizing impact on many smaller D&M organizations that already meet the existing reporting requirements. The articles from these organizations typically introduce relatively little risk in the system. The ARC therefore did not want to negatively impact these smaller organizations by requiring changes that were not likely to improve risk management.

8.2.2 Recommended Regulatory Changes

The proposed solution provides options for D&M organizations to declare the means by which to report. This is evidenced by enabling either reporting in accordance with the existing § 21.3(c) or reporting under a process-based methodology in the new § 21.3(d).

The current part 21 does not provide a complete set of COS requirements. The risk management of a product or article following a design approval is a necessary function to assure the public's expectation of safety. Most, if not all, D&M organizations have implemented COS programs. The TC/PC holders and larger STC, PMA, and TSOA holders typically operate sophisticated COS systems. The new § 21.3(e) establishes regulatory expectations to implement COS systems for all D&M organizations and provides a clearer path for FAA oversight of these systems.

Section 21.3(e) contains minimum COS requirements. Section 21.3(e)(1) attempts to take advantage of existing processes many affected parties may have that comply with § 21.137, Quality system, and that use the existing list of occurrences in § 21.3(c) to report to the FAA. Section 21.3(e)(2) aligns with § 21.3(d) and is consistent with many existing COS agreements between ACOs and D&M organizations.

The change in § 21.3(g)(1) to increase the time to report to 72 hours was originally proposed in the FAA's initial submittal to the ARC. Increasing reporting time from 24 hours to 72 hours aligns with EASA. However, EASA has other stipulations that are not represented in the proposed change.

<u>The ARC recommends implementing the changes to §§ 21.3 and 21.4 identified in the following table.</u>

Table 4. Recommended Changes to §§ 21.3 and 21.4

Section	Recommended Change	Existing 21.3 regulation, Amendment 21–92, Wording
21.3 Title	Failures, malfunctions and defects	Reporting of failures, malfunctions, and defects
21.3 (a)	(a) The holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate must report any failure, malfunction, or defect in any product or article manufactured by it, that has *resulted in:* *(1) Any occurrence listed in paragraph (c) or* *(2) Any occurrences identified by the holder as determined by their safety analysis process in accordance with paragraph (d) of this section.*	(a)The holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate must report any failure, malfunction, or defect in any product or article manufactured by it that it determines has ~~resulted in any of the occurrences listed in paragraph (c) of this section.~~
21.3(b)	(b) The holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate must report*, in accordance with paragraph (c) or (d) of this section, any defect in any product or article manufactured by it, that could result in:* *(1) Any occurrence listed in paragraph (c) or* *(2) Any occurrences identified by the holder as determined by their safety analysis process in accordance with paragraph (d) of this section.*	(b) The holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate must report ~~any defect in any product or article manufactured by it that has left its quality system and that it determines could result in any of the occurrences listed in paragraph (c) of this section.~~
21.3(c)	No Change	No Change
21.3(d)	*(d) Occurrences, as determined by a safety analysis process developed by the holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate, and approved by the Administrator, must be reported as provided in paragraphs (a) and (b) of this section of which it is aware that has resulted in or may result in a finding of an unsafe condition by the Administrator.*	New requirement. Resulted in renumbering of existing requirements so § 21.3(d) becomes § 21.3(f).

Section	Recommended Change	Existing 21.3 regulation, Amendment 21–92, Wording
21.3(e)	*(e) The holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate must:* *(1) Identify, analyze, and initiate appropriate corrective action for any of the occurrences reported under paragraph (c) of this section, or otherwise;* *(2) Monitor reported service problems, analyze, and initiate appropriate corrective action for any of the occurrences reported under paragraph (d) of this section.*	New requirement. Resulted in renumbering of existing requirements so § 21.3(e) becomes § 21.3(g).
21.3(f)	The requirements of paragraph (a) of this section do not apply to— (1) Failures, malfunctions, or defects that the holder of a type certificate (including amended or supplemental type certificates), PMA, TSO authorization, or the licensee of a type certificate determines— (i) Were caused by improper maintenance or use; (ii) Were reported to the FAA by another person under this chapter; or (iii) Were reported under the accident reporting provisions of 49 CFR part 830 of the regulations of the National Transportation Safety Board. (2) Failures, malfunctions, or defects in products or articles— (i) Manufactured by a foreign manufacturer under a U.S. type certificate issued under § 21.29 or under an approval issued under § 21.621; or (ii) Exported to the United States under § 21.502.	§ 21.3(f) is same as current § 21.3(d)

Section	Recommended Change	Existing 21.3 regulation, Amendment 21–92, Wording
21.3(g)(1)	Each report required by this section— (1) Must be made to the Aircraft Certification Office in the region in which the person required to make the report is located within *72* hours after it has determined *a reportable occurrence has occurred.* However, a report that is due on a Saturday or a Sunday may be delivered on the following Monday and one that is due on a holiday may be delivered on the next workday;	§ 21.3(g) is same as current (e) Formerly § 21.3(e)(1) (e)(1) Must be made to the Aircraft Certification Office in the region in which the person required to make the report is located within ~~24~~ hours after it has determined ~~that the failure, malfunction, or defect required to be reported has occurred~~. However, a report that is due on a Saturday or a Sunday may be delivered on the following Monday and one that is due on a holiday may be delivered on the next workday;
21.3(g)(2) and (3)	(2) Must be transmitted in a manner and form acceptable to the FAA and by the most expeditious method available; and (3) Must include as much of the following information as is available and applicable: (i) The applicable product and article identification information required by part 45 of this chapter; (ii) Identification of the system involved; and (iii) Nature of the failure, malfunction, or defect.	§ 21.3(g)(2) and (3) are same as current (e)(2) and (3)
21.3(h)	If an accident investigation or service difficulty report shows that a product or article manufactured under this part is unsafe because of a manufacturing or design data defect, the holder of the production approval for that product or article must, on request of the FAA, report to the FAA the results of its investigation and any action taken or proposed by the holder of that production approval to correct that defect. If action is required to correct the defect in an existing product or article, the holder of that production approval must send the data necessary for issuing an appropriate airworthiness directive to the appropriate aircraft certification office.	§ 21.3(h) is same as current (f)
21.4	§ 21.4(a)(5) The type certificate holder must identify the sources and content of data that it will use for its system. The data must be adequate to evaluate the specific cause of any in-service problem reportable under this section or § 21.3 that could affect the safety of ETOPS.	Refer to section 8.2.4 on Relationship to § 21.4, ETOPS Reporting Requirements

8.2.3 Alignment With Other Existing and Potential Regulations

The recommended changes to §§ 21.3(d) and 21.3(e) align with organizations that—

1. Hold an ODA under part 183;
2. Will be required to comply with the proposed SMS Requirements in part 5; and
3. Will implement an approved DO concept and associated reporting requirements.

ODAs that meet the requirements of § 183.63, Continuing requirements: Products, parts or appliances, should be able to show that the related processes will comply with the new §§ 21.3(d) and 21.3(e). Further, processes developed in accordance with part 5 will facilitate compliance to § 21.3(e)(2). Duplication of requirements will be avoided while allowing future changes in safety management.

<u>The ARC recommends developing or revising the following guidance materials to support the recommended rule changes and facilitate FAA oversight:</u>

1. <u>Criteria for consistent understanding of the language in § 21.3(d) “has resulted in or may result in a finding of an unsafe condition by the Administrator”.</u>
2. <u>Acceptable compliance demonstration and verification regarding the safety analysis referenced in § 21.3(d).</u>
3. <u>Changes to AC 21–9B, Manufacturers Reporting of Failure, Malfunctions, or Defects, to include the recommended guidance for §§ 21.3(d) and 21.3(e).</u>

8.2.4 Relationship to § 21.4, ETOPS Reporting Requirements

The ARC also considered the potential impact to § 21.4, ETOPS Reporting Requirements. Section 21.4(a)(5) will need to be amended to include applicability of the new § 21.3(d) by deleting only reference to § 21.3(c) as follows:

> <u>*(5) The type certificate holder must identify the sources and content of data that it will use for its system. The data must be adequate to evaluate the specific cause of any in-service problem reportable under this section or § 21.3 that could affect the safety of ETOPs.*</u>

8.2.5 Short-Term Risk Management

8.2.5.1 Background

FAA Order VS8000.367A, Aviation Safety (AVS) Safety Management System Requirements, requires the FAA to define a process for acceptable safety risk in the short term while long-term safety risk control/mitigation plans are developed and implemented. In some situations there can be a short-term design solution that adequately mitigates the risk in the short term but is not fully certifiable because it does not adequately address a known hazard. From a safety risk management perspective, it may be desirable to enhance the safety of the in-service fleet by implementing the short-term solution. For economic reasons, it may also be desirable to continue delivering products with the short-term design solution until the long-term solution can be developed.

Current part 21 regulations, policy, and guidance require any changes in type deign to be fully compliant to all applicable regulations at the installation or product level, regardless of whether the change improves the safety or product capability. There are ongoing situations where time-limited exemptions are required to allow the incorporation of a product safety enhancement for an interim period until a fully compliant product-level change can be identified. There are also situations in which a product improvement that maintains or enhances the product safety cannot be incorporated without an exemption because the installation or product level cannot be shown to fully comply. The nature of the exemption process does not lend itself to expeditiously addressing in-service fleet safety concerns.

Occasionally after a TC has been issued, the FAA discovers the product does not comply with one or more of the applicable airworthiness provisions. If the noncompliant product is considered airworthy, manufacture and operation of that product type is allowed to continue. However, certificating a major change for that product, even if the change clearly improves the level of safety, currently requires the applicant to bring the product back to the level of safety intended by its basis of certification or be granted an exemption. This may place an inequitable burden on major design changes, which is clearly a deterrent to discretionary product improvements as well as production incorporation of improvements mandated by an AD. A short-term solution to a known hazard may be available faster than the process for obtaining an exemption and therefore may prolong the incorporation of a safety enhancement into the fleet.

SMS is intended to move to a more risk-based approach and aligns the responsibility of safety management with the product or service provider while ensuring compliance to the airworthiness regulations. To achieve this objective, the regulations for changes to type design should reflect and allow for incorporation of short term product and safety enhancements when the risk is shown to be acceptable, even though the installation or product may not fully comply, provided there is a plan for a long-term design change that does comply with the airworthiness regulations. Accordingly, the changes to part 21 compliance regulations should be tied to part 5 SMS applicability to products. Additionally, there should be criteria for when an exemption is necessary.

8.2.5.2 Recommended Regulatory Changes

The ARC recommends that it continue to develop regulatory proposals aligned with SMS philosophies to enhance safety. The objective would be to complete the task by October 2014 by providing an addendum to this report.

The regulatory applicability would be limited to non-substantial, non-significant § 21.101 changes to type design and hence only be major changes per § 21.93, Classification of changes in type design. The TC holder would rely on their SMS SRM processes to define the short and long-term acceptable risk while presenting a plan for a long-term design change that complies with the airworthiness regulations.

Criteria is needed for when the part 21 process should be used instead of an exemption,[10] defining the long-term compliance plan, process for applicant and regulatory authority agreement on short-term mitigation and safety assurance of the short-term risk mitigation or product enhancements. The proposal should enhance part 21 so parts 5, 11, and 21 function more systemically to maintain or enhance safety of the product while ensuring compliance with the airworthiness regulations.

The ARC recommends changes to part 21 to address situations described above, examples of which are provided below:

- Short-term solutions:
  - There is an unacceptable risk in the fleet, and a short-term solution that adequately mitigates the risk is available but not fully certifiable because it does not fully address a known hazard. For economic reasons it may also be desirable to continue delivering products with the short-term design solution until the long-term solution can be developed.
  - There is a known noncompliance in production for which the holder has defined a recovery plan. An interim fix is available that mitigates some of the risk, but is not fully compliant.
- Product enhancements that maintain or enhance product safety:
  - Some types of changes are often considered where because of the constraints of having to comply with the latest regulatory requirements, whether because of safety issues or revisions to regulations, it becomes economically impractical to implement the change even though those changes would provide an incremental improvement in the performance, functionality, reliability, or safety of the product. These fall under the following categories:
    - Product improvements for—
      - Added or improved functionality,
      - Reliability enhancements,
      - Improved performance,
      - Maintainability enhancements, and
      - Producibility enhancements;
    - Part obsolescence; and
    - Alternate or substitute parts.

<u>The ARC recommends developing proposed regulation changes and guidance or process proposals to address safety risk that is acceptable in the short term while long-term safety risk control/mitigation plans are developed and implemented.</u>

[10] In the context of product improvements that do not have a plan for a long-term fully compliant product change, NATCA's position is an exemption should be required.

Recommendation 4—Part 21 Cleanup and TSO Modernization: The ARC recommends FAA consideration of several proposed changes and updates to various part 21 regulations, which primarily reflect clarifications to eliminate confusion, modernization to reflect current practices, and updates to align with other recommendations in this report for a systems approach to certification.

9.0 PART 21 CLEANUP & TSO MODERNIZATION

9.1 PART 21 CLEANUP

The following proposed changes are cleanup issues that would eliminate confusion and inability to comply in the current regulation, if addressed. They do not affect product safety.

9.1.1 SECTION 21.8 AND 21.9 ISSUE PAPER

As recommended by the 14 CFR Part 23 Reorganization ARC's 2013 report, the part 21/SMS ARC recommends—

1. Clarifying the applicability of § 21.8, Approval of articles, and § 21.9, Replacement and modification articles; and
2. Adding provisions to § 21.9 for the productions of parts allowed under the authority of § 21.8.

Over the past decade there have been discussions regarding approved parts and unapproved parts. The level of activity seems to parallel the FAA field applications regarding the Suspected Unapproved Parts program. There numerous opinions regarding the applicability of §§ 21.8 and 21.9.

It is important to highlight that in the 1995 Suspected 'Unapproved Parts' Program Plan, which was prepared and submitted to the Administrator by the FAA Suspected 'Unapproved Parts' Task Force, the task force clarified that an "approved part" is not synonymous with "a part that has received a formal FAA approval."

The terms "approved parts" and "unapproved parts" as used in this report are not legal definitions, but a reflection of the need to have a broad term that identifies parts that should, or should not, be installed on an aircraft. In this report, parts that should be used on an aircraft (that is, "approved parts") are described as parts "acceptable for installation" or "eligible for installation."

9.1.1.1 Applicability of § 21.8

Section 21.8 begins with the scope of the section by stating "If an article is required to be approved under this chapter ..." In clarifying the scope of § 21.8, which chapter is this regulation addressing?

> **§ 21.8 Approval of articles.**
>
> If an article is required to be approved under this chapter, it may be approved—
>
> (a) Under a PMA;
>
> (b) Under a TSO;
>
> (c) In conjunction with type certification procedures for a product; or
>
> (d) In any other manner approved by the FAA.

Part 21 is contained within chapter I, Federal Aviation Administration, Department of Transportation of 14 CFR. Therefore when § 21.8 refers to an article required to be approved under “this chapter” it is referring to chapter I, the Federal Aviation Regulations. Although this is readily apparent for required equipment within subchapter C, Aircraft, as these required equipment are approved via the type certification process, the applicability is not as apparent for non-required/optional equipment nor certain applicability’s within part 91, General Operating and Flight Rules. Part 91, carries specific criterion for operational equipment which are often absent from specific “approval” requirements.

The following are examples of regulatory language that cause the confusion:

- Section 91.205(b)(11) serves as an example where the article must be approved: “For small civil airplanes certificated after March 11, 1996, in accordance with part 23 of this chapter, an approved aviation red or aviation white anti-collision light system.”
- Section 91.225(a)(1) serves as an example where the article is approved by specific TSO: “After January 1, 2020, and unless otherwise authorized by ATC, no person may operate an aircraft in Class A airspace unless the aircraft has equipment installed that— Meets the requirements in TSO-C166b ...”
- Section 91.215(a) serves as an example where the article must meet the performance of the TSO standards but not necessarily be approved to the TSO: “For operations not conducted under part 121 or 135 of this chapter, ATC transponder equipment installed must *meet the performance and environmental requirements* of any class of TSO-C74b (Mode A) or any class of TSO-C74c (Mode A with altitude reporting capability) as appropriate, or the appropriate class of TSO-C112 (Mode S).”
- Section 91.205(d)(2) serves as an example of where the operating rules are silent on the subject of approval: “Two-way radio communication and navigation equipment suitable for the route to be flown.”

9.1.1.2 Applicability of § 21.9

Under the final rule for the Production and Airworthiness Approvals, Part Marking, and Miscellaneous Amendments (74 FR 53368, October 16, 2009) the FAA clarified “The provisions of § 21.9 apply to the *producer* of any part that may be used as a replacement or modification article, not just parts that were produced specifically as replacement or modification articles.”

When answering questions submitted by the U.S. Small Business Administration, the Administrator reiterated that “Section 21.9 governs the production, not the sale, of articles and does not prohibit distributors from selling articles,”[11] and “The requirements of this rule apply to products or articles as they are manufactured.”[12]

Therefore, it is clear that the applicability of § 21.9 is for the production of replacement and modification parts and does not apply to the sale, distribution or installation of parts.

[11] 74 FR 53368, 53373.
[12] 74 FR 53368, 53374.

9.1.1.3 Recommendations

The ARC recommends AC 20–62, Eligibility, Quality, and Identification of Aeronautical Replacement Parts, paragraph 6, Discussion, be amended to include an explanation of the scope of §§ 21.8 and 21.9.

Specifically, the ARC recommends adding the following paragraphs to AC 20–62:

6. DISCUSSION. [...]

d. Applicability of Section 21.8. Section 21.8 requires that if an article is required to be approved under the Federal Aviation Regulations, that the part may be approved under a PMA, TSO, in conjunction with type certification procedures for a product; or in any other manner approved by the FAA. If the regulations are mute about explicit approval requirements such as for non-essential, non-required equipment, section 21.8 does not apply and the installer will default to section 43.13 for in-service installations. Section 21.8 applies to—

(1) All required equipment within subchapter C,

(2) Anywhere in part 91 where the equipment requirements explicitly require approval, and

(3) Any required equipment in part 121, 129, and part 135.

e. Applicability of Section 21.9. Section 21.9 applies to the production of replacement and modification parts and is does not apply to the sale, distribution or installation of parts.

Proposed Revision to § 21.9

A recent development originating with the ARC highlighted an apparent unintended limitation of § 21.9. Although § 21.8 allows for parts to be approved "In any other manner approved by the FAA." (§ 21.8(d)) there are no provisions within § 21.9 to produce those "otherwise approved" parts. As such, it is the recommendation of the ARC to include similar language to § 21.8(d) within § 21.9.

The ARC recommends amending § 21.9(a) to add paragraph (a)(7), which reads: "Produced in any other manner approved by the FAA."

9.1.2 SECTION 21.335, RESPONSIBILITY OF EXPORTERS

Section 21.335(b) states that each exporter of aircraft parts must "[p]reserve and package products and articles as necessary to protect them against corrosion and damage during transit or storage and state the duration of effectiveness of such preservation and packaging." The requirement to state the duration of a packaging's effectiveness arises from ATA Spec 300, Specification for Packaging of Airlines Supplies. However, Spec 300 does not describe or contemplate a duration requirement for a single-use packaging. The duration and effectiveness of single-use packaging is not a metric that is typically available from packaging manufacturers, thus making it impossible to satisfy § 21.335(b) under current industry standards and practices. Furthermore, the FAA has produced no guidance material to explain to industry or FAA personnel the appropriate methods for determining and stating the duration and effectiveness of packaging, and it is unclear whether the provision offers any safety benefits, as it has never been treated as an enforcement priority. The ARC therefore recommends the FAA remove the phrase "and state the duration of effectiveness of such preservation and packaging" from § 21.335(b). A copy of the Aviation Suppliers Association (ASA) white paper providing additional details on this proposal is located in appendix M to this report.

The ARC recommends the removal of § 21.335(b) from 14 CFR.

9.1.3 TSO Cleanup Recommendations Not Tied to ARC Objectives

The TSO Sub team identified four items it would like to see changed that were not tied to the ARC charter or taskings.

For these four items the ARC recommends—

- Maintaining the privilege for TSO holders to make minor or insignificant (sub-minor) changes to articles without further approval;
- Clarifying the TSO application data, manufacturer data and furnished data requirements. (Refer to the TSO Sub team Report, included as appendix H to this report);
- Developing expanded guidance to promote the uniform definition and treatment of integrated non-TSO functions by applicants, installation developers, and the FAA. (Refer to the TSO Subteam Report, included as appendix H to this report); and
- An applicant should submit to the Administrator a signed undertaking to carry out the responsibilities as a DAH before issuance of a design approval.

9.2 Part 21 Recommendations for TSO Program

Regarding the TSO program value and challenges identified in appendix C to the TSO Subteam Report included as appendix H to this report, the TSO Subteam reviewed the list of issues and problem statements from the three sources (FAA, ARC members, and FAA-industry workshop), to distill the key issues that, if appropriately addressed, would lead to material improvements in the effectiveness and efficiency of the TSO program. These key issues are—

- Acceptance/approval of integrated non-TSO functions,
- Management of post-TSOA design discrepancies,
- Definition of substantiation data and data submittal items,
- Minimizing re-review of TSOA substantiation data at installation approval, and
- Elimination of unnecessary TSO deviation requests.

The TSO Subteam continued to develop six rulemaking recommendations and proposals for related policy and guidance, for consideration by the ARC in its final report to the FAA. Although the recommendation in section 9.2.1 below is written with reference to a "certified TSO organization," these recommendations are generally intended to be implementable by either a certified TSO organization or an expanded FAA (ODA) delegation system, incorporating TSO design functions.

9.2.1 TSO RECOMMENDATIONS

The TSO system has been described as a “self-certification” process, but currently requires FAA involvement to verify the manufacturer’s compliance statement and issue an authorization to apply TSO marking for each article. The FAA could better manage its resources and streamline the TSO process by allowing the traditional FAA review portion to be performed by certified TSO organizations or appropriately delegated organizations, up to and including issuance of the TSOA letter. The FAA already has a rule basis to qualify TSO organizations under § 21.605, but part 21 subpart O, Technical Standard Order Approvals, currently requires an application to be submitted to the ACO (under § 21.603, Application) and the FAA to issue the authorization (under § 21.611, Issuance).

<u>The ARC recommends allowing TSO organizations to issue their own TSOAs, relative to scalable privileges for particular types of TSO standards. (Alternate approaches via a certified TSO organization or expansion of TOS ODA functions.)</u>

Under current rules, the holder of a TSOA is expected to maintain the performance of the TSO article relative to the TSO standard. However, to support airworthiness or contractual requirements, TSO manufacturers are typically required by their customers to maintain performance of the article relative to requirements that are not part of the TSO standard. The TSO system could be modified to allow manufacturers to better align their requirements under the TSO system with those requirements they are electing to meet as part of airworthiness or contractual obligations. EASA’s system supports the declaration of this type of manufacturer-defined performance by requiring the submission of a Declaration of Design and Performance (DDP), and expects TSO manufacturers to control the article’s performance relative to that DDP. Refer to appendix M to this report.

<u>The ARC recommends clarifying the types of data that can be approved under a TSOA (that is, type design of the article and declared performance of the article including non-TSO functions and incomplete TSO), and expectations for acceptance of approved TSO data for installation. (Require and approve DDP via revision to § 21.601(b)(2) and proposed new § 21.601(b)(2) and § 21.603(b)(3).)</u>

Non-TSO functions have become increasingly prevalent in avionics systems mainly because of added processing capabilities in newer integrated circuits as well as larger and cheaper memory capabilities. However, mechanical systems TSOs, such as seats, can also contain provisions to host non-TSO functions (for example, embedded passenger entertainment devices). These added non-TSO functions are mainly market or original equipment manufacturer driven to optimize installation capabilities while minimizing certification costs. Added non-TSO functions have historically been handled through FAA policy, because part 21 subpart O does not specifically address or codify their embedded existence. This resulted in a problem with some ACOs who feel the current part 21 subpart O does not allow for a more detailed evaluation of non-TSO functions at the time of TSO approval, even though the added non-TSO functions are inseparable from the hosting TSO article design at the time of manufacture.

The ARC’s proposed change would provide several benefits. For the TSO applicant, an initial review of the manufacturer-declared performance can be made, and credit for software, hardware, and environmental testing in support of installation can be acknowledged in the TSOA letter. For the FAA, more efficient use of engineering resources because the review of the added functions can be more thoroughly accomplished with the TSO manufacturer as opposed to attempting to accomplish this review during each subsequent installation approval. Both the TSO article as well as the integrated non-TSO functions, must be appropriate to support the intended installation.

<u>The ARC recommends proposed new §§ 21.603(a)(3) and 21.619(d), Design changes, for subsequent design changes. (Additional guidance including a "decision table" to assist in differentiating between TSO supporting features and integrated non-TSO functions.)</u>

Current regulations require the use of model numbers to maintain configuration control of TSOAs. From a practical perspective, however, model numbers are frequently used as marketing identifiers; they do not consistently provide a meaningful reference for configuration control of TSO article designs.

<u>The ARC recommends rule revision to remove the term "model number" from TSO rules and replace it with a requirement for a "unique identifier." (Revision to §§ 21.603(b) and 21.619 for subsequent design changes.)</u>

Currently § 21.603(a)(1) implies that application for TSO is made after all design and development is completed. Designing and developing a TSO article is a lengthy process especially for complex articles. During this time, TSOs could be revised or new TSOs could be introduced. Current policy, as defined in FAA Order 8150.1C, Technical Standard Order Program, paragraph 6–1(b), allows an applicant 6 months from release of a newer revision to apply with the previous revision. Although 6 months seems to be a reasonable timeframe, many complex system developments take significantly longer and the 6 month grace period is not sufficient. The two current options to address this situation are—

1. Request a petition for exemption (per 14 CFR part 11, General Rulemaking Procedures), which an applicant is required to submit at least 120 days before the exemption is needed. After submission, approval can take many months because of the requirement of publication in the Federal Register and a public comment period.
2. Comply with the newer revision TSO or add a newly released TSO.

If a new revision of a TSO or newly introduced TSO provides no benefit or does not impact flight safety, this additional work to submit a petition for exemption or complying with the latest TSO during an in-process development project could be a large burden on an applicant, potentially driving redesign and/or retesting and preventing expeditious introduction of safety enhancing products to market. Because TSOA is a self-certification based on a statement of conformance, the responsibility of reviewing and ensuring any new or revised TSO(s) does not affect the certification basis or design is the burden of the TSO applicant regardless of when application is made.

If the applicant is allowed to declare the effective TSO revision levels at the beginning of a project, FAA/applicant communication on complex certification issues could be improved. Currently, when an application is submitted, there could be several iterations because of certification basis disagreements causing potential applicant design rework and weeks to months of delay in issuance of a TSOA letter. Based on the regulation change, adoption of the new or recently revised TSO(s) would be voluntary unless the change is because of a safety-of-flight issue or required for other reasons, such as interoperability, and deemed mandatory by the FAA. The benefits of this change can be tracked through improved turnaround time of TSOA letter issuance from the FAA, on final submittal of a statement of conformance certifying that the applicant has met the requirements of the subpart and that the article meets the applicable TSO(s).

<u>The ARC recommends changing part 21 to establish the effective TSO revision level at the beginning of the project, not at the end. (Revision to § 21.603(a).)</u>

Before the changes to part 21 and part 45, Identification and Registration Marking, implemented by amendment 21–92, dated April 16, 2011, and amendment 45–26, dated April 16, 2011, respectively, the requirement that an article meet applicable TSO performance standards to be so marked was defined in § 21.603 as shown below:

> "With the part 21 and 45 amendment changes implemented in April 16, 2011, the previous § 21.603(a) requirements were re-codified into § 45.10(b) as shown below, which still requires the article to meet applicable performance standards before marking can be applied."

Currently, when a TSO holder identifies a design deficiency, the holder must stop shipment (that is, stop marking per § 45.10(b), Marking) and report the deficiency to the ACO. If the ACO determines the deficiency does not result in an unsafe condition (that is, does not require a § 39.19 action), then to resume shipping of articles the TSO holder must either correct the deficiency immediately (which may not be practical) or request a deviation under § 21.618, Approval for deviation. However, the intent of the § 21.618 provision was to provide a means for the TSO "applicant" to propose a true "equivalent level of safety" (ELOS) to a TSO performance requirement, and was not meant to forgive a design deficiency or oversight of the TSO holder.

The ARC's proposal provides for a risk-based approach to handle TSO design deficiencies that do not rise to the level of an "unsafe" condition. It may also be in the public's interest in the case where the stop shipment could result in a major economic burden to the end-user of the article.

<u>The ARC recommends a process for the TSO holder to continue marking TSO articles following a determination of "a design discrepancy that does not result in an unsafe condition." (Revision of § 45.10(b) and proposed new§ 21.616(i), Responsibility of the holder.)</u>

10.0 BUILDING BLOCK APPROACH TO DESIGN ORGANIZATION

The ARC was concerned with the anticipated challenges in implementing a DO system in the current state, so the ARC chose to recommend a voluntary DO approach, combined with a "building block" transition plan, to better position the FAA and industry for a future DO environment. This building block approach would allow the FAA and industry to immediately begin taking steps to improve processes and make the changes necessary for DO implementation. These steps will enable a much more manageable transition to DO in the future.

The building block approach requires the FAA and industry to make changes, including—

- Establishing accountability framework/applicant showing as the foundation for a CAS,
- Transitioning to a centralized, systemic oversight model, and
- Optimizing use of the existing ODA system.

One of the key aspects of the U.S. aviation industry is its continuous innovation and ability to foster entrepreneurs to develop the next generation of safety improvements. Therefore, it was important to the ARC's DO Working Group to establish a "lower overhead" path that would allow for "low-risk" innovation but leverage the strengths of established organizations for "higher risk" designs. By making DO voluntary, each organization would be making the decision to become a DO based on the cost/benefit (business case) for the organization. This approach promotes actions by both industry and the FAA to ensure the benefits of the privileges of a DO outweigh the costs and burden of implementation and maintenance. In addition, all organizations that meet the minimum requirements are eligible to apply to become a DO (refer to section 6 of this report); DOs do not require an FAA determination of need.

Therefore, the ARC recommends that promulgation to establish DO requirements would make it a voluntary choice for organizations to obtain, which means there is no need to define applicability thresholds for any design approval applicants or considerations for small business and cost/benefit.

The following sections provide additional details on how the FAA and industry can achieve these steps.

10.1 Evolution of FAA Oversight: Centralized and Performance-Based

Recommendation 3—Evolution of FAA Oversight Toward Performance-Based Systems Safety (SMS) Approaches: The ARC recommends development of a performance-based single surveillance oversight approach that aligns with proposed changes to design and production organizational requirements and a systems approach to certification. The three key oversight areas are: Organizational - Transition from traditional show/find compliance to organizational PBO model; Product and Articles - Transition from the FAA's traditional role of direct project involvement to a LOPI approach focused on performing governmental functions and enhanced showing capabilities; Post Certification (COS) - Transition from a traditional reactionary approach to a systemic (process based) surveillance model. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data that will drive the risk-based modeling controls, and allow for a highly trained staff in system surveillance, skill management, and a single source for corrective actions. As companies continue to evolve to a systems safety-based certification and organizational oversight, a centralized FAA oversight system will provide consistent and progressive assessment and surveillance processes leading to the performance-based standard.

Establishing a single FAA oversight model is a fundamental first step in the building block approach to DO. As companies evolve from ODA processes to CAS and SMS systems, a centralized FAA oversight system will provide consistent and progressive assessment and surveillance processes leading to the performance-based standard. The ARC recommends FAA oversight teams report to a centralized organization, which will—

- Achieve standard surveillance practices.
- Centralize policy responsibility ensuring consistency in interpretations.
- Allow the ACO to focus on safety-critical functions.
- Provide "third-party objectivity," as the office does not work programs with the DO.
- Provide a single source/repository for the oversight data, which will drive the risk-based modeling controls.
- Manage skill development practices for surveillance staff.
- Allow for a highly trained staff in system surveillance.
- Provide a single source for oversight of corrective actions.

The FAA oversight team will be a team of individuals that have a corresponding role with the organization. For example, if a company holds design, manufacturing, and/or repair certificates, the oversight team will consist of engineers (ASEs), manufacturing and flight standards inspectors (ASIs), and AEG members to parallel the DO's capabilities. The surveillance activities are system-level, not program-specific. Therefore, policy will not contain specific criteria by which the FAA will inspect and evaluate the organization. The oversight team will base its surveillance on the procedures contained within the organization's operating manual, adherence to the procedures/processes, and evaluating the process outcomes for quality.

To address these concerns, the ARC recommends the FAA create a single oversight presence to address three key oversight areas:

- Organizational: Transition from traditional show/find compliance to organizational PBO model.
- Product and Articles: Transition from the FAA's traditional role of direct project involvement to a LOPI approach focused on performing governmental functions.
- Post-Certification (COS): Transition from traditional reactionary approach to a systemic (process-based) surveillance model.

10.1.1 Oversight of the Organization

For organizational oversight, capability is shown or determined by an organization's experience or demonstration of capability based on the existence of adequate processes used to conduct projects with FAA involvement before DO. Additional third-party suppliers can be used to achieve capability not already existing within the DO. FAA oversight consists of organization processes such as company-required processes (SMS, CAS, and QMS) as well as Maintenance, Repair, and Alteration (MRA) and manufacturing processes. The FAA will focus on the process evaluation as opposed to individual product or article compliance.

10.1.2 Oversight of Product/Article Certification

The design/manufacturing oversight model for product or article certification includes the introduction of FAA LOPI. If a company has previously demonstrated its engineering and design capabilities (applicant showing) and is not seeking to expand that capability, the LOPI should be "0" outside of any required governmental functions, and the company will be expected to have the autonomy to complete all certification efforts.

Once these efforts are complete, the company makes a declaration of compliance, which does not require an FAA assessment before it issues the certification/approval to the company for that product or article. In cases where special conditions, ELOS, issue papers, alternate methods of compliance, or any other governmental functions are required, there will be a LOPI by the FAA. A LOPI is required but should minimize impact to the company's critical path activities. In terms of oversight, surveillance of the company is expected to be the primary function performed by the FAA, regardless of the LOPI. Company activities that required LOPI for a specific product or article can be used as demonstration of capability for future efforts.

10.1.3 Oversight of Post-Certification (COS)

The FAA and certificate holders will transition from the traditional reactionary model to a systemic (process-based) surveillance model. The level of surveillance will depend on processes for hazard identification, criticality of products, and risk-based safety criteria determinations. The process will include outputs for corrective actions to the FAA (such as service bulletins, ADs, and special airworthiness information bulletins). Parameters must be set to ensure these corrective actions do not impose added costs to operators.

Hazard identification will include monitoring and trending safety analysis data with multilevel inputs by incorporating a data-driven, risk-based approach for safety assurance and SRM. Current governmental and holder processes (such as Monitor Safety/Analyze Data (MSAD) and processes at Boeing and Bombardier) should be evaluated for effectiveness and readiness. For more information on hazard identification, refer to the SMS Working Group Report in appendix F to this report.

A company with a functional SMS will be responsible for proposing to the FAA the corrective actions required to address safety issues. For example, a company could request the FAA release an AD based on the company's risk assessment.

10.1.4 Oversight Assessment Methodologies

10.1.4.1 Initial Assessment

The initial assessment[13] of a company should be an evaluation of its ability to satisfy the requirements for an applicant showing/DO. The initial assessment establishes that the organization meets the basic requirements for the authority, and has the necessary process capabilities in place. The FAA will assess the organization's effectiveness in ensuring compliance, product safety, and SRM using performance measures that will determine the frequency and depth of ongoing surveillance activities.

The initial assessment is intended to establish whether an organization has the required process coverage and level of process maturity. Several models are used across the industry to assess process maturity. In April 2012, the SM ICG published the Safety Management System Evaluation Tool as an objective method "to indicate the expected standard of an organization's SMS in terms of compliance with the SMS regulation and its performance to effectively manage safety risk."[14] This tool provides an internationally harmonized standard for assessing process maturity, and can be expanded to include additional regulatory requirements for a DO.

The ARC's Oversight Working Group expanded the ICG's SMS assessment tool to include requirements for a CAS and QMS. These components—SMS, CAS, and QMS—form the basic components of a CDO. In advance of final requirements for CAS and QMS, the working group used the draft proposed regulations from the 2008 CDO ARC Report. The working group presented this "prototype" tool in appendix C to its report (included as appendix G to this report), as an example of what an assessment tool could look like. Before endorsing this as a tool for broader use, the FAA and industry should revise the model to incorporate lessons learned from recent applications of the ICG's SMS assessment tool.

In the 2008 CDO ARC Report, the CDO ARC recommended that "an organization applying for a CDO certificate or an expansion of its existing certificate undertake a self-assessment. This self-assessment should be a formal undertaking with records generated of the findings and observations of the evaluators." The self-assessment should apply the same evaluation tool as

[13] Referred to as "appraisal" in section IV. J of the 2008 CDO ARC Report.
[14] http://www.skybrary.aero/bookshelf/books/1774.pdf

the FAA assessment; however, the FAA may consider the extent and thoroughness of the self-assessment in developing its plan for assessment. Following satisfactory completion of the self-assessment, the candidate organization may submit its application for CDO to the central FAA DO office.

The application process (preferably electronic/online), will be defined by FAA policy and should consist of a completed application form, a written request for assessment, identification of requested capabilities, and an enclosure of self-assessment.

10.1.4.2 Surveillance

As part of its fundamental oversight responsibilities, the FAA will conduct surveillance on the organizations to evaluate performance through inspection. This surveillance will use a systematic approach focused on validating the processes/procedures by means of inspection, and a verification of the organizations' capability to follow its procedures through an evaluation of the products and/or approvals that result from the system. Surveillance could include, but is not limited to—

- Reviewing the company process/procedures within the operating manual,
- Reviewing the company self-assessment/self-surveillance data and corrective actions,
- Inspecting the company for compliance with its process/procedures within the operating manual,
- Reviewing the work performed and evaluating performance for quality assurance,
- Ensuring required training has been completed,
- Providing constructive feedback, and
- Taking corrective action, as necessary.

Surveillance does not include program-specific involvement; it is based at the system and process levels. The FAA will still have the responsibilities contained in governmental functions. However, the ARC has termed these actions as LOPI and will be the tasks required of the FAA office in charge of the respective program and not within the FAA oversight office's job duties.

Risk-Based Decisionmaking: The interval and depth of surveillance activities should be based on the safety risk of the product or article, capability of the organization, past performance of the organization, complexity of the programs, and authority/privileges granted to the organization. An organization's self-surveillance activity, including its performance in addressing voluntary disclosures and notifications of noncompliance, is an indication of a closed-loop system that will ensure continual improvement of the organization and address lessons learned. In addition, an organization's performance, as indicated by the following factors, will determine the level and frequency of surveillance:

- Capability,
- Past performance, including—
  - ADs/safety findings on approved products,

    - Quality escapes,
    - Noncompliances, and
    - Self-surveillance findings;
- Complexity, including—
    - New and novel technology concerning current processes,
    - LOPI from ACO (If the program has a high level of involvement from the ACO, is it a good candidate for oversight?),
    - The ability to manage and maintain control over large programs, and
    - Process robustness; and
- Multiple authorizations/privileges/certificates.

10.1.4.3 Expansion Assessment

When a company requests an expansion to the scope of its authority that involves substantially new processes that have not been previously demonstrated, the company must demonstrate it is capable of operating under its proposed processes before receiving an amended certificate with the expanded capabilities. As a tool in the performance of the self-assessment and the subsequent FAA evaluation, the DO applicant should have traceability between its processes and the regulatory requirements they are intended to address.

Self-assessment: The application for expanded scope would include a self-assessment to show a company's readiness to function with the new processes, and exercise its capabilities to make determinations under the changed scope. The self-assessment should be a formal undertaking with records generated of the findings and observations of the evaluators using the same process/performance measures used for the initial assessment. This assessment may be abbreviated based on the difference between regulatory requirements regarding the additional capabilities requested. The FAA may use this assessment in focusing its assessment activities.

FAA assessment: Following company application for expanded scope, the FAA will perform an assessment based on the criteria used for the initial assessment to determine that the company has shown it is fully capable of operating within the changed scope.

In the case of an expansion in scope for a company in good standing, the FAA may rely on the self-assessment in issuing the expansion of the applicant showing/DO certificate.

- If the expansion in scope is minor, the applicant showing/DO self-assessment may be sufficient to allow the FAA to expand the certificate scope with no further demonstration.
- The use of the applicant's self-assessment to adjust the scope of FAA activities is solely at the FAA's discretion and should follow the safety management principles of targeting safety-critical efforts.
- The FAA is under no obligation to complete its assessment within a minimum time limit or number of projects.

The ARC recommends a centralized, systemic (process-based) oversight approach for initial and ongoing assessments. The assessment methodology will cover a standardized approach to quality, design, and safety. In support of this recommendation, the ARC's Oversight Working Group has provided a capability-based assessment tool, PROs/CONs analysis of oversight management options, and supporting rationale for the recommendation. FAA oversight teams would report to a centralized FAA organization. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data that will drive the risk-based modeling controls, and allow for a highly trained staff in system surveillance, skill management, and a single source for corrective action.

10.1.5 FAA Collaborative Oversight

10.1.5.1 Define and Teach Systems Engineering

Systems engineering is a cultural shift the FAA must understand and undergo. This change in culture will only help the FAA and industry when moving toward systemic self-surveillance and collaborative oversight. Understanding systems engineering means that in some cases FAA employees may move from a subject matter expert role to a systems engineering role. The FAA must be able to maintain its current level of oversight to assist in maintaining the current U.S. safety rating. As stated in section 2.5, if the anticipated industry growth continues by 0.7 percent per year through 2022 and the FAA employment remains level, the rate at which the FAA is able to support critical activities becomes increasingly more difficult.

A Systems Engineering Management Plan (SEMP) is a technical planning document used in a variety of industries to develop, oversee, and maintain high risk and geographically dispersed programs and processes. This type of document can be used to assist the FAA in understanding how to audit a set of processes. This technique includes understanding that company processes are not a universal solution and that there could be more than one correct way of performing a function, documenting a process, and meeting regulatory compliance. Auditing a process is confirming the process is performing well, not auditing a specific product.

A SEMP is generally used by the organization responsible for generating and managing technical programs. The SEMP should be coordinated with the project plan for integration of the technical planning and modifications related to the allocated resources including cost, schedule, personnel, facilities, and deliverables required. The SEMP is also used to evaluate the team's technical approach, make technical risk assessments, and measure progress. It may identify key milestones where the FAA has assigned oversight. This is the area of the SEMP where the FAA and industry would use the plan jointly, similarly to the way interagency agreements are used between government agencies. The SEMP can identify specific processes used in the design environment.

In a system engineering environment, the process will be the FAA's area of oversight, compared to its current history of product oversight. As long as the process meets the intent of the requirements, it may be defined at the discretion of the company. Processes will vary from company to company. The SEMP assists the FAA in ensuring the organization is following its process and the process is working well, in turn assuring the FAA that products are being designed according to the required regulations. Figure 4 below provides an illustration of the systems engineering concept.

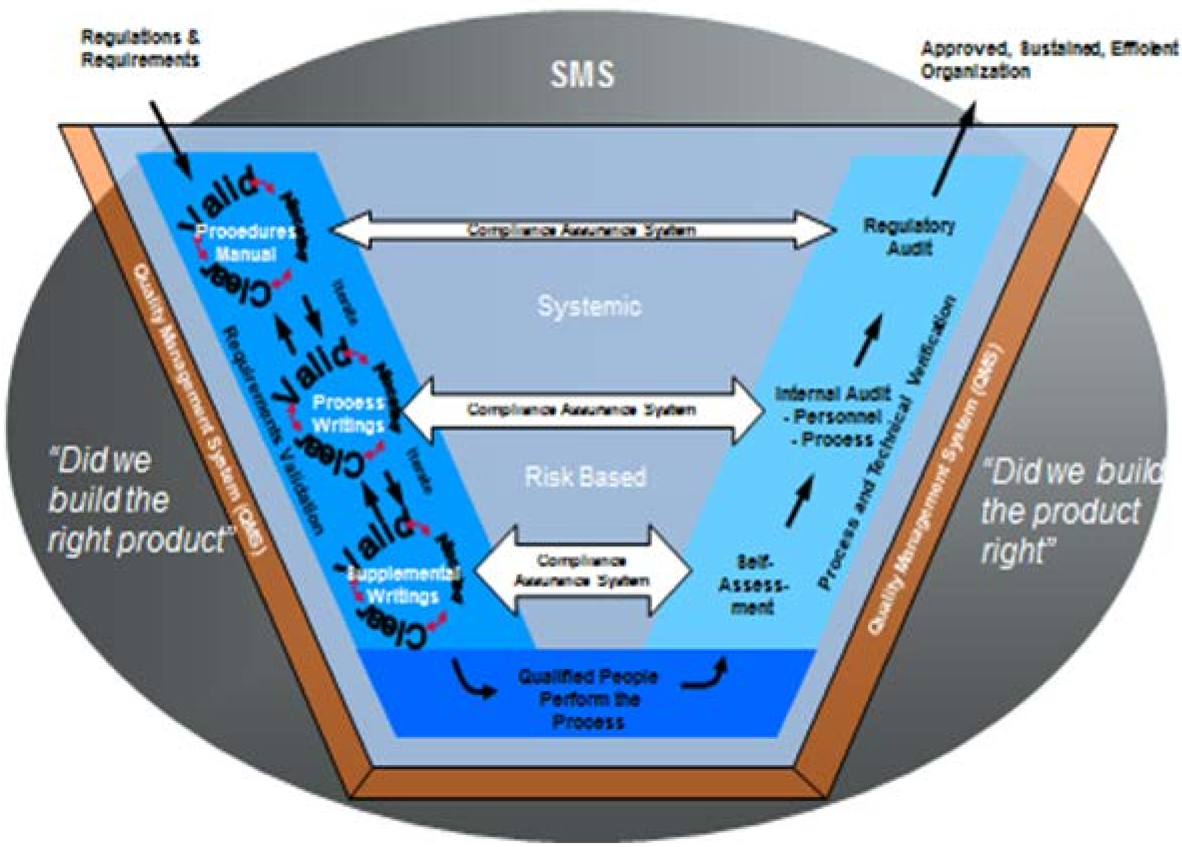

Figure 4. Systems Engineering Approach to Process Management and Oversight

This illustration describes how an effective assessment will validate that the organization has procedures and supporting processes in place to satisfy the requirements, and verify that the processes are followed by personnel who meet the qualifications defined in those processes. The validation step can be described as "did you build the right product?," and the verification step can be thought of as "did you build the product right?"

It is important to ensure both steps are effective. For example, an applicant should rely on the expectation that when people in the organization follow approved processes, compliant products will result. This requires effective validation of the processes during their development and initial assessment. Effective validation ensures all applicable requirements are allocated to the procedures (no requirements are missed), requirements captured are valid (based in regulatory requirements), and supporting processes define clear, unambiguous steps to be performed. Refer to NATCA's dissenting opinion in section 12 of this report.

Furthermore, the industry should expect a CDO to meet its obligations, and ensure qualified personnel follow its approved processes. This includes the individual performing a self-assessment of their own work, the organization performing self-assessments of its own activities, and the FAA performing ongoing surveillance activity of the DO.

Moving the FAA workforce to this kind of systems-based thinking will require training, practice, and a cultural shift. However, this is an attainable goal with an agile workforce that is willing to learn. The concepts can be promoted through webinars, orientation sessions, and pilot projects. Implementing and recognizing systems engineering concepts at an earlier stage will assist the workforce transition. This will provide for a phased-in approach for the FAA and industry.

10.1.5.2 Central Oversight

Table 5–1 of the Oversight Working Group Report (refer to appendix G to this report) provides a detailed analysis of options for oversight management. Although this analysis was developed in the context of a DO oversight model, all of the principles are equally applicable in an ODA environment. Refer to section 3.3 of this report for more information about the ARC's recommended future oversight model.

<u>The ARC recommends the oversight implementation include three major transition steps:</u>

1. <u>Proof of Concept—Pre-Implementation: Ensure through proof-of-concept plans that the requirements proposed by the ARC are practical, effective, and efficient. Determine if the transition from "mature ODA" to DO has benefits to the FAA and industry.</u>
2. <u>FAA Transition Plan Transition Principle: The FAA should not release a final rule before it has demonstrated the necessary cultural shift to perform system oversight. To achieve a cultural shift, policy and organizational changes may be required.</u>
3. <u>Industry Transition Plan: The organization must establish the systems required of an approved organization while still working as a non-certificated applicant or a delegated organization. Applicants working toward becoming a DO demonstrate compliance to those requirements on an "as ready" basis.</u>

10.2 ACCOUNTABILITY FRAMEWORK/APPLICANT SHOWING COMPLIANCE ASSURANCE

10.2.1 INDUSTRY

A CAS that includes the following aspects will be a key feature of an approved organization that can determine compliance without direct FAA involvement.

10.2.1.1 Engineering Accountability for Compliance

Experience has shown that when compliance responsibility is embedded within the organizations that develop the design, resultant designs are less likely to encounter certification problems and associated delays. Engineering organizations that develop certification plans, take ownership for the certification requirements, and are accountable for certification issues are more effective in ensuring compliance.

The accountability framework begins with Congressional statutes and is applied through FAA regulations that establish clear roles and responsibilities for both the FAA and industry. This framework is largely derived from part 21 and 49 U.S.C., and addresses the roles and responsibilities of applicants, certificate holders, and the FAA. This framework includes each stakeholder's role in the certification process and continued airworthiness, as well as FAA's role in developing standards, policy, and guidance, and its enforcement responsibility.

The DO concept uses an accountability framework as a foundation that clearly distinguishes the roles and responsibilities of the FAA and industry. Currently, applicants lacking certification experience, as well as the use of numerous FAA designees by many companies, sometimes results in a blurred distinction between the showing of compliance by industry and the finding of compliance by the FAA. The FAA and industry must be able to strengthen and understand each of their roles in the aviation system for the DO vision to work. Figure 5 below summarizes the accountability framework.

The FAA promotes aviation safety by:	• **Issuing regulations.** • **Specifying the certification basis consistent with issued regulations.** • **Providing guidance regarding acceptable means of compliance.** • **Overseeing compliance.** • **Taking enforcement actions as necessary.** • **Issuing certificates and approvals.** • **Mandating corrective action as necessary.**
Applicants for a design approval have a regulatory obligation to:	• **Use means of compliance acceptable to the FAA.** • **Show their designs are compliant.**
Applicants for a production approval have a regulatory obligation to:	• **Establish a fabrication inspection system or a quality control system.** • **Demonstrate they can produce products that meet the approved design.**
DAHs have an ongoing regulatory obligation to:	• **Maintain compliant designs with no unsafe feature.** • **Report all known failures, malfunctions, and defects for their products.**

Figure 5. Accountability Framework

10.2.1.2 DAH Manual

A required DAH manual will identify all processes the DAH will used to perform certification work and meet the requirements for a DAH. This manual may ultimately serve as the manual for the DO but does not need to have requirements unique to a DO included until needed to support a DO application. The transition period should be used to ensure the DAH manual requirements are sufficient to satisfy DO requirements for certification and compliance assurance or any other processes applicable to the DAH.

The ARC's DO Working Group provided guidance on what the DAH manual should contain. A summary can be found in section IV(C)(1) of the DO Working Group Report (refer to appendix E to this report). The 14 CFR Part 23 Reorganization ARC also provided recommendations on manual content based on AS 9100 requirements that could satisfy the DAH manual requirements. A manual template using this process is available from the part 23 activity.

Only top-level requirements should be in the DAH manual. However, these requirements should identify lower-level processes and work instructions in separate documents that satisfy top-level requirements. The FAA may review the DAH manual and any referenced documents as needed to audit the DAH.

The ODA manual focuses on requirements for the holder to act like the FAA in finding compliance. The DAH manual must focus on CAS processes for determining compliance with regulations and processes for self-surveillance.

Many companies planning to become DOs already have many of the processes necessary to satisfy the DO manual requirements in a condition that is acceptable or, with relatively minor changes, could be acceptable. Using existing documented processes "as is" or with minor revisions will minimize the amount of effort required to satisfy the DO manual requirements.

In addition, the DO Working Group recommended establishing an OCS, DMS, and CCS. These are described in more detail in the working group's report, included as appendix E to this report.

The ARC recommends further discussion on the necessary level of detail to include in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual.

10.2.1.3 Applicant Showing Process and FAA LOPI

The FAA has generally not promulgated regulations governing the substantiation or "showing" of compliance, but has focused instead on regulating the "finding." Under the accountability framework, the applicant is responsible for ensuring the substantiation data is correct (showing compliance), and the FAA decides what inspections and tests it will witness or conduct and what data it will review. This establishes the FAA LOPI. FAA involvement is not required for the applicant to show compliance and fulfill their regulatory obligations. Using this discretionary function authorized by statute, the FAA may choose to rely on an applicant showing and statement of compliance instead of making a discrete finding of compliance. For more on the accountability framework and applicant showing, refer to appendixes N and O to this report, respectively.

The accountability framework requires applicants to document the determination of compliance in a way that would support an understanding of how compliance was demonstrated in a subsequent audit or investigation. Moreover, it requires the identification of auditable processes that ensure the substantiation data will be consistently developed in an acceptable manner. The accountability framework requires applicants and DAHs to take responsibility for ensuring compliance. An organization authorized to perform applicant showing may use ODA UMs or DERs to validate compliance determinations, but when doing so, it must be clear that they are acting on behalf of the applicant or holder, not the Administrator.

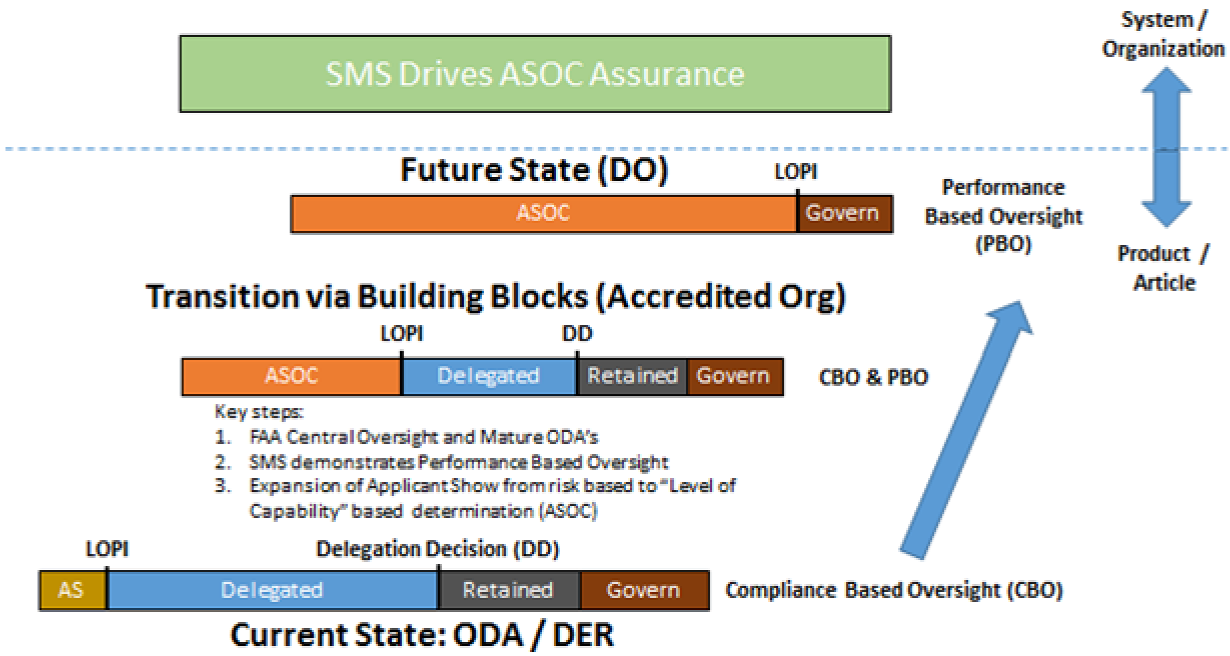

Figure 6. Building Block Evolution

The current state is one of delegation and very limited applicant showing application. Oversight is compliance-based, meaning every "show" has a "find" from the FAA or a delegate (ODA or DER). Expanding the applicant showing system would result in an increase in required FAA resources on a qualitative basis. This is driven by the requirement that the FAA would need to review each "show" process to ensure the determination could be left to the applicant for a CBO system. The solution to this is a movement to a PBO system. Applicants rely on their SMS umbrella to drive assurance of their show processes. FAA resources are then used for surveillance of the applicants' SMS instead of individual applicant showing processes.

10.2.1.4 Compliance Library

An essential part of an applicant showing system is a collection of FAA-approved best practice methods of compliance applicable to the design. Industry has made various efforts to develop and document these methods with limited success. In some cases, the methods were developed to be so specific that they had only limited applicability. In other cases, applicants relied on a pattern or history of substantiation without definitive documentation of the methods.

A compliance library would include methods of compliance that lead an applicant from the regulation to an FAA-accepted compliance determination using a documented process. The methods could make use of ACs, FAA policy, or ASTM, SAE, RTCA, or other FAA-recognized consensus standards to determine compliance following a prescribed process. To maximize the opportunity for applicant showing and minimize the FAA LOPI, the applicant should have, or have access to, a compliance library containing an FAA-approved means of compliance to all of the regulations for which the applicant would normally be expected to determine compliance. ASTM means of compliance consensus standards being developed with the FAA and other CAAs for use with part 23 aircraft would be an acceptable compliance library as applicable.

A possible approach to creating the initial version of the compliance library has the applicant identifying all of the regulations they wish to have included in their library, then identifying one of their recent compliance reports that successfully showed compliance and is FAA-approved. This could potentially be used as an interim means of compliance until the applicant has the time to put the means of compliance process in an on-purpose format for the library. To ensure this is not continued indefinitely, a limit could be placed on the number of times its use would be allowed, or a conversion date could be set.

10.2.2 FAA

10.2.2.1 Comprehensive Plan to Accept Applicant Showing Only

Recommendation 1a—Systems Approach to Certification – Voluntary Initiatives: The ARC recommends that FAA issue policy and guidance to promote the understanding of the accountability framework as a basis for a systems approach to certification and facilitate voluntary approaches to implementation through FAA recognition and acceptance of applicant enhanced showings.

One of the limitations on implementing applicant showing has been lack of instruction to FAA personnel in applying and overseeing the concept. The FAA should publish an order providing instruction to personnel on the appropriate (risk-based) uses of applicant showing, the expectations for accountability framework, and any special oversight considerations unique to applicant showing processes. Because applicant showing is applied in low-risk areas, the oversight should be minimal.

10.2.3 FAA and Industry (Metrics)

The FAA and industry should work together to define metrics to measure the effectiveness of the accountability framework and applicant showing in focusing FAA and industry resources on safety-critical areas. The metrics should be able to show where systemic issues may exist across multiple DOs and where there may be isolated issues. It should also show where the company statement of compliance is working well and does not require attention. Use of these metrics would help identify when an organization is ready for DO, and after achieving DO certification, how well it is performing.

<u>The ARC recommends the FAA consider the DO model's impact on the existing accountability framework, particularly regarding how a design approval applicant, DAH, and DO are related.</u>

10.3 Systems Engineering

Systems engineering can be defined as an interdisciplinary, collaborative approach that derives, evolves, and verifies a life-cycle balanced system solution that satisfies customer expectations and meets public acceptability.[15]

[15] IEEE P1220, Standard for Application and Management of the Systems Engineering Process, [Final Draft], September 26, 1994).

The FAA and industry are beginning to embrace the concept of systems engineering. The SEMP concept (refer to section 10.1.5.1 of this report) can be applied to technical planning documents used in a variety of industries to develop, oversee, and maintain high-risk and geographically dispersed programs and processes. The SEMP is designed to be an integrated planning document for the conduct and management of a specific effort, project, program, or set of processes.

Systems engineering is the field that enables systemic self-surveillance and collaborative oversight to occur. These are two key components of the systems engineering field. These two components are key pieces of aircraft certification that will allow the industry to continue on its current growth path and the FAA to perform oversight at a manageable level.

10.3.1 INDUSTRY

10.3.1.1 Systemic Self-Surveillance

Internal systemic self-surveillance can play a vital role in obtaining and maintaining a healthy compliance system. Quality management is a significant player in the systemic self-surveillance piece of systems engineering.

Systemic self-surveillance can be achieved through quality process management, performing internal audits, regular program and process reviews, continuous risk management, enhanced internal communication, and employee reporting programs. Employee reporting programs are noteworthy in that the employee must be open to report and identify risks and issues without fear of retribution.

Errors, variability, omissions, and other process problems cost time, program resources, and lives. It is the employee’s responsibility to know how the quality of the process affects their projects and related processes to achieve an optimal level of process quality by encouraging best practices. A self-correcting feedback loop should be built into the systems engineering process starting from the conceptual phase throughout the life cycle of the system. The system’s life cycle remains a continuous feedback loop.

These important areas are not the only components of a systemic self-surveillance system, but contribute to systems-managed processes and assist the FAA in understanding the overall health of the organization. Under a DO, establishing a QMS working in conjunction with the CAS will provide systemic self-surveillance and corrective action for the CAS processes.

10.3.1.2 Commitment to Continuous Improvement

A strong commitment to continuous improvement is an important indicator that an organization has a healthy system. An organization where employees may report risks or issues without fear of retribution is more likely to meet requirements and process and system goals. Continuous improvement can be illustrated in many ways; however, employee participation is a primary component. A company’s trust in its employees, and employee trust in management, will build strong relationships internally, enhance communication, and assist in identifying potentially costly risks at an earlier stage by following defined processes and openness to report problems as soon as they are realized. Additionally, training and staying up on new technology provides an open forum for questions and answers. This assists with internal communication and openness to report risk identified in the process.

10.3.2 FAA and Industry (Metrics)

The FAA and industry should work together to define metrics to measure the effectiveness of the efforts to shift to a more systemic approach to oversight.

10.4 Optimum Use of ODA

10.4.1 Industry

10.4.1.1 ODA Optimization

To reach a point at which the FAA and industry can effectively implement a DO model, it is important to continue optimizing the current ODA delegation system. As discussed in section 1.4 of this report, numerous studies have found a need to shift FAA certification processes from a detailed product approach to a systems safety approach. This shift is highlighted in the ACPRR ARC report as a key recommendation. The FAA and industry should continue to implement the recommendations of the ACPRR ARC and Consistency of Regulatory Interpretation ("section 313") ARC activities and work to improve the efficiency and effectiveness of current certification processes.

10.4.2 FAA

10.4.2.1 Full ODA Minus Limitations

FAA Order 8100.15 states, "The OMT may impose any limitations on an ODA holder's authority, as warranted by the ODA holder's staffing and experience, that the OMT determines appropriate. The OMT must limit the authority based on the qualifications and capabilities of the ODA UMs. The OMT may, for example, retain authority for the approval of test plans, requiring them to be submitted for approval by the ACO." However, the FAA often retains compliance findings in areas that do not have documented limitations.

Under a more systemic approach, any time a delegation is withheld, the FAA would provide a written reason for withholding delegation. An ODA that has no documented limitations would enjoy full ODA authority, and have delegation to perform all activities with the exception of those defined as inherently governmental.

10.4.2.2 Improve the Issue Paper Process to Reduce Governmental Activity

In revision B to FAA Order 8100.15, the FAA added a requirement that the "PNL response must identify the rationale for all [FAA] specific findings and reasons for any other FAA participation." Preliminary data gathered from program notification letter (PNL) responses indicates a large majority of FAA involvement in ODA activity is associated with items considered inherently governmental. Further analysis of this data indicates much of this activity could be reduced or eliminated with a more strategic approach to the development of MOCs, ELOS, and special condition issue papers. Because many of these issue papers are developed for specific installations, subtle variations in the design often require developing a new issue paper. This results in long lead times, project delays, and additional FAA work statements for issues where the compliance path has already been established.

The FAA should provide instructions to the responsible directorates that will increase the usability of issue papers, thereby reducing the volume of inherently governmental activity. Such instruction would include, but not be limited to, multi-use statements, bounding design variables (for example, covering a range of seat pitch and cant angles), and multi-model issue papers.

10.4.3 FAA and Industry (Metrics)

The FAA and industry should work together to define metrics to measure the effectiveness of the efforts to optimize the usage of ODA capability.

10.5 Bilateral Considerations for Products and Articles Certification

The ARC has acknowledged that its recommendations will impact the bilateral agreements pertaining to airworthiness and environmental certification, which the U.S. Government has developed and agreed with its international partners to ease the export of U.S. products and the import of non-U.S. products.

The foundations of the bilateral agreements on airworthiness and environmental certification rely on a mutual trust between the FAA and its bilateral CAAs' partners that their respective certification systems provide equivalent results. These agreements may be based on systems that use different certification processes and procedures. What matters is not the way the certification of the products or articles is performed but that the bilateral partners mutually accept that their systems produce equivalent results. This mutual trust in each other's systems relies on effective communication between the authorities that will keep each other informed of any changes in their certification systems (such as their statutory responsibilities, organizational structure, airworthiness and environmental standards and procedures, production quality control system oversight, or delegated or contracted functions).

These bilateral agreements provide the ground for reciprocal acceptance of compliance demonstrations, findings, and approvals through a "type validation" process. This process is typically developed into technical implementation procedures, which specify the principles by which the validation authority accepts the compliance demonstrations, findings, and approvals made by the prime certification authority system. These procedures also define the validation items, which are the compliance demonstrations items of particular interest to the validation authority and for which its involvement will normally go beyond the familiarization process. Those validation items must be justified, for example by technical differences in the standards. Except for those justified validation items, the key concept of the validation process is that the validation authority should depend on the compliance determination made by the certification authority system to the maximum extent possible.

Those bilateral agreements are of primary importance for the industry because they streamline the importation and exportation of products and articles between the bilateral partners and reduce the cost of certification while producing an equivalent level of safety. They are also very effective for the CAAs of the importing countries, which can focus their involvement on the limited significant standards differences and otherwise rely on the compliance determinations of the exporting country's certification system for all the other compliance items.

The ARC recognizes the significant changes introduced by the DO model and its associated FAA-industry accountability framework will have an impact on the bilateral agreements and their associated technical implementation procedure. Under the terms of these agreements, the FAA will need to communicate to its bilateral partners about those changes in its certification system and to implement the necessary changes in the bilateral documentation.

Considering the importance of the validation process for the industry and authorities, the ARC recommends the following high-level objectives be considered in this task of reviewing the bilateral documentation:

- **Validation by the FAA bilateral partners of U.S. products and articles certified using a LOPI process:** The certification of products and articles under a LOPI approach will be considered equivalent to the current system and should not lead to an increase of the validation items by the validation authorities.
- **Validation by the FAA of non-U.S. products and articles certified under an FAA bilateral partner deemed as equivalent to the FAA certification process:** The involvement of the FAA in the validation activities should, in most cases, be limited to issues that are risk-based and meet the requirements for LOPI for the validation items as defined in the bilateral technical implementation procedures. Under this principle, validation activities will no longer include retained findings of compliance.

10.5.1 Bilateral Agreement DO Considerations for Products and Articles Certification

One privilege of a CDO is the authority to make determinations of compliance, and present the Administrator with a statement of compliance the FAA may rely on to issue a certificate.

Principle of Reciprocal Acceptance. Current U.S. bilateral airworthiness agreements with other states contain the clause that each party recognizes and accepts the other party's safety oversight and regulatory system. That principle of reciprocal acceptance has allowed one authority to act on behalf of the other in making compliance determinations, and performing other functions as defined within the bilateral agreement.

This principle also includes accepting each other's system of delegation, if applicable. As a matter of policy, the FAA has decided to use its delegation system in performing specific functions or when making compliance determinations to foreign airworthiness requirements when requested under a bilateral agreement.

Bilateral reciprocal acceptance also has enabled "approved" data to be used internationally to facilitate CAA-approval of manuals, repairs, and modifications. This has considerably reduced the compliance finding burden on the FAA and the schedule burden on the industry during type validation programs.

Need for Bilateral Changes Relevant to DOs. Because the ARC's future vision will be a new organizational approval system, the FAA is obligated to notify its bilateral partners under the terms of the existing bilateral agreements. These authorities have the right to evaluate the new FAA system and determine whether it meets the intent of the bilateral agreement and can be accepted. It is envisioned that importing (validating) authorities will rely on the exporting (domestic) authority's overall system for aeronautical product design, certification, and production. Specifically, the importing (validating) authority would—

- Evaluate the state's system requirements for regulatory compliance, including SMS and system oversight.
- Mutually recognize the two systems as equivalent, or define where there are differences and address them with the bilateral partner.

As it cannot be assumed that a new FAA organizational approval system will be accepted internationally, the FAA must engage with other CAAs through early and regular communication of the FAA's DO concept to help gain international acceptance.

11.0 CERTIFICATION COST/BENEFIT OVERVIEW

Historically, aviation safety rulemaking cost-benefit analysis (CBA) has focused on preventing of accidents and lives lost as the benefit justification to offset the costs of implementing new rules. The ARC's purpose in evaluating the proposed transition to a systems-based approach to new rules was not to create a rule that relies on accident prevention as a justification, but rather a rule that can be justified and supported by enhanced improvements to effectiveness and efficiency for both the FAA and industry. As a result, the ARC's Cost-Benefit Analysis Working Group was tasked to find new ways of capturing the benefits and costs associated with such improvements and identify a supporting methodology.

The working group found that overall change is needed for both the FAA and industry. This conclusion is a combination of statistical data, quantitative and qualitative analysis, and assumptions gathered by the working group. There appears to be a uniform concern that the current certification system is not sustainable given industry growth and the FAA change in resources and budgetary constraints of recent years. The working group could not, within its limited scope, collectively conclude that a DO with the inclusion of SMS is the appropriate change; however, it is increasingly apparent that a major change to the current certification system is needed.

The constraints and advantages of the working group led to the following findings:

- The cost vs. benefit of implementing SMS without a DO must be further researched. Given the late decision by the ARC's Organization Working Group to recommend DO as optional, the CBA Working Group did not have sufficient time to gather data on SMS independent of a DO.

Regarding the data gathered from small organizations pertaining to implementing mandatory DO with SMS, a scaled DO (AO), or the modified current model (refer to section 7 of this report), the CBA Working Group made the following key findings:

- The 2013 MARPA Conference was extremely useful because small business does not always have the resources to participate full time on ARCs. Holding a workshop and distributing a survey during the MARPA conference proved small business has a strong interest in proposed changes to certification. Additionally, there is a common feeling that a change to the current system is needed.
- The resulting average estimated cost increases of adopting mandatory DO with SMS, an AO, or the modified current model were approximately—
  - 15 percent for DO with SMS,
  - 20 percent for an AO, and
  - Modified Current Model was approximately 8.3 percent for the modified current model.
- The data also revealed that the resulting average estimated increase in revenue from immediate project initiation (no sequencing queue delay) was approximately 15 percent. This is a significant benefit that may compensate for cost of a DO with SMS or an AO.

- Respondents estimated the effect on revenues if their company was not required to wait in the sequencing or project prioritization queue to initiate a project. The purpose of the question was to gauge the perceived benefit of privileges associated with both the mandatory DO and AO models. The resulting average estimated time savings as a result of immediate project initiation (no sequencing queue) was approximately 4 months.

Regarding the data gathered from large organizations pertaining to implementing mandatory DO with SMS, the working group made the following key findings:

- The large company survey responses considered a mandatory DO system to be far from cost-beneficial. Two companies provided no cost-benefit estimates, stating estimates were "difficult to estimate at this time" or "too premature to determine." One company's responses were large outliers, so just four useful responses were received. This gave a median response of approximately 2 to 1, costs to benefits.
- Discussion with ARC company representatives suggests possible reasons for this result are that the large company representatives believe—
    - The DO system provides no additional benefits beyond what is provided by the ODA, or that will be provided when ODA is "fully matured;"
    - The DO proposal is premature because ODA has not fully matured; or
    - The DO system is far from cost beneficial now, but could be cost beneficial after other companies have adopted it and worked out issues with implementation.
- Additionally, informal discussions with company representatives after the survey was completed indicated the companies did not sufficiently focus on their potential benefits in responding to the survey. This finding suggests greater attention must be given to potential benefits in future surveys.

Additional key findings of the working include the following:

- Manufacturers had difficulty articulating baseline certification costs. Part 21 is a process-oriented rule, which made for a very broad and difficult rule to cost out. The majority of participants calculated cost in a more general format and described it mostly in percentages.
- Large and small manufacturers had difficulty articulating benefits. Although participants understood the benefits from a conceptual level, most were unable to express benefits in monetary values. Therefore, a benefits survey is strongly encouraged as a follow-on activity to this ARC and to future rulemaking efforts.

Lastly, in the event a formal rulemaking project takes place, the formal cost-benefit analysis should consider the following recommendations in addition to the traditional process:

- Consider a separate survey to gather benefit data. A key finding was that respondents had significant difficulty articulating benefits. Gathering data from multiple benefit questions can provide adequate data to calculate efficiencies.

- Relying on the industry to calculate this information is not a viable solution. In the case of SMS and changes to part 21, process-oriented requirements are far too broad to calculate in one question.
- When benefits were described in the form of a question, respondents were better able to estimate cost savings.
- Efficiencies can be calculated through a number of equations commonly used in industry and by other agencies. The most simple of these includes the following:

  Efficiency = Expense/Revenue

  This is only one example of a possible solution to calculating efficiencies in typical business operations.
- Efficiencies must be broken out into tangible items whenever possible. In areas where this is not possible, a qualitative assessment is acceptable to the Office of Management and Budget (OMB), according to OMB Circular A–4, Regulatory Analysis.
- The working group did not examine SMS independent of a DO; however, a common response by the industry was to consider the following:
- Identify industry cost of maintaining and satisfying multiple SMSs *compared with* single SMS accepted internationally. The industry expressed substantial concern with developing and maintaining a SMS for multiple countries. The concern related to cost of development, implementation, maintenance, and accommodation of external audits. This is a specific area of concern and should be further researched.

The CBA Working Group took a proactive approach to identify cost and benefits at a preliminary stage. The methodology applied focused on collecting real data and active interaction with the parties impacted, including small and large business and the FAA. Data gathered by the working group is *supporting data only* and does *not* represent a formal economic analysis. All data gathered by the working group has been shared with the FAA's Office of Aviation Policy and Plans Economic Analysis Division (APO–300) with the intent to serve as supporting data, and may be referenced during the formal economic analysis in the event a rulemaking project takes place. The CBA Working Group Report located in appendix J to this report contains the details of the methodology as well as results from all data gathered.

12.0 DISSENTING OPINIONS

All of the ARC members were offered the opportunity to present a dissenting opinion on the ARC's decisions and recommendations. All dissenting opinions are collected in this section with a reference back to the section they apply to.

Dissenting Opinion—Approved Data

The following dissenting opinion to Approved Data in section 6.8 was submitted by a member of the ARC's DO Working Group from General Electric:

> A member of the working group does not agree with the opinion expressed above, related to data considered to be approved by the FAA. A working group member agrees that the type design, as defined in § 21.31, is not only found to comply to applicable airworthiness requirements but is considered to be approved by the FAA, with the issuance of a design approval. Thus, the issue is with the FAA desire to not call the substantiating data "approved data."
>
> While it could be argued from the above discussions that there is nothing changed about the data itself by not calling it "approved," an ARC member fails to see the need for the FAA to change several orders and reeducate the entire international aviation community on why it is not calling substantiating data approved, when in fact the character of the data has not change.
>
> For many decades the FAA has called that "found-to-comply" data "approved data." The words "approved data" have been common place within the U.S. aviation system and have been recognized as having significance by international authorities. Any change to this entrenched concept in U.S. aviation, and the enormous task of reeducating FAA employees, U.S. industry, ICAO, and other airworthiness authorities, should only be undertaken after the FAA has presented a good cause argument for that change. In all of the discussions of this issue, FAA has never defined the problem they are trying to correct or the new message they are trying to convey by no longer allowing substantiating data to be called "approved data."

Dissenting Opinion—Correcting Non-Compliances

This dissenting opinion was expressed by NATCA during an ARC meeting and will not be found elsewhere in the report.

> NATCA recommends the DO regulations, either part 5 SMS or part 21, include a requirement to report and provide a corrective action plan for non-compliances to the airworthiness regulations that are discovered by the DO. This would be similar to the current reporting requirement of 14 CFR 183.63(b)(2) and the associated procedures required for ODA in Order 8100.15 for production products.

Section 5.1.1: NATCA does not have a position on the portion of the recommendation that part 5 be revised from the NPRM proposal based on the Design and Manufacturing sector comments. NATCA did not review the NPRM because it was titled "Safety Management Systems for part 121 Certificate Holders" when it was published for comments on November 5, 2010. The title of the rulemaking did not include any indication it would apply to parts of 14 CFR other than part 121 air carrier operations. The final rule is now at OMB for review, so providing comments to the FAA through this ARC, which is outside the NPRM docket, might be considered a violation of DOT ex parte policy. NATCA will therefore review the final rule and consider submitting comments to the final rule docket or to the new rulemaking docket if FAA publishes a new NPRM that would apply SMS requirements in part 5 to part 21.

Note, FAA submitted a summary of an ex part meeting with industry on the NPRM docket number FAA-2009-0671, item FAA-2009--671-0136, titled "Summary of an Safety Management System Aviation Rulemaking Committee Meeting held on November 16, 2010." It includes the following explanation that part 5 will be reopened for comment should a NPRM be issued to apply part 5 SMS requirements to other parts, including part 21:

"The docket item includes the following: "First, the ARC members were concerned that the title of the NPRM would not adequately notify others, such as repair stations, part 135 operators, and aircraft design and manufacturers, who may be impacted by this rulemaking in the future through expansion of the applicability requirements of part 5. The FAA noted that the NPRM states that although the proposed rule would only apply to 14 CFR part 121 certificate holders, the FAA may consider applying the part 5 SMS requirements to parts 135, 145, and 21, as appropriate. In the event that the FAA would extend the general requirements to these populations, the FAA would initiate rulemaking and these populations would have an opportunity to comment on the requirements and the applicability through future NPRMs."

Section 6.1 and section 10.1.5.1: NATCA recommended the qualification requirements for staff show and verify compliance to the airworthiness regulations should be addressed prior to DO rulemaking activity, and that consideration should include certification or licensing.

Section 6.7.9, Environmental Compliance Determinations: NATCA does not agree with the statement in the recommendation that "*the process-based approach to compliance, as established by DO program principles, is far more robust than traditional delegation process.*" However, NATCA understands that FAA is moving toward a DO process. Given a DO process will be utilized in the future, NATCA does not see a reason it should not also be applied to 14 CFR parts 34 and 36.

Section 8.1, Changes to 14 CFR 21.21: NATCA disagrees with the proposal to replace 21.21(a) and (b) with the proposed text. The existing 21.21(a) provides for type certification of surplus aircraft from the U.S. Armed Forces. The existing 21.21(b) provides requirements that an applicant (1) provides data to show the product meets the applicable sections of subchapter C and (2) that "*For an aircraft, that no feature or characteristic makes it unsafe for the category in which certification is requested*." These existing requirements of 14 CFR 21.21 need to remain and would apply equally to DOs, although an alternate provision to 21.21(b)(1) could be developed that applied more directly to DOs.

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APPENDIX A—PART 21/SMS ARC MEMBERSHIP

MEMBERS AND ALTERNATES

Mr. Walter Desrosier, *Co-Chair*, GAMA

Mr. Michael Reinert, *Co-Chair*, FAA AIR–150

Mr. Rick Baggette, Boeing

Mr. Glenn Baxter, Bombardier

Mr. Edmond Boullay, *Alternate*, ASD/US Crest

Mr. Rafael Borges, *Observer*, ANAC

Mr. John Bouma, Cessna

Mr. Dave Chapel, GE

Ms. Maria Clara, *Observer*, ANAC

Mr. Michael Collins, NATCA

Mr. Robert Cook, FAA AIR–200

Mr. Peter Corbeel, *Observer*, EASA

Ms. Doris Costa, *Observer*, ANAC

Ms. Jodi Diamant-Boustead, *Alternate*, AIAC/Pratt Canada

Mr. Jason Dickstein, MARPA

Mr. Tomaso DiPaolo, *Alternate*, NATCA

Mr. Chris Eick, Honeywell

Mr. Jimmy Eyl, Banyan Air Service

Mr. Robert Ferguson, *Observer*, TCCA

Ms. Amy Garzaro, FAA AIR–150

Mr. Scott Geddie, FAA AIR–110

Mr. Paul Greer, FAA AGC

Mr. Julian Hall, *Observer*, EASA

Mr. David Hempe, FAA AIR–100

Ms. Katrina Holiday, FAA ARM

Mr. Charles Huber, FAA SMS/ANM–100

Mr. Daniel Leach, FAA APO

Mr. Eric Lesage, Airbus

Mr. Michael Linegang, FAA AIR–110

Mr. Mark Lopez, *Alternate*, A4A

Mr. Stacey Mason, *Observer*, TCCA

Ms. Linda Navarro, *Observer*, FAA AIR–150

Mr. George Novak, AIA

Ms. Jan Novak, *Observer*, EASA

Mr. Ric Peri, AEA

Mr. Dennis Piotrowski, BELAC

Mr. Tom Rogozinski, Honeywell

Mr. Dan Shapiro, Sikorsky General

Mr. Eric Sivel, *Observer*, EASA

Mr. Roger Southgate, Rockwell Collins

Mr. Giles Strickler, FAA ARM

Mr. Marcus Tittiger, *Observer*, TCCA

Mr. Scott VanBuren, *Observer*, FAA AVP (SMS)

Mr. Mark Watton, Delta Airlines

Mr. Bill Whitton, Gulfstream

PROGRAM SUPPORT

Mr. Larry Van Dyke, GAMA

APPENDIX B—GLOSSARY

Term	Definition	Source
Acceptable Risk	The level of risk that individuals or groups are willing to accept given the benefits gained. Each organization will have its own acceptable risk level, which is derived from its legal and regulatory compliance responsibilities, its threat profile, and its business/organizational drivers and impacts.	AVS Order 8000.367A
Accident	An unplanned event or series of events that results in death, injury, or damage to, or loss of, equipment or property.	AVS Order 8000.367A FAA Order 8040.4A
Accountable Manager	(a) Accountable manager means the person designated by an applicant or design approval holder who is responsible for and has the authority over all design approval operations that are conducted under part 21, including ensuring that design approval holder personnel follow the regulations and serving as the primary contact with the FAA.	14 CFR Part 145.3(a) modified for use by DAH
Accountability Framework	An established set of responsibilities and commitments of the FAA and industry	Refer to appendix O to this report.
Aerospace System	U.S. airspace, all manned and unmanned vehicles operating in that airspace, all U.S. aviation operators, airports, airfields, air navigation services, pilots, regulations, policies, procedures, facilities, equipment, and all aviation-related industry.	AVS Order 8000.367A FAA Order 8040.4A
Aircraft Accident	An occurrence associated with the operation of an aircraft that takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage.	49 CFR 830.2
Analysis	The process of identifying a question or issue to be addressed, examining the issue, investigating the results, interpreting the results, and possibly making a recommendation. Analysis typically involves using scientific or mathematical methods for evaluation.	FAA Order 8040.4A
Applicant Show With Capability (ASOC)	Based on the Oversight Working Group’s model of DOs getting recognized for demonstrated capabilities.	

Term	Definition	Source
Approved Data	Data approved by FAA employees, its designees, or a DO acting under the authority of its certificate.	
Assessment	Process of measuring or judging the value or level of something.	FAA Order 8040.4A
Certificate Surveillance	FAA actions to monitor the DO certificate holder and to determine the holder's compliance with the provisions of its certificate. Note: In the Oversight section we discuss managing these organizations through surveillance.	
Compliance Assurance System (CAS)	DO holder's system for ensuring that it complies with the applicable regulations.	
Compliance Finding	FAA decision (either directly or through a designee) that compliance has been shown with the applicable regulatory requirements.	
Control	Refer to Safety Risk Control.	AVS Order 8000.367A
Corrective Action	Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity or other undesirable situation. An action required to be taken by the DO to address noncompliances and problems with the organization's procedures or performance. The noncompliances may result from— • Internal audits conducted by the DO, • FAA surveillance, • DO employee observations, and • Voluntary disclosures.	AVS Order 8000.367A
Culture of Compliance	Knowledge, beliefs, attitudes, and behaviors of an organization that are focused on ensuring regulatory compliance with all its activities.	

Term	Definition	Source
Descriptive Data	From the DO Working Group: • Data that defines the type design that needs to be determined compliant to the applicable airworthiness standards. The descriptive data is what is approved by the FAA when a design approval certificate is issued. • The drawings and specifications necessary to define the configuration shown to comply.	
Determination of Compliance	A decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. [Note: The ARC has referred to "regulatory requirements" rather than just "airworthiness standards" because its recommendation that DOs eventually include determination of compliance with other 14 CFR parts, such as parts 26, 34, and 36.] It may also be a decision made by the certificate holder that data previously approve by the FAA or data determined to comply by another CAA under the provisions of a bilateral airworthiness agreement between the United States and a foreign country or jurisdiction, are valid and applicable to the design of the product, part, or appliance for which it is to be used, including the applicable certification or approval basis.	
DO Executive	The company individual directly responsible for ensuring that the DO meets all of its regulatory responsibilities.	
DO Point(s) of Contact	The individual(s) within the DO responsible for all communications with the FAA.	
Eligible Data	Data developed under an approved DO system, assuming a specified, but not FAA-established, certification basis, and product type design if appropriate.	

Term	Definition	Source
Enforcement	An action taken by the FAA most appropriate to promote safety and compliance with the statutory and regulatory requirements. The program provides a wide range of options for addressing noncompliance: • Educational and remedial training efforts, • Administrative action in the form of either a warning notice or letter of correction, • Certificate suspensions for a fixed period of time, • Civil penalties, • Indefinite certificate suspensions pending compliance or demonstration of qualifications, • Certificate revocations, • Injunctions, and • Referrals for criminal prosecution.	14 CFR Part 13
Evaluation	Determining the adequacy and effectiveness of an organization through a review of organizational policies, procedures, and systems.	
FAA Oversight Team	FAA personnel assigned to provide guidance and oversight of the DO in meeting its regulatory requirements.	
Hazard	A condition that could foreseeably cause or contribute to an accident.	AVS Order 8000.367A FAA Order 8040.4A
Inspection	A formal systematic and independent review of organizational policies, procedures, and systems.	
Interoperability	The ability for each SMS to be part of the system or systems through interdependent processes and/or components with shared principles, information, and governance.	AVS Order 8000.367A

Term	Definition	Source
Level of Project Involvement (LOPI)	The interactive process that the DO shares with its assigned Aircraft Certification Office (ACO) for specific engineering/design elements and with the Manufacturing Inspection District Office (MIDO) for specific production elements during certification projects. The criteria/factors influencing the decision of when to be involved will include but is not limited to Governmental functions, such as— • Novel or unusual features which may require issuance of Special Conditions, • Significant issues which may require Issue Papers, and • Defining Equivalent Level(s) of Safety (ELOS).	
Likelihood	The estimated probability or frequency, in quantitative or qualitative terms, of a hazard's effect or outcome.	AVS Order 8000.367A FAA Order 8040.4A
Management System	See the definition for System.	
Methods (or) Means of Compliance	Need a definition from DO Working Group Notes: • Method: Process • Means: Capability	
Mitigation	A means to reduce the risk of a hazard. Refer to Safety Risk Control.	AVS Order 8000.367A FAA Order 8040.4A
Nonconformity	Non-fulfillment of a requirement. This includes but is not limited to noncompliance with Federal regulations. It also includes an organization's requirements, policies, and procedures as well as requirements of safety risk controls developed by the organization.	AVS Order 8000.367A

Term	Definition	Source
Novel or Unusual	"The phrase "novel or unusual" as used in 14 CFR 21.16 is a very relative term. As used hereafter in applying a4 CFR 21.16 to justify the issuance of special conditions, "novel or unusual" will be taken with respect to the state of technology envisaged by the applicable airworthiness standards of this subchapter. It must be recognized that in some areas which will vary from time to time the state of the regulations may somewhat lag the state of the art in new design because of the rapidity in which the state of the art is advancing in civil aeronautical design and because of the time required to develop the experience base needed by the FAA to proceed with general rule making. Applicants for type certification of a new design have the opportunity to mitigate the impact of not knowing the precise airworthiness standards to be applied for "novel or unusual design features: by consulting with the FAA early in their certification planning when such features are suspected or known by the applicant to exist. It should also be recognized that, because of the intentional objective nature of the airworthiness standards of this subchapter, many new design features which might be thought of as "novel or unusual design features" may already be adequately covered by existing regulations, thus obviating the need to issue special conditions." Preamble material to 14 CFR 21.16.	
Oversight	A systems approach to review an organization's performance, validate the development of their defined system and verify compliance to the requirements of a certified DO to determine sufficiency. Oversight activities include— • Reviewing the work performed, • Evaluating performance for quality assurance, • Ensuring that required training has been completed, • Providing constructive feedback, and • Taking corrective action, including enforcement as necessary.	

Term	Definition	Source
Procedure	A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.	
Product/Service Provider	An organization engaged in the delivery of aviation products or services.	AVS Order 8000.367A
Quality Management System	From the DO Working Group—A set of interrelated or interacting quality processes accomplished by the organization through the establishment of policy and objectives, and achieving those objectives.	
Risk	Refer to Safety Risk. The terms risk and safety risk are used synonymously.	AVS Order 8000.367A FAA Order 8040.4A
Safety	The state in which the risk of harm to persons or property damage is acceptable.	AVS Order 8000.367A FAA Order 8040.4A
Safety Assurance	Processes within the SMS that function systematically to ensure the performance and effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information.	AVS Order 8000.367A FAA Order 8040.4A
Safety Culture	The shared values, actions, and behaviors that demonstrate a commitment to safety over competing goals and demands. The product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to an organization's safety programs.	AVS Order 8000.367A
Safety Management	The act of understanding and making decisions and taking actions to lower risk, inherent in all human activity, to acceptable levels.	
Safety Management System (SMS)	The formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk.	AVS Order 8000.367A
Safety Objective	A measurable goal or desirable outcome related to safety.	AVS Order 8000.367A
Safety Performance	Realized or actual safety accomplishment relative to the organization's safety objectives.	AVS Order 8000.367A

Term	Definition	Source
Safety Policy	The organization's documented commitment to safety, which defines its safety objectives and the accountabilities and responsibilities of its employees in regards to safety.	AVS Order 8000.367A
Safety Promotion	A combination of training and communication of safety information to support the implementation and operation of an SMS in an organization.	AVS Order 8000.367A
Safety Requirement	A safety condition or capability that must be met or passed by a system to satisfy a contract, standard, specification, or other formally imposed document or need.	AVS Order 8000.367A
Safety Risk	The composite of predicted severity and likelihood of the potential effect of a hazard. Initial—The predicted severity and likelihood of a hazard's effects or outcomes when it is first identified and assessed; includes the effects of preexisting risk controls in the current environment. Current—The predicted severity and likelihood at the current time. Residual—The remaining predicted severity and likelihood that exists after all selected risk control techniques have been implemented.	AVS Order 8000.367A FAA Order 8040.4A
Safety Risk Control	A means to reduce or eliminate the effects of hazards.	AVS Order 8000.367A FAA Order 8040.4A
Safety Risk Management (SRM)	A process within the SMS composed of describing the system, identifying the hazards, and analyzing, assessing, and controlling risk.	AVS Order 8000.367A FAA Order 8040.4A
Senior Company Management	Those in the company management chain above the DO Executive who are accountable for the actions of the DO.	
Severity	The consequence or impact of a hazard's effect or outcome in terms of degree of loss or harm.	AVS Order 8000.367A FAA Order 8040.4A
Showing	Determination of compliance to the Airworthiness Regulations by the applicant.	
Show/Find	The process by which the applicant "shows" how they complied with a regulation and the FAA "finds" that the applicant has adequately shown compliance to the regulation.	FAA Order 8110.4C

Term	Definition	Source
Statement of Compliance	A statement from the DO to the Administrator certifying that compliance with the applicable regulatory requirements has been determined and the procedures listed in its FAA-approved DO procedures manual have been followed.	
Substantiating Data	Documentation related to a design approval applicant's showing or compliance to the applicable airworthiness standards.	
Substitute risk	Risk unintentionally created as a consequence of safety risk control(s).	AVS Order 8000.367A
Supplier DO	A separate DO entity in its own right provides an article to an applicant/holder DO.	
Surveillance	The combination of evaluation and inspection to accomplish a review of organizational system to determine the adequacy and effectiveness of an organization.	
System	An integrated set of constituent elements that are combined in an operational or support environment to accomplish a defined objective. These elements include people, hardware, software, firmware, information, procedures, facilities, services, and other support facets.	AVS Order 8000.367A FAA Order 8040.4A
System State	An expression of the various conditions, characterized by quantities or qualities, in which a system can exist.	AVS Order 8000.367A
Validation	Validation is the process of proving that the functions, procedures, controls, and safety standards are correct and the right system is being built. i.e. the requirements are unambiguous, correct, complete, and verifiable.	
Verification	The process that ensures that the system requirements have been met by the design solution and the system is ready to be used in the operational environment for which it is intended.	

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APPENDIX C—ACRONYMS

AAQG	Americas Aerospace Quality Group
AC	Advisory Circular
ACO	Aircraft Certification Office
ACPRR	Aircraft Certification Process Review and Reform
AD	Airworthiness Directive
ADO	Agent Design Organization
AEE	Office of Environment and Energy
AEG	Aircraft Evaluation Group
AFS	Flight Standards Service
AIA	Aerospace Industries Association
AIR	Aircraft Certification Service
ANAC	National Civil Aviation Agency of Brazil
AO	Accredited Organization
APO–300	Office of Aviation Policy and Plans, Economic Analysis Division
ARC	Aviation Rulemaking Committee
ASA	Aviation Suppliers Association
ASE	Oversight Team of Engineers
ASI	Aviation Safety Inspector
ASTM	ASTM International
ATC	Air Traffic Control
AVS	FAA Office of Aviation Safety
BTS	Bureau of Transportation Statistics
CAA	Civil Aviation Authority (of another country)
CAAC	Civil Aviation Administration of China

CAP	Compliance Assurance Procedure
CAR	Civil Aviation Regulation
CAS	Compliance Assurance System
C.A.S.E.	Coordinating Agency for Supplier Evaluation
CBA	Cost Benefit Analysis
CBO	Compliance Based Oversight
CCS	Compliance Certification System
CDO	Certified Design Organization
CFR	Code of Federal Regulations
CMIS	Certificate Management Information System
CONOPS	Concept of Operations
COS	Continued Operational Safety
D&M	Design and Manufacturing
DAH	Design Approval Holder
DAR	Designated Airworthiness Representative
DAS	Designated Alteration Station
DDP	Declaration of Design and Performance
DER	Designated Engineering Representative
DMIR	Designated Manufacturing Inspection Representative
DMS	Design Management System
DO	Design Organization
DOA	Design Organization Approval
DPE	Designated Pilot Examiner
DPO	Design Production Organization
EASA	European Aviation Safety Agency

ELOS	Equivalent Level of Safety
EPA	Environmental Protection Agency
ETOPS	Extended Operations
FAA	Federal Aviation Administration
FOEB	Flight Operations Evaluations Board
FSB	Flight Standardization Board
FSDO	Flight Standards District Office
GAO	General Accountability Office
IAQG	International Aerospace Quality Group
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Standards Organization
LOPI	Level of Project Involvement
MIDO	Manufacturing Inspection District Office
MMEL	Master Minimum Equipment List
MOC	Memorandum of Cooperation
MRA	Maintenance, Repair, and Alteration
MRB	Maintenance Review Board
MSAD	Monitor Safety/Analyze Data
MSG	Maintenance Steering Group
NATCA	National Air Traffic Controllers Association
NPRM	Notice of Proposed Rulemaking
OCS	Organization Control System
ODA	Organization Designation Authorization

ODAR	Organizational Designated Airworthiness Representative
OIG	Office of Inspector General
OMB	Office of Management and Budget
OMT	Organizational Management Team
PAH	Production Approval Holder
PBO	Performance-Based Oversight
PI	Principal Inspector
PMA	Parts Manufacturer Approval
PNL	Project Notification Letter
POC	Point of Contact
QMS	Quality Management System
QSA	Quality System Audit
R&D	Research and Development
RBRT	Risk-based Resource Targeting
RPM	Revenue Passenger Miles
RTCA	Radio Technical Commission for Aeronautics
RTM	Revenue Ton Miles
SA	Supplier Audit
SAE	Society of Automotive Engineers
SEMP	Systems Engineering Management Plan
SFAR	Special Federal Aviation Regulation
SM ICG	Safety Management International Collaboration Group
SMM	Safety Management Manual
SMS	Safety Management System
SRM	Safety Risk Management

SSP	Specialty Service Providers
STC	Supplemental Type Certificate
TC	Type Certificate
TCCA	Transport Canada Civil Aviation
TSO	Technical Standard Order
TSOA	Technical Standard Order Authorization
UAS	Unmanned Aircraft Systems
UM	Unit Member
U.S.C.	United States Code
USITC	U.S. International Trade Commission

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APPENDIX D—PART 21/SMS ARC CHARTER

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Aviation Rulemaking Committee Charter

Effective Date:
10/5/2012

SUBJ: 14 CFR 21 / Safety Management Systems Aviation Rulemaking Committee

1. **PURPOSE.** This Charter creates the Aviation Rulemaking Committee (ARC) for Part 21 / Safety Management Systems (SMS) according to the Administrator's authority under Title 49 of the United States Code (49 U.S.C.) 106(p)(5). This charter also outlines the committee's organization, responsibilities, and tasks.

2. **BACKGROUND.**

On May 22, 2012, the Aircraft Certification Process Review and Reform ARC submitted a report to the FAA recommending that we undertake a review to update part 21 certification procedures to reflect a systems safety approach to product certification processes and oversight of design organizations. Design organizations must have full responsibility and accountability through the establishment of regulatory requirements for minimum qualification, performance, and management systems.

Consistent with FAA Order VS 8000.367, and the International Civil Aviation Organization (ICAO) Annex 8, the Aircraft Certification Service (AIR) has been actively developing and implementing an internal and external SMS. The initial focus was primarily on developing an internal set of processes, tools, and methodologies that facilitate the transition into the future state. AIR began that effort in 2005 and has made progress in defining key processes and tools. Later, with support from industry participants, the activities expanded to include development of standards for design and manufacturing organizations. Through implementation of pilot SMS projects with certain companies, the FAA is collecting information that will help define the scope of the SMS for Design Approval Holders (DAHs), validate certain best practices, and expand the knowledge base within the workforce and industry with respect to the essential elements of a robust SMS for manufacturers.

SMS requires a proactive approach to discovering and addressing hazards before they exhibit safety consequences. SMS also includes processes that seek to identify potential organizational breakdowns and necessary process improvements which allow management to address a safety issue before a noncompliant or unsafe condition results. SMS is not a substitute for compliance with FAA regulations or FAA oversight activities.

3. **OBJECTIVES AND TASKS OF THE ARC.** AIR wants to evaluate certain improvements to the effectiveness and efficiency of existing "certification procedures for products and parts," along with incorporating SMS in the design and manufacturing environment. This includes considering the effects of certain changes to the existing regulations, such as applicant qualifications, hazard (or safety) reporting, compliance assurance, and continued operation safety assurance systems for

Distribution: Initiated By:

all DAHs. The intent is to facilitate shifting towards a systems approach for DAHs that is similar to that used for production approval holder requirements, which involves a clear understanding of roles, responsibilities, and privileges. As part of this evaluation, we want to determine the best way industry and the FAA can effectively fulfill their respective compliance and safety responsibilities.

The ARC will provide a forum for the U.S. aviation community to discuss and provide recommendations to the FAA. The committee is expected to provide general information and guidance regarding proposed changes to part 21 and the AVS SMS program as it relates to design and manufacturing certificate and approval holders.

a. The ARC will provide the FAA recommendations, which may include proposals for rulemaking, suggested processes, policies and guidance, and any further action it determines the agency should contemplate for part 21 to align with the SMS requirements documented in proposed 14 CFR part 5, which is the central component of the NPRM entitled *Safety Management Systems for Part 121 Certificate Holders* [Docket No. FAA–2009–0671; Notice No. 10–15].

b. The ARC, serving in an advisory capacity, is expected to present and discuss whatever input, guidance, and recommendations its members consider critical to the FAA's ultimate disposition, development, and implementation of proposed regulatory requirements and related guidance and policy as necessary to the future direction for part 21 to include applicant pre-qualifications, approval holder recognition, and SMS considerations.

c. The ARC will also consider proposed revisions to clarify and update engineering/design-oriented regulatory requirements to part 21. In support of design certification and continued airworthiness, the evaluation should include improvements in the areas of:

    1. Application process
    2. Applicant qualifications
    3. Standardized certification criteria
    4. Identifying design approval holder responsibilities and privileges
    5. Clarifying continued airworthiness requirements
    6. Clarifying design approvals needing Instructions for Continued Airworthiness
    7. Clarifying TSO design approval processes
    8. Process definition for determining eligibility of U.S. surplus military aircraft in the restricted category

    This proposal additionally corrects regulatory language, implements editorial changes for clarification, and standardizes regulatory language to reflect the global aviation environment. While this information will be shared with the ARC, responses to "clean-up" proposals are not required as part of the deliverables.

d. Proposed part 5 and International Civil Aviation Organization (ICAO) Annex 8 and Annex 19 (draft) serve as the foundation for the ARC's consideration regarding how the FAA will address its responsibilities for developing and implementing SMS

requirements and the management and oversight of its regulated product/service providers. The ARC must respect the framework outlined in proposed part 5 and the ICAO Annexes when it provides the FAA recommendations with respect to application of SMS. However, the FAA will consider proposed changes to part 5 as deemed necessary from a design and manufacturing perspective.

Recommendation Report. The ARC shall make recommendations and submit a report addressing the following:

a. Improvements, which may include proposals for rulemaking, processes, policies and guidance for 14 CFR part 21 that reflect a systems approach for safety. This will promote an effective and efficient certification process, which includes considering the effects of certain changes to the existing regulations, such as:
   1. Minimum qualifications and organizational requirements for design approval applicants and holders including responsibilities and privileges
   2. SMS for design approval holders
   3. Compliance assurance
   4. Continued operational safety assurance
   5. Hazard reporting

b. Cost and benefit and other impact information in support of developing the required Regulatory Evaluation(s) and Regulatory Flexibility economic analysis for applying any proposed changes to 14 CFR part 21 FAA certificate and approval holders. Cost and benefit analysis should include information obtained through the AIR SMS pilot project and should identify the specific areas of impact and present this information in quantitative terms to the extent possible.

c. Part 21 design and production approval holder organizations to which the proposed SMS requirements should apply, taking into consideration cost and benefit information as well as public comments to the part 5 NPRM and the SMS-ARC *Design and Manufacturing Working Group Report – High-Level Recommendations for SMS Requirements* dated March 12, 2010.

d. Changes to the FAA oversight methodology based on any recommendations for changes to part 21 that takes into account existing FAA processes and oversight and delegation programs for design and manufacturing related certificates and approvals and authorizations.

e. Definitions and processes to be included in advisory, policy, and procedures material for addressing safety risk management responsibilities within a design and/or manufacturing organization. These definitions and processes should include:

   1. An operational definition of a "hazard" throughout the life cycle of a product in safety risk management.
   2. Definition of the term "organization" with respect to design and production approval holders to identify the limits of applicability of proposed SMS requirements, in

consideration of the broad range of organizational structures and activities within modern design and/or manufacturing organizations.
3. Hazard identification procedures.
4. Processes for the determination of acceptable safety risk.
5. Procedures to be included in advisory, policy, and procedures material for addressing safety assurance responsibilities within a design and/or manufacturing organization, including specific recommendations regarding "employee reporting systems".

The Director of Aircraft Certification Service (AIR-1) may propose additional tasks as necessary in support of a potential part 21 rulemaking action. The ARC may also request that AIR-1 add other tasks deemed relevant to the success of this initiative.

4. ARC PROCEDURES

a. The ARC advises and provides written recommendations to AIR-1 and acts solely in an advisory capacity. Once the ARC recommendations are delivered to AIR-1, it is within his/her discretion to determine when and how the report of the ARC is released to the public.
b. The ARC may propose additional tasks as necessary to AIR-1 for approval.
c. The ARC will submit a report detailing recommendations within 18 months from the effective date of this charter. The chair of the ARC sends the recommendation report to both AIR-1 and the Director of the Office of Rulemaking.
d. The ARC may reconvene following the submission of its recommendations for the purposes of providing advice and assistance to the FAA, at the discretion of AIR-1, provided the charter is still in effect.

5. ARC ORGANIZATION, MEMBERSHIP, AND ADMINISTRATION. The FAA will establish a committee of members of the aviation community. Members will be selected based on their familiarity with 14 CFR part 21, Safety Management Systems analysis, and regulatory compliance. Membership will be balanced in viewpoints, interests, and knowledge of the committee's objectives and scope. ARC membership is limited to promote discussion. Active participation and commitment by members will be essential for achieving the ARC's objectives. Attendance is essential for continued membership on the committee. When necessary, the ARC may set up specialized work groups that include at least one ARC member and invited subject matter experts from industry and government.

This ARC will consist of members from U.S. and foreign industry including representatives from designers and manufacturers holding part 21 certificates and approvals and other private sector aviation industry associations and advocacy groups. Invited foreign authorities and International Civil Aviation Organization (ICAO) representatives provide a valuable perspective from the global aviation community. These representatives are encouraged to fully participate in committee discussions; however, their participation does not include voting privileges on committee issues. The FAA's participation and support for the ARC will come from all affected lines-of-business.

a. The ARC sponsor is AIR-1 who:
   1. Appoints members or organizations to the ARC, at the Director's sole discretion;

2. Selects the industry chair(s) from the ARC membership;
3. Selects the FAA's designated federal official for the ARC;
4. Receives all ARC recommendations and reports; and
5. Provides administrative support for the ARC through the Safety Management Design and Analysis Branch (AIR-150).

b. Once appointed, the industry chair(s) will:
1. Coordinate required committee and subcommittee (if any) meetings in order to meet the ARC's objectives and timelines;
2. Provide notification to all ARC members of the time and place for each meeting;
3. Ensure meeting agendas are established and provided to the committee members in a timely manner;
4. Keep meeting minutes;
5. Perform other responsibilities as required to ensure the ARC's objectives are met; and
6. Provide status updates in writing to AIR-1 at 6 months and 12 months from the effective date of this charter.

6. **COST AND COMPENSATION.** The estimated operating cost (including *pro rata* share of salaries of FAA employees) to the Federal Government for this ARC is approximately $400,000 annually. All travel costs for government employees will be the responsibility of the government employee's organization. Non-government representatives serve without government compensation and bear all costs related to their participation on the committee.

7. **PUBLIC PARTICIPATION.** ARC meetings are not open to the public. Persons or organizations outside of the ARC who wish to attend a meeting must get approval in advance of the meeting from a committee co-chairperson or designated federal official.

8. **AVAILABILITY OF RECORDS.** Consistent with the Freedom of Information Act, Title 5, U.S.C., section 522, records, reports, agendas, working papers, and other documents that are made available to or prepared for or by the committee will be available for public inspection and copying at the FAA's Office of the Director, Aircraft Certification Service (AIR-1), 800 Independence Avenue SW, Washington, DC 20591. Fees will be charged for information furnished to the public according to the fee schedule published in Title 49 of the Code of Federal Regulations, part 7.

   You can find this charter on the FAA Web Site at:
   http://www.faa.gov/about/committees/rulemaking/.

9. **DISTRIBUTION.** This order is distributed to director-level management in the Office of the Associate Administrator for Aviation Safety, the Office of Aviation Policy and Plans, the Office of Rulemaking, and the director- and division-level management in the Aircraft Certification Service.

10. **EFFECTIVE DATE AND DURATION.** This committee is effective upon issuance of this charter. The committee shall remain in existence for 2 years, unless sooner terminated or

extended by the Administrator.

The effective date of this charter is October 5, 2012.

Michael P. Huerta
Acting Administrator

APPENDIX E—KEY CONSIDERATIONS SUPPORTING ARC RECOMMENDATIONS

This appendix provides a comprehensive summary of all recommendations from the ARC report that support the four main recommendations and can be used as reference material. Each supporting recommendation has been grouped under the appropriate core recommendation as a key consideration. The purpose of this appendix is to provide any future rulemaking team a comprehensive overview of the key considerations the ARC feels should be taken into consideration for each of these areas if a rulemaking effort takes place.

RECOMMENDATION 1: SYSTEMS APPROACH TO CERTIFICATION—KEY CONSIDERATIONS

The systems approach to certification will be separated into three subsections that must be satisfied to move from the current state to a DO:

a. Promote accountability framework and enhanced applicant showing.

b. Establish minimum requirements for design approval applicant/holder.

c. Establish requirements for voluntary certificated DOs.

1a. PROMOTE ACCOUNTABILITY FRAMEWORK AND ENHANCED APPLICANT SHOWING

Key Considerations:

1. DAH Procedures Manual: The ARC recommends further discussion on the necessary level of detail to include in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual. (Refer to section 10.2.1.2.)
2. Accountability Framework: The ARC recommends the FAA consider the DO model's impact on the existing accountability framework, particularly regarding how a design approval applicant, DAH, and DO are related. (Refer to section 10.2.3.)

1b. ESTABLISH MINIMUM REQUIREMENTS FOR DESIGN APPROVAL APPLICANT/HOLDER

Key Considerations:

1. Establish minimum standards for design approval applicant/holder qualification and obligations to ensure applicants fully understand the type certification process and their roles and responsibilities.

1c. ESTABLISH REQUIREMENTS FOR VOLUNTARY CERTIFICATED DOs

Key Considerations:

1. Proposed Regulations, Preamble Language, and Guidance Material: The ARC recommends that proposed regulations, preamble language, and guidance material should be discussed as a follow-on activity to mature the information provided in this report. (Refer to section 6.)
2. Supplier Oversight "Pooling": The ARC recommends DO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities in a manner similar to what is currently done by manufacturing facilities and airlines under the

Coordinating Agency for Supplier Evaluation (C.A.S.E.), http://www.caseinc.org/. (Refer to section 6.5.1.)

3. Specialty Service Providers (SSP): The ARC recommends the FAA give priority to developing a means for recognizing an accreditation system for SSPs (for example, Nadcap or similar). (Refer to section 6.5.3.)

4. Establish requirements for the issuance and oversight of certificated DOs that includes the necessary compliance assurance, safety management, and controls to make all compliance determinations through applicant showing and verification processes. Through FAA certificate management oversight and direct project involvement in defined risk-based areas, the FAA may rely on the DO compliance determinations to make its finding for the issuance of a design approval. This report builds on the recommendations submitted to the FAA by the CDO ARC in May 2008.

   However, the ARC had significant concerns about attempting to set a specific date when a certified DO would be required. It was felt that this could cause both industry and the FAA to have to push other things aside just to satisfy the DO schedule requirements, affecting industry's ability to deliver its products in a timely manner and the FAA's ability to support that activity. After much deliberation, it was determined that a phased approach to the DO implementation would be more feasible than a single-step process.

   The Part 21/SMS ARC recommends a building block approach to implementing DO, which includes establishing a clear accountability framework, particularly regarding how a design approval applicant, DAH, and DO are related; transitioning the FAA's oversight of design activities to a centralized systematic model; optimizing full use of ODA authorization; and implementing new organizational and SMS requirements. (Refer to section 10.)

   Summary of the Building Block Approach to a Design Organization: The phased approach is described as a building block approach that would let a company build pieces of the DO requirements on a more flexible schedule. This building block approach would allow the FAA and industry to immediately begin taking steps to improve processes and make the changes necessary for DO implementation. These steps shown in figure E–1 below will enable a much more manageable transition to DO in the future.

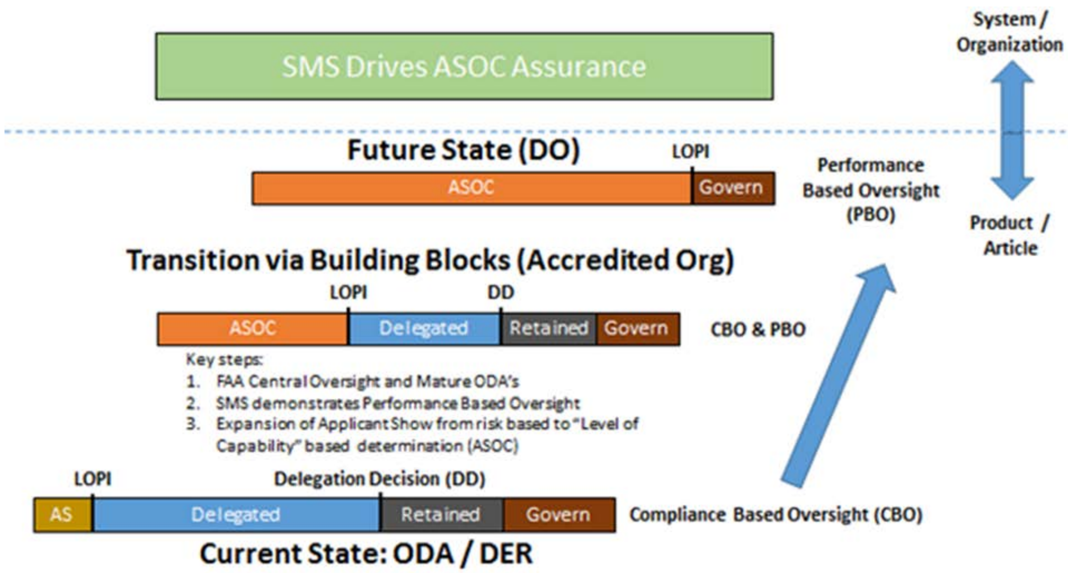

Figure E–1. Building Block Approach to DO

With successful implementation of these building blocks, the ARC supports a future rulemaking to consider mandatory implementation of DO. (Refer to section 10.2.1.3.)

5. Business Structure Variation: The ARC recommends further development of how business structure variations will be accommodated under the DO framework. (Refer to section 6.6.)

6. Form of the DO Certificate: The ARC recommends a certificate structure similar in nature to the EASA DOA certificate and terms of approval. (Refer to section 6.7.3.)

7. DA Transfer: The ARC recommends non-DO design approval transfer requirements be provided by a separate follow-on activity to the ARC. (Refer to section 6.7.4.)

8. Maintenance Aspects of ICA: The ARC recommends the DO determine maintenance technical material aspects of ICA requirements. (Refer to section 6.7.8.)

9. Environmental Compliance Determinations: The ARC recommends the FAA propose to the EPA that the process-based approach to compliance, as established by DO program principles (which is far more robust than the normal delegation process) is sufficient to ensure compliance with the environmental aspects of 14 CFR parts 34 and 36. (Refer to section 6.7.9.)

10. Form for DO Transmittal of Approved Data: DO-issued service bulletins should be a means for DOs to provide "approved data" for general use. When issued, service bulletins constitute a change in type design by the holder and convey the necessary "approved data" to implement the change by owner/operators under part 43. A new or revised form is also needed for domestic and international recognition of "approved data" created under the DO concept. The ARC recommends the form be similar to the FAA Forms 8110–3 and 8100–9 currently used to approve data in the FAA's delegation system. (Refer to section 6.8.1.)

11. DO Is a Choice: The ARC recommends DO applicability thresholds for any design approval applicants or DAHs should be optional. (Refer to section 10.)

Recommendation 2: Safety Management System—Key Considerations

In addition to the Safety Management Systems Requirements section in the report (section 4.2), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

Key Considerations:

1. The ARC evaluated the proposed § 5.27 and determined it is not necessary for D&M organizations. Therefore, the ARC recommends the FAA modify part 21 to make part 5, excluding § 5.27, the SMS requirements for organizations meeting the SMS applicability threshold. The ARC will continue to develop guidance material for D&M implementation of part 5 and appreciates the FAA's willingness to engage industry in this regard. (Refer to section 5.1.1.)
2. Establish a requirement for implementing SMS consistent with the proposed part 5 for design and production approval organizations. The ARC recommends this new requirement apply to organizations that design or manufacture type-certificated products (under a TC or production certificate) and those that design or manufacture articles (under a TSO or PMA) or make changes to products (under an STC) that could directly prevent continued safe flight and landing if they fail. (Refer to section 5.1.2.)
3. Policy and Guidance Material: The ARC recommends the FAA and industry develop SMS guidance for organizations that: design or manufacture products (that is, aircraft, engines, or propellers); design or manufacture articles (TSO, PMA) whose failure could directly prevent continued safe flight and landing; or make design changes to a product through an STC, failure of which could directly prevent continued safe flight and landing. The ARC developed SMS regulatory material and a basis for preamble, policy, and guidance material, as provided in this report; however, it determined more work was necessary to produce supporting guidance material. The ARC recommends the SMS Working Group continue to develop supporting guidance material with a goal of completing the task by Spring 2015 by providing an addendum to this report through the ARC. (Refer to section 5.3.)
4. SMS Concept of Operations (CONOPS): The ARC has developed a CONOPS describing the intent of the part 5 SMS framework (safety policy, SRM, safety assurance, and safety promotion) for D&M organizations as it applies to each life cycle phase (design and certification, production and airworthiness certification, and continued airworthiness) of a product or article. The ARC recommends the CONOPS form the basis for the development of preamble, policy, and guidance material for D&M organizations. The ARC also recommends that, as described in the CONOPS, existing processes and procedures should be considered as meeting the intent of part 5. (Refer to section 5.3.)

5. Availability of Data for SRM: The ARC recommends the FAA develop an approach to make fleet data already provided to the FAA (hours, flights, reported failures, malfunctions, and defects and service difficulty reports) readily available to D&M organizations, in support of executing SRM (§ 5.71). (Refer to section 5.3.)
6. The ARC recommends implementing the changes to §§ 21.3 and 21.4 identified in the table found in section 8.2.2 of the ARC report. (Refer to section 8.2.2.)
7. The ARC recommends developing or revising the following guidance materials to support the recommended rule changes and facilitate FAA oversight: (1) criteria for consistent understanding of the language in § 21.3(d) "has resulted in or may result in a finding of an unsafe condition by the Administrator"; (2) acceptable compliance demonstration and verification regarding the safety analysis referenced in § 21.3(d); (3) changes to AC 21–9B, Manufacturers Reporting of Failure, Malfunctions or Defects, to include the recommended guidance for §§ 21.3(d) and 21.3(e). (Refer to section 8.3.2.)
8. The ARC recommends developing proposed regulation changes and guidance or process proposals to address safety risk that is acceptable in the short term while long-term safety risk control/mitigation plans are developed and implemented. (Refer to section 8.2.5.2.)

Recommendation 3: Evolution of Oversight—Key Considerations

In addition to the Evolution of Oversight section in the report (section 4.3), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

Key Considerations:

1. Performance-Based Oversight: The ARC developed proposed practices for FAA oversight that is correlated with recommended D&M organizational changes. This enables a shift to performance-based oversight where the FAA can effectively allocate resources based on D&M system risk management performance, and moves the FAA from a total dependence on discrete compliance findings, audits, and inspections. The ARC recommends chartering a dedicated effort with the FAA and industry to develop guidance for determining performance indicators that are mutually acceptable before implementation of the new oversight model. (Refer to section 3.3.)
2. Single Centralized Oversight Organization: The ARC recommends a single centralized oversight presence and systemic (process-based) approach for initial and ongoing assessments. The three key oversight areas are: (1) Organizational—transition from traditional show/find compliance to organizational PBO model; (2) Product and Articles—transition from the FAA's traditional role of direct project involvement to a LOPI approach focused on performing governmental functions; (3) Post-Certification (COS)—transition from traditional reactionary approach to a systemic (process-based) surveillance model discussed in more detail later in this section.

3. The assessment methodology will cover a standardized approach to quality, design, and safety. In support of this recommendation, the ARC's Oversight Working Group has provided a capability-based assessment tool, PROs/CONs analysis of oversight management options, and supporting rationale for the recommendation. FAA oversight teams would report to a centralized FAA organization. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data that will drive the risk-based modeling controls, and allow for a highly trained staff in system surveillance, skill management, and a single source for corrective actions. (Refer to section 10.1.4.3.)

4. The recommended three transitional steps to the centralized oversight organization are—

   1. Proof of Concept—Pre Implementation: Ensure through proof of concept plans that the requirements proposed by the ARC are practical, effective, and efficient. Determine if the transition from "mature ODA" to DO has benefits to the FAA and industry.

   2. FAA Transition Plan Transition Principle: The FAA should not release a final rule before it has demonstrated the necessary cultural shift to perform system oversight. To achieve a cultural shift, policy and organizational changes may be required.

   3. Industry Transition Plan: The organization must establish the systems required of an approved organization while still working as a non-certificated applicant or a delegated organization. Applicants working toward becoming a DO demonstrate compliance to those requirements on an "as ready" basis. (Refer to section 10.1.5.2.)

Recommendation 4: TSO Modernization and Part 21 Miscellaneous Cleanup

In addition to the Part 21 Miscellaneous Cleanup and TSO Modernization section in the report (section 4.4), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

TSO Modernization

Key Considerations:

The ARC recommends the following changes to modernize the TSO requirements:

1. Allow TSO organizations to issue their own TSOAs, relative to scalable privileges for particular types of TSO standards. (Alternate approaches via a certified TSO organization or expansion of TSO ODA functions.) (Refer to section 9.2.1.)

2. Clarify the types of data that can be approved under a TSOA (that is, type design of the article and declared performance of the article including non-TSO functions and incomplete TSO), and expectations for acceptance of approved TSO data for installation. (Require and approve DDP via revision to § 21.601(b)(2) and proposed new § 21.603(a)(3).) (Refer to section 9.2.1.)

3. Proposed new §§ 21.603(a)(3) and 21.619(d), Design changes, for subsequent design changes to declare non-TSO functions. (Additional guidance including a "decision table" to assist in differentiating between TSO supporting features and integrated non-TSO functions.) (Refer to section 9.2.1.)

4. Rule revision to remove the term “model number” from TSO rules and replace it with a requirement for a “unique identifier.” (Revision to §§ 21.603(b) and 21.619 for subsequent design changes.) (Refer to section 9.2.1.)
5. The ARC recommends changing part 21 to establish the effective TSO revision level at the beginning of the project, not at the end. (Revision to § 21.603(a).) (Refer to section 9.2.1.)
6. The ARC recommends a process for the TSO holder to continue marking TSO articles following a determination of “a design discrepancy that does not result in an unsafe condition.” (Revision of § 45.10(b) and proposed new § 21.616(i), Responsibility of the holder.) (Refer to section 9.2.1.)
7. The ARC recommends maintaining the privilege for TSO holders to make minor or insignificant (sub-minor) changes to articles without further approval. (Refer to section 9.1.3.)
8. The ARC recommends clarifying the TSO application data, manufacturer data and furnished data requirements. (Refer to the TSO Subteam Report, included as appendix H to this report). (Refer to section 9.1.3.)
9. The ARC recommends developing expanded guidance to promote the uniform definition and treatment of integrated non-TSO functions by applicants, installation developers, and the FAA. (Refer to the TSO Subteam Report, included as appendix H to this report). (Refer to section 9.1.3.)
10. The ARC recommends an applicant should submit to the Administrator a signed undertaking to carry out the responsibilities as a DAH before issuance of a design approval. (Refer to section 9.1.3.)

MISCELLANEOUS PART 21 CLEANUP

Key Considerations:

The ARC recommends—

1. AC 20–62, Eligibility, Quality, and Identification of Aeronautical Replacement Parts, paragraph 6, Discussion, be amended to include an explanation of the scope of §§ 21.8 and 21.9. (Refer to section 9.1.1.3.)
2. Amending § 21.9(a) to add paragraph (a)(7), which reads: “Produced in any other manner approved by the FAA.” (Refer to section 9.1.1.3.)
3. The removal of § 21.335(b) from 14 CFR. (Refer to section 9.1.2.)

APPENDIX A—PART 21/SMS ARC MEMBERSHIP

MEMBERS AND ALTERNATES

Mr. Walter Desrosier, *Co-Chair*, GAMA

Mr. Michael Reinert, *Co-Chair*, FAA AIR–150

Mr. Rick Baggette, Boeing

Mr. Glenn Baxter, Bombardier

Mr. Edmond Boullay, *Alternate*, ASD/US Crest

Mr. Rafael Borges, *Observer*, ANAC

Mr. John Bouma, Cessna

Mr. Dave Chapel, GE

Ms. Maria Clara, *Observer*, ANAC

Mr. Michael Collins, NATCA

Mr. Robert Cook, FAA AIR–200

Mr. Peter Corbeel, *Observer*, EASA

Ms. Doris Costa, *Observer*, ANAC

Ms. Jodi Diamant-Boustead, *Alternate*, AIAC/Pratt Canada

Mr. Jason Dickstein, MARPA

Mr. Tomaso DiPaolo, *Alternate*, NATCA

Mr. Chris Eick, Honeywell

Mr. Jimmy Eyl, Banyan Air Service

Mr. Robert Ferguson, *Observer*, TCCA

Ms. Amy Garzaro, FAA AIR–150

Mr. Scott Geddie, FAA AIR–110

Mr. Paul Greer, FAA AGC

Mr. Julian Hall, *Observer*, EASA

Mr. David Hempe, FAA AIR–100

Ms. Katrina Holiday, FAA ARM

Mr. Charles Huber, FAA SMS/ANM–100

Mr. Daniel Leach, FAA APO

Mr. Eric Lesage, Airbus

Mr. Michael Linegang, FAA AIR–110

Mr. Mark Lopez, *Alternate*, A4A

Mr. Stacey Mason, *Observer*, TCCA

Ms. Linda Navarro, *Observer*, FAA AIR–150

Mr. George Novak, AIA

Ms. Jan Novak, *Observer*, EASA

Mr. Ric Peri, AEA

Mr. Dennis Piotrowski, BELAC

Mr. Tom Rogozinski, Honeywell

Mr. Dan Shapiro, Sikorsky General

Mr. Eric Sivel, *Observer*, EASA

Mr. Roger Southgate, Rockwell Collins

Mr. Giles Strickler, FAA ARM

Mr. Marcus Tittiger, *Observer*, TCCA

Mr. Scott VanBuren, *Observer*, FAA AVP (SMS)

Mr. Mark Watton, Delta Airlines

Mr. Bill Whitton, Gulfstream

Program Support

Mr. Larry Van Dyke, GAMA

APPENDIX B—GLOSSARY

Term	Definition	Source
Acceptable Risk	The level of risk that individuals or groups are willing to accept given the benefits gained. Each organization will have its own acceptable risk level, which is derived from its legal and regulatory compliance responsibilities, its threat profile, and its business/organizational drivers and impacts.	AVS Order 8000.367A
Accident	An unplanned event or series of events that results in death, injury, or damage to, or loss of, equipment or property.	AVS Order 8000.367A FAA Order 8040.4A
Accountable Manager	(a) Accountable manager means the person designated by an applicant or design approval holder who is responsible for and has the authority over all design approval operations that are conducted under part 21, including ensuring that design approval holder personnel follow the regulations and serving as the primary contact with the FAA.	14 CFR Part 145.3(a) modified for use by DAH
Accountability Framework	An established set of responsibilities and commitments of the FAA and industry	Refer to appendix O to this report.
Aerospace System	U.S. airspace, all manned and unmanned vehicles operating in that airspace, all U.S. aviation operators, airports, airfields, air navigation services, pilots, regulations, policies, procedures, facilities, equipment, and all aviation-related industry.	AVS Order 8000.367A FAA Order 8040.4A
Aircraft Accident	An occurrence associated with the operation of an aircraft that takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage.	49 CFR 830.2
Analysis	The process of identifying a question or issue to be addressed, examining the issue, investigating the results, interpreting the results, and possibly making a recommendation. Analysis typically involves using scientific or mathematical methods for evaluation.	FAA Order 8040.4A
Applicant Show With Capability (ASOC)	Based on the Oversight Working Group's model of DOs getting recognized for demonstrated capabilities.	

Term	Definition	Source
Approved Data	Data approved by FAA employees, its designees, or a DO acting under the authority of its certificate.	
Assessment	Process of measuring or judging the value or level of something.	FAA Order 8040.4A
Certificate Surveillance	FAA actions to monitor the DO certificate holder and to determine the holder's compliance with the provisions of its certificate. Note: In the Oversight section we discuss managing these organizations through surveillance.	
Compliance Assurance System (CAS)	DO holder's system for ensuring that it complies with the applicable regulations.	
Compliance Finding	FAA decision (either directly or through a designee) that compliance has been shown with the applicable regulatory requirements.	
Control	Refer to Safety Risk Control.	AVS Order 8000.367A
Corrective Action	Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity or other undesirable situation. An action required to be taken by the DO to address noncompliances and problems with the organization's procedures or performance. The noncompliances may result from— • Internal audits conducted by the DO, • FAA surveillance, • DO employee observations, and • Voluntary disclosures.	AVS Order 8000.367A
Culture of Compliance	Knowledge, beliefs, attitudes, and behaviors of an organization that are focused on ensuring regulatory compliance with all its activities.	

Term	Definition	Source
Descriptive Data	From the DO Working Group: • Data that defines the type design that needs to be determined compliant to the applicable airworthiness standards. The descriptive data is what is approved by the FAA when a design approval certificate is issued. • The drawings and specifications necessary to define the configuration shown to comply.	
Determination of Compliance	A decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. [Note: The ARC has referred to "regulatory requirements" rather than just "airworthiness standards" because its recommendation that DOs eventually include determination of compliance with other 14 CFR parts, such as parts 26, 34, and 36.] It may also be a decision made by the certificate holder that data previously approve by the FAA or data determined to comply by another CAA under the provisions of a bilateral airworthiness agreement between the United States and a foreign country or jurisdiction, are valid and applicable to the design of the product, part, or appliance for which it is to be used, including the applicable certification or approval basis.	
DO Executive	The company individual directly responsible for ensuring that the DO meets all of its regulatory responsibilities.	
DO Point(s) of Contact	The individual(s) within the DO responsible for all communications with the FAA.	
Eligible Data	Data developed under an approved DO system, assuming a specified, but not FAA-established, certification basis, and product type design if appropriate.	

Term	Definition	Source
Enforcement	An action taken by the FAA most appropriate to promote safety and compliance with the statutory and regulatory requirements. The program provides a wide range of options for addressing noncompliance: • Educational and remedial training efforts, • Administrative action in the form of either a warning notice or letter of correction, • Certificate suspensions for a fixed period of time, • Civil penalties, • Indefinite certificate suspensions pending compliance or demonstration of qualifications, • Certificate revocations, • Injunctions, and • Referrals for criminal prosecution.	14 CFR Part 13
Evaluation	Determining the adequacy and effectiveness of an organization through a review of organizational policies, procedures, and systems.	
FAA Oversight Team	FAA personnel assigned to provide guidance and oversight of the DO in meeting its regulatory requirements.	
Hazard	A condition that could foreseeably cause or contribute to an accident.	AVS Order 8000.367A FAA Order 8040.4A
Inspection	A formal systematic and independent review of organizational policies, procedures, and systems.	
Interoperability	The ability for each SMS to be part of the system or systems through interdependent processes and/or components with shared principles, information, and governance.	AVS Order 8000.367A

Term	Definition	Source
Level of Project Involvement (LOPI)	The interactive process that the DO shares with its assigned Aircraft Certification Office (ACO) for specific engineering/design elements and with the Manufacturing Inspection District Office (MIDO) for specific production elements during certification projects. The criteria/factors influencing the decision of when to be involved will include but is not limited to Governmental functions, such as— • Novel or unusual features which may require issuance of Special Conditions, • Significant issues which may require Issue Papers, and • Defining Equivalent Level(s) of Safety (ELOS).	
Likelihood	The estimated probability or frequency, in quantitative or qualitative terms, of a hazard's effect or outcome.	AVS Order 8000.367A FAA Order 8040.4A
Management System	See the definition for System.	
Methods (or) Means of Compliance	Need a definition from DO Working Group Notes: • Method: Process • Means: Capability	
Mitigation	A means to reduce the risk of a hazard. Refer to Safety Risk Control.	AVS Order 8000.367A FAA Order 8040.4A
Nonconformity	Non-fulfillment of a requirement. This includes but is not limited to noncompliance with Federal regulations. It also includes an organization's requirements, policies, and procedures as well as requirements of safety risk controls developed by the organization.	AVS Order 8000.367A

Term	Definition	Source
Novel or Unusual	"The phrase "novel or unusual" as used in 14 CFR 21.16 is a very relative term. As used hereafter in applying a4 CFR 21.16 to justify the issuance of special conditions, "novel or unusual" will be taken with respect to the state of technology envisaged by the applicable airworthiness standards of this subchapter. It must be recognized that in some areas which will vary from time to time the state of the regulations may somewhat lag the state of the art in new design because of the rapidity in which the state of the art is advancing in civil aeronautical design and because of the time required to develop the experience base needed by the FAA to proceed with general rule making. Applicants for type certification of a new design have the opportunity to mitigate the impact of not knowing the precise airworthiness standards to be applied for "novel or unusual design features: by consulting with the FAA early in their certification planning when such features are suspected or known by the applicant to exist. It should also be recognized that, because of the intentional objective nature of the airworthiness standards of this subchapter, many new design features which might be thought of as "novel or unusual design features" may already be adequately covered by existing regulations, thus obviating the need to issue special conditions." Preamble material to 14 CFR 21.16.	
Oversight	A systems approach to review an organization's performance, validate the development of their defined system and verify compliance to the requirements of a certified DO to determine sufficiency. Oversight activities include— • Reviewing the work performed, • Evaluating performance for quality assurance, • Ensuring that required training has been completed, • Providing constructive feedback, and • Taking corrective action, including enforcement as necessary.	

Term	Definition	Source
Procedure	A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.	
Product/Service Provider	An organization engaged in the delivery of aviation products or services.	AVS Order 8000.367A
Quality Management System	From the DO Working Group—A set of interrelated or interacting quality processes accomplished by the organization through the establishment of policy and objectives, and achieving those objectives.	
Risk	Refer to Safety Risk. The terms risk and safety risk are used synonymously.	AVS Order 8000.367A FAA Order 8040.4A
Safety	The state in which the risk of harm to persons or property damage is acceptable.	AVS Order 8000.367A FAA Order 8040.4A
Safety Assurance	Processes within the SMS that function systematically to ensure the performance and effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information.	AVS Order 8000.367A FAA Order 8040.4A
Safety Culture	The shared values, actions, and behaviors that demonstrate a commitment to safety over competing goals and demands. The product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to an organization's safety programs.	AVS Order 8000.367A
Safety Management	The act of understanding and making decisions and taking actions to lower risk, inherent in all human activity, to acceptable levels.	
Safety Management System (SMS)	The formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk.	AVS Order 8000.367A
Safety Objective	A measurable goal or desirable outcome related to safety.	AVS Order 8000.367A
Safety Performance	Realized or actual safety accomplishment relative to the organization's safety objectives.	AVS Order 8000.367A

Term	Definition	Source
Safety Policy	The organization's documented commitment to safety, which defines its safety objectives and the accountabilities and responsibilities of its employees in regards to safety.	AVS Order 8000.367A
Safety Promotion	A combination of training and communication of safety information to support the implementation and operation of an SMS in an organization.	AVS Order 8000.367A
Safety Requirement	A safety condition or capability that must be met or passed by a system to satisfy a contract, standard, specification, or other formally imposed document or need.	AVS Order 8000.367A
Safety Risk	The composite of predicted severity and likelihood of the potential effect of a hazard. Initial—The predicted severity and likelihood of a hazard's effects or outcomes when it is first identified and assessed; includes the effects of preexisting risk controls in the current environment. Current—The predicted severity and likelihood at the current time. Residual—The remaining predicted severity and likelihood that exists after all selected risk control techniques have been implemented.	AVS Order 8000.367A FAA Order 8040.4A
Safety Risk Control	A means to reduce or eliminate the effects of hazards.	AVS Order 8000.367A FAA Order 8040.4A
Safety Risk Management (SRM)	A process within the SMS composed of describing the system, identifying the hazards, and analyzing, assessing, and controlling risk.	AVS Order 8000.367A FAA Order 8040.4A
Senior Company Management	Those in the company management chain above the DO Executive who are accountable for the actions of the DO.	
Severity	The consequence or impact of a hazard's effect or outcome in terms of degree of loss or harm.	AVS Order 8000.367A FAA Order 8040.4A
Showing	Determination of compliance to the Airworthiness Regulations by the applicant.	
Show/Find	The process by which the applicant "shows" how they complied with a regulation and the FAA "finds" that the applicant has adequately shown compliance to the regulation.	FAA Order 8110.4C

Term	Definition	Source
Statement of Compliance	A statement from the DO to the Administrator certifying that compliance with the applicable regulatory requirements has been determined and the procedures listed in its FAA-approved DO procedures manual have been followed.	
Substantiating Data	Documentation related to a design approval applicant's showing or compliance to the applicable airworthiness standards.	
Substitute risk	Risk unintentionally created as a consequence of safety risk control(s).	AVS Order 8000.367A
Supplier DO	A separate DO entity in its own right provides an article to an applicant/holder DO.	
Surveillance	The combination of evaluation and inspection to accomplish a review of organizational system to determine the adequacy and effectiveness of an organization.	
System	An integrated set of constituent elements that are combined in an operational or support environment to accomplish a defined objective. These elements include people, hardware, software, firmware, information, procedures, facilities, services, and other support facets.	AVS Order 8000.367A FAA Order 8040.4A
System State	An expression of the various conditions, characterized by quantities or qualities, in which a system can exist.	AVS Order 8000.367A
Validation	Validation is the process of proving that the functions, procedures, controls, and safety standards are correct and the right system is being built. i.e. the requirements are unambiguous, correct, complete, and verifiable.	
Verification	The process that ensures that the system requirements have been met by the design solution and the system is ready to be used in the operational environment for which it is intended.	

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APPENDIX C—ACRONYMS

AAQG	Americas Aerospace Quality Group
AC	Advisory Circular
ACO	Aircraft Certification Office
ACPRR	Aircraft Certification Process Review and Reform
AD	Airworthiness Directive
ADO	Agent Design Organization
AEE	Office of Environment and Energy
AEG	Aircraft Evaluation Group
AFS	Flight Standards Service
AIA	Aerospace Industries Association
AIR	Aircraft Certification Service
ANAC	National Civil Aviation Agency of Brazil
AO	Accredited Organization
APO–300	Office of Aviation Policy and Plans, Economic Analysis Division
ARC	Aviation Rulemaking Committee
ASA	Aviation Suppliers Association
ASE	Oversight Team of Engineers
ASI	Aviation Safety Inspector
ASTM	ASTM International
ATC	Air Traffic Control
AVS	FAA Office of Aviation Safety
BTS	Bureau of Transportation Statistics
CAA	Civil Aviation Authority (of another country)
CAAC	Civil Aviation Administration of China

CAP	Compliance Assurance Procedure
CAR	Civil Aviation Regulation
CAS	Compliance Assurance System
C.A.S.E.	Coordinating Agency for Supplier Evaluation
CBA	Cost Benefit Analysis
CBO	Compliance Based Oversight
CCS	Compliance Certification System
CDO	Certified Design Organization
CFR	Code of Federal Regulations
CMIS	Certificate Management Information System
CONOPS	Concept of Operations
COS	Continued Operational Safety
D&M	Design and Manufacturing
DAH	Design Approval Holder
DAR	Designated Airworthiness Representative
DAS	Designated Alteration Station
DDP	Declaration of Design and Performance
DER	Designated Engineering Representative
DMIR	Designated Manufacturing Inspection Representative
DMS	Design Management System
DO	Design Organization
DOA	Design Organization Approval
DPE	Designated Pilot Examiner
DPO	Design Production Organization
EASA	European Aviation Safety Agency

ELOS	Equivalent Level of Safety
EPA	Environmental Protection Agency
ETOPS	Extended Operations
FAA	Federal Aviation Administration
FOEB	Flight Operations Evaluations Board
FSB	Flight Standardization Board
FSDO	Flight Standards District Office
GAO	General Accountability Office
IAQG	International Aerospace Quality Group
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
IEEE	Institute of Electrical and Electronics Engineers
ISO	International Standards Organization
LOPI	Level of Project Involvement
MIDO	Manufacturing Inspection District Office
MMEL	Master Minimum Equipment List
MOC	Memorandum of Cooperation
MRA	Maintenance, Repair, and Alteration
MRB	Maintenance Review Board
MSAD	Monitor Safety/Analyze Data
MSG	Maintenance Steering Group
NATCA	National Air Traffic Controllers Association
NPRM	Notice of Proposed Rulemaking
OCS	Organization Control System
ODA	Organization Designation Authorization

ODAR Organizational Designated Airworthiness Representative

OIG Office of Inspector General

OMB Office of Management and Budget

OMT Organizational Management Team

PAH Production Approval Holder

PBO Performance-Based Oversight

PI Principal Inspector

PMA Parts Manufacturer Approval

PNL Project Notification Letter

POC Point of Contact

QMS Quality Management System

QSA Quality System Audit

R&D Research and Development

RBRT Risk-based Resource Targeting

RPM Revenue Passenger Miles

RTCA Radio Technical Commission for Aeronautics

RTM Revenue Ton Miles

SA Supplier Audit

SAE Society of Automotive Engineers

SEMP Systems Engineering Management Plan

SFAR Special Federal Aviation Regulation

SM ICG Safety Management International Collaboration Group

SMM Safety Management Manual

SMS Safety Management System

SRM Safety Risk Management

SSP	Specialty Service Providers
STC	Supplemental Type Certificate
TC	Type Certificate
TCCA	Transport Canada Civil Aviation
TSO	Technical Standard Order
TSOA	Technical Standard Order Authorization
UAS	Unmanned Aircraft Systems
UM	Unit Member
U.S.C.	United States Code
USITC	U.S. International Trade Commission

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APPENDIX D—PART 21/SMS ARC CHARTER

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Aviation Rulemaking Committee Charter

Effective Date:
10/5/2012

SUBJ: 14 CFR 21 / Safety Management Systems Aviation Rulemaking Committee

1. **PURPOSE.** This Charter creates the Aviation Rulemaking Committee (ARC) for Part 21 / Safety Management Systems (SMS) according to the Administrator's authority under Title 49 of the United States Code (49 U.S.C.) 106(p)(5). This charter also outlines the committee's organization, responsibilities, and tasks.

2. **BACKGROUND.**

   On May 22, 2012, the Aircraft Certification Process Review and Reform ARC submitted a report to the FAA recommending that we undertake a review to update part 21 certification procedures to reflect a systems safety approach to product certification processes and oversight of design organizations. Design organizations must have full responsibility and accountability through the establishment of regulatory requirements for minimum qualification, performance, and management systems.

   Consistent with FAA Order VS 8000.367, and the International Civil Aviation Organization (ICAO) Annex 8, the Aircraft Certification Service (AIR) has been actively developing and implementing an internal and external SMS. The initial focus was primarily on developing an internal set of processes, tools, and methodologies that facilitate the transition into the future state. AIR began that effort in 2005 and has made progress in defining key processes and tools. Later, with support from industry participants, the activities expanded to include development of standards for design and manufacturing organizations. Through implementation of pilot SMS projects with certain companies, the FAA is collecting information that will help define the scope of the SMS for Design Approval Holders (DAHs), validate certain best practices, and expand the knowledge base within the workforce and industry with respect to the essential elements of a robust SMS for manufacturers.

   SMS requires a proactive approach to discovering and addressing hazards before they exhibit safety consequences. SMS also includes processes that seek to identify potential organizational breakdowns and necessary process improvements which allow management to address a safety issue before a noncompliant or unsafe condition results. SMS is not a substitute for compliance with FAA regulations or FAA oversight activities.

3. **OBJECTIVES AND TASKS OF THE ARC.** AIR wants to evaluate certain improvements to the effectiveness and efficiency of existing "certification procedures for products and parts," along with incorporating SMS in the design and manufacturing environment. This includes considering the effects of certain changes to the existing regulations, such as applicant qualifications, hazard (or safety) reporting, compliance assurance, and continued operation safety assurance systems for

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all DAHs. The intent is to facilitate shifting towards a systems approach for DAHs that is similar to that used for production approval holder requirements, which involves a clear understanding of roles, responsibilities, and privileges. As part of this evaluation, we want to determine the best way industry and the FAA can effectively fulfill their respective compliance and safety responsibilities.

The ARC will provide a forum for the U.S. aviation community to discuss and provide recommendations to the FAA. The committee is expected to provide general information and guidance regarding proposed changes to part 21 and the AVS SMS program as it relates to design and manufacturing certificate and approval holders.

a. The ARC will provide the FAA recommendations, which may include proposals for rulemaking, suggested processes, policies and guidance, and any further action it determines the agency should contemplate for part 21 to align with the SMS requirements documented in proposed 14 CFR part 5, which is the central component of the NPRM entitled *Safety Management Systems for Part 121 Certificate Holders* [Docket No. FAA–2009–0671; Notice No. 10–15].

b. The ARC, serving in an advisory capacity, is expected to present and discuss whatever input, guidance, and recommendations its members consider critical to the FAA's ultimate disposition, development, and implementation of proposed regulatory requirements and related guidance and policy as necessary to the future direction for part 21 to include applicant pre-qualifications, approval holder recognition, and SMS considerations.

c. The ARC will also consider proposed revisions to clarify and update engineering/design-oriented regulatory requirements to part 21. In support of design certification and continued airworthiness, the evaluation should include improvements in the areas of:

   1. Application process
   2. Applicant qualifications
   3. Standardized certification criteria
   4. Identifying design approval holder responsibilities and privileges
   5. Clarifying continued airworthiness requirements
   6. Clarifying design approvals needing Instructions for Continued Airworthiness
   7. Clarifying TSO design approval processes
   8. Process definition for determining eligibility of U.S. surplus military aircraft in the restricted category

   This proposal additionally corrects regulatory language, implements editorial changes for clarification, and standardizes regulatory language to reflect the global aviation environment. While this information will be shared with the ARC, responses to "clean-up" proposals are not required as part of the deliverables.

d. Proposed part 5 and International Civil Aviation Organization (ICAO) Annex 8 and Annex 19 (draft) serve as the foundation for the ARC's consideration regarding how the FAA will address its responsibilities for developing and implementing SMS

requirements and the management and oversight of its regulated product/service providers. The ARC must respect the framework outlined in proposed part 5 and the ICAO Annexes when it provides the FAA recommendations with respect to application of SMS. However, the FAA will consider proposed changes to part 5 as deemed necessary from a design and manufacturing perspective.

Recommendation Report. The ARC shall make recommendations and submit a report addressing the following:

a. Improvements, which may include proposals for rulemaking, processes, policies and guidance for 14 CFR part 21 that reflect a systems approach for safety. This will promote an effective and efficient certification process, which includes considering the effects of certain changes to the existing regulations, such as:
   1. Minimum qualifications and organizational requirements for design approval applicants and holders including responsibilities and privileges
   2. SMS for design approval holders
   3. Compliance assurance
   4. Continued operational safety assurance
   5. Hazard reporting

b. Cost and benefit and other impact information in support of developing the required Regulatory Evaluation(s) and Regulatory Flexibility economic analysis for applying any proposed changes to 14 CFR part 21 FAA certificate and approval holders. Cost and benefit analysis should include information obtained through the AIR SMS pilot project and should identify the specific areas of impact and present this information in quantitative terms to the extent possible.

c. Part 21 design and production approval holder organizations to which the proposed SMS requirements should apply, taking into consideration cost and benefit information as well as public comments to the part 5 NPRM and the SMS-ARC *Design and Manufacturing Working Group Report – High-Level Recommendations for SMS Requirements* dated March 12, 2010.

d. Changes to the FAA oversight methodology based on any recommendations for changes to part 21 that takes into account existing FAA processes and oversight and delegation programs for design and manufacturing related certificates and approvals and authorizations.

e. Definitions and processes to be included in advisory, policy, and procedures material for addressing safety risk management responsibilities within a design and/or manufacturing organization. These definitions and processes should include:

   1. An operational definition of a "hazard" throughout the life cycle of a product in safety risk management.
   2. Definition of the term "organization" with respect to design and production approval holders to identify the limits of applicability of proposed SMS requirements, in

consideration of the broad range of organizational structures and activities within modern design and/or manufacturing organizations.

3. Hazard identification procedures.
4. Processes for the determination of acceptable safety risk.
5. Procedures to be included in advisory, policy, and procedures material for addressing safety assurance responsibilities within a design and/or manufacturing organization, including specific recommendations regarding "employee reporting systems".

The Director of Aircraft Certification Service (AIR-1) may propose additional tasks as necessary in support of a potential part 21 rulemaking action. The ARC may also request that AIR-1 add other tasks deemed relevant to the success of this initiative.

4. ARC PROCEDURES

a. The ARC advises and provides written recommendations to AIR-1 and acts solely in an advisory capacity. Once the ARC recommendations are delivered to AIR-1, it is within his/her discretion to determine when and how the report of the ARC is released to the public.
b. The ARC may propose additional tasks as necessary to AIR-1 for approval.
c. The ARC will submit a report detailing recommendations within 18 months from the effective date of this charter. The chair of the ARC sends the recommendation report to both AIR-1 and the Director of the Office of Rulemaking.
d. The ARC may reconvene following the submission of its recommendations for the purposes of providing advice and assistance to the FAA, at the discretion of AIR-1, provided the charter is still in effect.

5. ARC ORGANIZATION, MEMBERSHIP, AND ADMINISTRATION. The FAA will establish a committee of members of the aviation community. Members will be selected based on their familiarity with 14 CFR part 21, Safety Management Systems analysis, and regulatory compliance. Membership will be balanced in viewpoints, interests, and knowledge of the committee's objectives and scope. ARC membership is limited to promote discussion. Active participation and commitment by members will be essential for achieving the ARC's objectives. Attendance is essential for continued membership on the committee. When necessary, the ARC may set up specialized work groups that include at least one ARC member and invited subject matter experts from industry and government.

This ARC will consist of members from U.S. and foreign industry including representatives from designers and manufacturers holding part 21 certificates and approvals and other private sector aviation industry associations and advocacy groups. Invited foreign authorities and International Civil Aviation Organization (ICAO) representatives provide a valuable perspective from the global aviation community. These representatives are encouraged to fully participate in committee discussions; however, their participation does not include voting privileges on committee issues. The FAA's participation and support for the ARC will come from all affected lines-of-business.

a. The ARC sponsor is AIR-1 who:
   1. Appoints members or organizations to the ARC, at the Director's sole discretion;

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2. Selects the industry chair(s) from the ARC membership;
3. Selects the FAA's designated federal official for the ARC;
4. Receives all ARC recommendations and reports; and
5. Provides administrative support for the ARC through the Safety Management Design and Analysis Branch (AIR-150).

b. Once appointed, the industry chair(s) will:
1. Coordinate required committee and subcommittee (if any) meetings in order to meet the ARC's objectives and timelines;
2. Provide notification to all ARC members of the time and place for each meeting;
3. Ensure meeting agendas are established and provided to the committee members in a timely manner;
4. Keep meeting minutes;
5. Perform other responsibilities as required to ensure the ARC's objectives are met; and
6. Provide status updates in writing to AIR-1 at 6 months and 12 months from the effective date of this charter.

6. **COST AND COMPENSATION.** The estimated operating cost (including *pro rata* share of salaries of FAA employees) to the Federal Government for this ARC is approximately $400,000 annually. All travel costs for government employees will be the responsibility of the government employee's organization. Non-government representatives serve without government compensation and bear all costs related to their participation on the committee.

7. **PUBLIC PARTICIPATION.** ARC meetings are not open to the public. Persons or organizations outside of the ARC who wish to attend a meeting must get approval in advance of the meeting from a committee co-chairperson or designated federal official.

8. **AVAILABILITY OF RECORDS.** Consistent with the Freedom of Information Act, Title 5, U.S.C., section 522, records, reports, agendas, working papers, and other documents that are made available to or prepared for or by the committee will be available for public inspection and copying at the FAA's Office of the Director, Aircraft Certification Service (AIR-1), 800 Independence Avenue SW, Washington, DC 20591. Fees will be charged for information furnished to the public according to the fee schedule published in Title 49 of the Code of Federal Regulations, part 7.

   You can find this charter on the FAA Web Site at: http://www.faa.gov/about/committees/rulemaking/.

9. **DISTRIBUTION.** This order is distributed to director-level management in the Office of the Associate Administrator for Aviation Safety, the Office of Aviation Policy and Plans, the Office of Rulemaking, and the director- and division-level management in the Aircraft Certification Service.

10. **EFFECTIVE DATE AND DURATION.** This committee is effective upon issuance of this charter. The committee shall remain in existence for 2 years, unless sooner terminated or

extended by the Administrator.

The effective date of this charter is October 5, 2012.

Michael P. Huerta
Acting Administrator

APPENDIX E—KEY CONSIDERATIONS SUPPORTING ARC RECOMMENDATIONS

This appendix provides a comprehensive summary of all recommendations from the ARC report that support the four main recommendations and can be used as reference material. Each supporting recommendation has been grouped under the appropriate core recommendation as a key consideration. The purpose of this appendix is to provide any future rulemaking team a comprehensive overview of the key considerations the ARC feels should be taken into consideration for each of these areas if a rulemaking effort takes place.

RECOMMENDATION 1: SYSTEMS APPROACH TO CERTIFICATION—KEY CONSIDERATIONS

The systems approach to certification will be separated into three subsections that must be satisfied to move from the current state to a DO:

a. Promote accountability framework and enhanced applicant showing.

b. Establish minimum requirements for design approval applicant/holder.

c. Establish requirements for voluntary certificated DOs.

1a. PROMOTE ACCOUNTABILITY FRAMEWORK AND ENHANCED APPLICANT SHOWING

Key Considerations:

1. DAH Procedures Manual: The ARC recommends further discussion on the necessary level of detail to include in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual. (Refer to section 10.2.1.2.)
2. Accountability Framework: The ARC recommends the FAA consider the DO model's impact on the existing accountability framework, particularly regarding how a design approval applicant, DAH, and DO are related. (Refer to section 10.2.3.)

1b. ESTABLISH MINIMUM REQUIREMENTS FOR DESIGN APPROVAL APPLICANT/HOLDER

Key Considerations:

1. Establish minimum standards for design approval applicant/holder qualification and obligations to ensure applicants fully understand the type certification process and their roles and responsibilities.

1c. ESTABLISH REQUIREMENTS FOR VOLUNTARY CERTIFICATED DOs

Key Considerations:

1. Proposed Regulations, Preamble Language, and Guidance Material: The ARC recommends that proposed regulations, preamble language, and guidance material should be discussed as a follow-on activity to mature the information provided in this report. (Refer to section 6.)
2. Supplier Oversight "Pooling": The ARC recommends DO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities in a manner similar to what is currently done by manufacturing facilities and airlines under the

Coordinating Agency for Supplier Evaluation (C.A.S.E.), http://www.caseinc.org/. (Refer to section 6.5.1.)

3. Specialty Service Providers (SSP): The ARC recommends the FAA give priority to developing a means for recognizing an accreditation system for SSPs (for example, Nadcap or similar). (Refer to section 6.5.3.)

4. Establish requirements for the issuance and oversight of certificated DOs that includes the necessary compliance assurance, safety management, and controls to make all compliance determinations through applicant showing and verification processes. Through FAA certificate management oversight and direct project involvement in defined risk-based areas, the FAA may rely on the DO compliance determinations to make its finding for the issuance of a design approval. This report builds on the recommendations submitted to the FAA by the CDO ARC in May 2008.

   However, the ARC had significant concerns about attempting to set a specific date when a certified DO would be required. It was felt that this could cause both industry and the FAA to have to push other things aside just to satisfy the DO schedule requirements, affecting industry's ability to deliver its products in a timely manner and the FAA's ability to support that activity. After much deliberation, it was determined that a phased approach to the DO implementation would be more feasible than a single-step process.

   The Part 21/SMS ARC recommends a building block approach to implementing DO, which includes establishing a clear accountability framework, particularly regarding how a design approval applicant, DAH, and DO are related; transitioning the FAA's oversight of design activities to a centralized systematic model; optimizing full use of ODA authorization; and implementing new organizational and SMS requirements. (Refer to section 10.)

   Summary of the Building Block Approach to a Design Organization: The phased approach is described as a building block approach that would let a company build pieces of the DO requirements on a more flexible schedule. This building block approach would allow the FAA and industry to immediately begin taking steps to improve processes and make the changes necessary for DO implementation. These steps shown in figure E–1 below will enable a much more manageable transition to DO in the future.

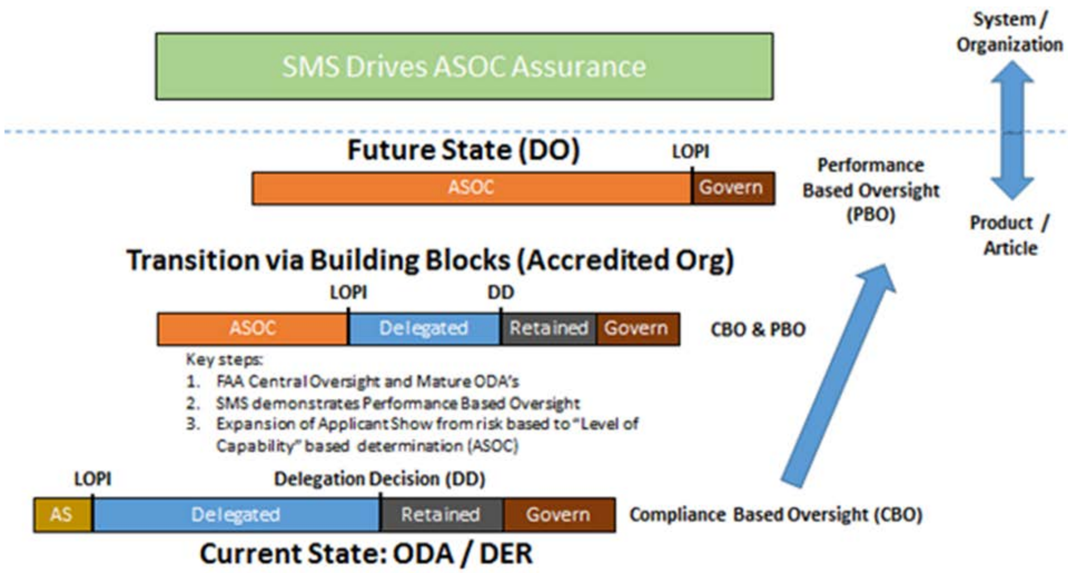

Figure E–1. Building Block Approach to DO

With successful implementation of these building blocks, the ARC supports a future rulemaking to consider mandatory implementation of DO. (Refer to section 10.2.1.3.)

5. Business Structure Variation: The ARC recommends further development of how business structure variations will be accommodated under the DO framework. (Refer to section 6.6.)

6. Form of the DO Certificate: The ARC recommends a certificate structure similar in nature to the EASA DOA certificate and terms of approval. (Refer to section 6.7.3.)

7. DA Transfer: The ARC recommends non-DO design approval transfer requirements be provided by a separate follow-on activity to the ARC. (Refer to section 6.7.4.)

8. Maintenance Aspects of ICA: The ARC recommends the DO determine maintenance technical material aspects of ICA requirements. (Refer to section 6.7.8.)

9. Environmental Compliance Determinations: The ARC recommends the FAA propose to the EPA that the process-based approach to compliance, as established by DO program principles (which is far more robust than the normal delegation process) is sufficient to ensure compliance with the environmental aspects of 14 CFR parts 34 and 36. (Refer to section 6.7.9.)

10. Form for DO Transmittal of Approved Data: DO-issued service bulletins should be a means for DOs to provide "approved data" for general use. When issued, service bulletins constitute a change in type design by the holder and convey the necessary "approved data" to implement the change by owner/operators under part 43. A new or revised form is also needed for domestic and international recognition of "approved data" created under the DO concept. The ARC recommends the form be similar to the FAA Forms 8110–3 and 8100–9 currently used to approve data in the FAA's delegation system. (Refer to section 6.8.1.)

11. DO Is a Choice: The ARC recommends DO applicability thresholds for any design approval applicants or DAHs should be optional. (Refer to section 10.)

Recommendation 2: Safety Management System—Key Considerations

In addition to the Safety Management Systems Requirements section in the report (section 4.2), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

Key Considerations:

1. The ARC evaluated the proposed § 5.27 and determined it is not necessary for D&M organizations. Therefore, the ARC recommends the FAA modify part 21 to make part 5, excluding § 5.27, the SMS requirements for organizations meeting the SMS applicability threshold. The ARC will continue to develop guidance material for D&M implementation of part 5 and appreciates the FAA's willingness to engage industry in this regard. (Refer to section 5.1.1.)
2. Establish a requirement for implementing SMS consistent with the proposed part 5 for design and production approval organizations. The ARC recommends this new requirement apply to organizations that design or manufacture type-certificated products (under a TC or production certificate) and those that design or manufacture articles (under a TSO or PMA) or make changes to products (under an STC) that could directly prevent continued safe flight and landing if they fail. (Refer to section 5.1.2.)
3. Policy and Guidance Material: The ARC recommends the FAA and industry develop SMS guidance for organizations that: design or manufacture products (that is, aircraft, engines, or propellers); design or manufacture articles (TSO, PMA) whose failure could directly prevent continued safe flight and landing; or make design changes to a product through an STC, failure of which could directly prevent continued safe flight and landing. The ARC developed SMS regulatory material and a basis for preamble, policy, and guidance material, as provided in this report; however, it determined more work was necessary to produce supporting guidance material. The ARC recommends the SMS Working Group continue to develop supporting guidance material with a goal of completing the task by Spring 2015 by providing an addendum to this report through the ARC. (Refer to section 5.3.)
4. SMS Concept of Operations (CONOPS): The ARC has developed a CONOPS describing the intent of the part 5 SMS framework (safety policy, SRM, safety assurance, and safety promotion) for D&M organizations as it applies to each life cycle phase (design and certification, production and airworthiness certification, and continued airworthiness) of a product or article. The ARC recommends the CONOPS form the basis for the development of preamble, policy, and guidance material for D&M organizations. The ARC also recommends that, as described in the CONOPS, existing processes and procedures should be considered as meeting the intent of part 5. (Refer to section 5.3.)

5. Availability of Data for SRM: The ARC recommends the FAA develop an approach to make fleet data already provided to the FAA (hours, flights, reported failures, malfunctions, and defects and service difficulty reports) readily available to D&M organizations, in support of executing SRM (§ 5.71). (Refer to section 5.3.)
6. The ARC recommends implementing the changes to §§ 21.3 and 21.4 identified in the table found in section 8.2.2 of the ARC report. (Refer to section 8.2.2.)
7. The ARC recommends developing or revising the following guidance materials to support the recommended rule changes and facilitate FAA oversight: (1) criteria for consistent understanding of the language in § 21.3(d) "has resulted in or may result in a finding of an unsafe condition by the Administrator"; (2) acceptable compliance demonstration and verification regarding the safety analysis referenced in § 21.3(d); (3) changes to AC 21–9B, Manufacturers Reporting of Failure, Malfunctions or Defects, to include the recommended guidance for §§ 21.3(d) and 21.3(e). (Refer to section 8.3.2.)
8. The ARC recommends developing proposed regulation changes and guidance or process proposals to address safety risk that is acceptable in the short term while long-term safety risk control/mitigation plans are developed and implemented. (Refer to section 8.2.5.2.)

Recommendation 3: Evolution of Oversight—Key Considerations

In addition to the Evolution of Oversight section in the report (section 4.3), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

Key Considerations:

1. Performance-Based Oversight: The ARC developed proposed practices for FAA oversight that is correlated with recommended D&M organizational changes. This enables a shift to performance-based oversight where the FAA can effectively allocate resources based on D&M system risk management performance, and moves the FAA from a total dependence on discrete compliance findings, audits, and inspections. The ARC recommends chartering a dedicated effort with the FAA and industry to develop guidance for determining performance indicators that are mutually acceptable before implementation of the new oversight model. (Refer to section 3.3.)
2. Single Centralized Oversight Organization: The ARC recommends a single centralized oversight presence and systemic (process-based) approach for initial and ongoing assessments. The three key oversight areas are: (1) Organizational—transition from traditional show/find compliance to organizational PBO model; (2) Product and Articles—transition from the FAA's traditional role of direct project involvement to a LOPI approach focused on performing governmental functions; (3) Post-Certification (COS)—transition from traditional reactionary approach to a systemic (process-based) surveillance model discussed in more detail later in this section.

3. The assessment methodology will cover a standardized approach to quality, design, and safety. In support of this recommendation, the ARC's Oversight Working Group has provided a capability-based assessment tool, PROs/CONs analysis of oversight management options, and supporting rationale for the recommendation. FAA oversight teams would report to a centralized FAA organization. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data that will drive the risk-based modeling controls, and allow for a highly trained staff in system surveillance, skill management, and a single source for corrective actions. (Refer to section 10.1.4.3.)
4. The recommended three transitional steps to the centralized oversight organization are—

   1. Proof of Concept—Pre Implementation: Ensure through proof of concept plans that the requirements proposed by the ARC are practical, effective, and efficient. Determine if the transition from "mature ODA" to DO has benefits to the FAA and industry.

   2. FAA Transition Plan Transition Principle: The FAA should not release a final rule before it has demonstrated the necessary cultural shift to perform system oversight. To achieve a cultural shift, policy and organizational changes may be required.

   3. Industry Transition Plan: The organization must establish the systems required of an approved organization while still working as a non-certificated applicant or a delegated organization. Applicants working toward becoming a DO demonstrate compliance to those requirements on an "as ready" basis. (Refer to section 10.1.5.2.)

Recommendation 4: TSO Modernization and Part 21 Miscellaneous Cleanup

In addition to the Part 21 Miscellaneous Cleanup and TSO Modernization section in the report (section 4.4), the following are key considerations that the ARC feels should be taken into consideration if a rulemaking effort takes place.

TSO Modernization

Key Considerations:

The ARC recommends the following changes to modernize the TSO requirements:

1. Allow TSO organizations to issue their own TSOAs, relative to scalable privileges for particular types of TSO standards. (Alternate approaches via a certified TSO organization or expansion of TSO ODA functions.) (Refer to section 9.2.1.)
2. Clarify the types of data that can be approved under a TSOA (that is, type design of the article and declared performance of the article including non-TSO functions and incomplete TSO), and expectations for acceptance of approved TSO data for installation. (Require and approve DDP via revision to § 21.601(b)(2) and proposed new § 21.603(a)(3).) (Refer to section 9.2.1.)
3. Proposed new §§ 21.603(a)(3) and 21.619(d), Design changes, for subsequent design changes to declare non-TSO functions. (Additional guidance including a "decision table" to assist in differentiating between TSO supporting features and integrated non-TSO functions.) (Refer to section 9.2.1.)

4. Rule revision to remove the term “model number” from TSO rules and replace it with a requirement for a “unique identifier.” (Revision to §§ 21.603(b) and 21.619 for subsequent design changes.) (Refer to section 9.2.1.)
5. The ARC recommends changing part 21 to establish the effective TSO revision level at the beginning of the project, not at the end. (Revision to § 21.603(a).) (Refer to section 9.2.1.)
6. The ARC recommends a process for the TSO holder to continue marking TSO articles following a determination of “a design discrepancy that does not result in an unsafe condition.” (Revision of § 45.10(b) and proposed new § 21.616(i), Responsibility of the holder.) (Refer to section 9.2.1.)
7. The ARC recommends maintaining the privilege for TSO holders to make minor or insignificant (sub-minor) changes to articles without further approval. (Refer to section 9.1.3.)
8. The ARC recommends clarifying the TSO application data, manufacturer data and furnished data requirements. (Refer to the TSO Subteam Report, included as appendix H to this report). (Refer to section 9.1.3.)
9. The ARC recommends developing expanded guidance to promote the uniform definition and treatment of integrated non-TSO functions by applicants, installation developers, and the FAA. (Refer to the TSO Subteam Report, included as appendix H to this report). (Refer to section 9.1.3.)
10. The ARC recommends an applicant should submit to the Administrator a signed undertaking to carry out the responsibilities as a DAH before issuance of a design approval. (Refer to section 9.1.3.)

MISCELLANEOUS PART 21 CLEANUP

Key Considerations:

The ARC recommends—

1. AC 20–62, Eligibility, Quality, and Identification of Aeronautical Replacement Parts, paragraph 6, Discussion, be amended to include an explanation of the scope of §§ 21.8 and 21.9. (Refer to section 9.1.1.3.)
2. Amending § 21.9(a) to add paragraph (a)(7), which reads: “Produced in any other manner approved by the FAA.” (Refer to section 9.1.1.3.)
3. The removal of § 21.335(b) from 14 CFR. (Refer to section 9.1.2.)

APPENDIX F—DESIGN ORGANIZATION WORKING GROUP REPORT

Design Organization
Concept Report

by

Design Organization Working Group
of the
Part 21/SMS Aviation Rulemaking Committee

7 February 2014

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TABLE OF CONTENTS

I. INTRODUCTION

This report provides concepts for a Design Organization (DO) developed by the Design Organization Working Group (WG) of the Part 21 / Safety Management System (SMS) Aviation Rulemaking Committee (ARC).

The intent of this report is to define and address the details necessary for the Federal Aviation Administration (FAA) to recognize a DO that meets organizational and system requirements sufficient to ensure that a DO is capable of making compliance statements upon which the FAA may rely. Specifically the DO framework, minimum requirements relationships, limitations, and privileges are addressed by this report.

This conceptual report establishes a framework and captures the intent of a DO. In many instances, the concepts put forth in this report are either identical or build upon the May 2008 Certified Design Organization (CDO) ARC report. The DO WG considered the CDO ARC report extensively and in many cases quoted language directly in this report without explicit citation.

I.A. Summary of Recommendations

The WG provides the following recommendations in response to the WG charter and associated taskings.

- **Proposed Regulations, Preamble Language, and Guidance Material:** The DO WG recommends that proposed regulations, preamble language, and guidance material should be discussed as a follow-on activity to mature the information provided in this report. See II.B – DO WG Report
- **Accountability Framework:** The WG recommends the FAA consider the DO model impact on the existing Accountability Framework, particularly with respect to how an design approval (DA) applicant, design approval holder (DAH) and DO are related. See III.A – Accountability Considerations
- **DAH responsibility statement:** The WG recommends that a separate, yet to be tasked WG, consider whether an applicant should submit to the Administrator a signed undertaking to carry out the responsibilities as a DAH prior to issuance of a DA. See III.B (1) – DO Model and Framework
- **DO is a choice:** Industry's recommendation is that there be <u>no mandatory</u> thresholds for any DA applicants or DAHs. All DOs would be optional. See IV.B (3) – Eligibility and Thresholds
- **Making the Failure Modes Effects (FME) Assessment Transparent:** The DO WG proposes to use the current regulations and guidance wherever possible, and

recommends encouraging the various directorates to work with industry to develop regulations and guidance where it is currently absent or unclear. See IV.B.(3) – Secondary “Risk Based” Threshold

- **Areas Without Existing FME Assessment Regulation/Guidance:** The DO WG recommends the various directorates work with industry to develop regulations and guidance for any areas where existing FME Assessment is absent, or unclear. See IV.B.(3) – Secondary “Risk Based” Threshold
- **Other disciplines and Product Level Safety Assessments:** The WG recommends that the secondary threshold be limited to Product Level Safety Risk Assessments. Any “other” secondary threshold assessment should be set using the criteria of will the potential failure mode “affect the continued safe flight and landing of the aircraft.” See IV.B.(3) – Secondary “Risk Based” Threshold
- **Major/Minor Determinations:** While Major/Minor determinations are out of scope of this WG, the DO WG recommends that the FAA and industry drive towards a consistent, easily understood, safety risk-based determination of Major/Minor change. See IV.B.(3) – Other Threshold Models Discussed
- **Significant Change:** While significant change determinations are out of scope of this WG, the DO WG recommends that the FAA and industry drive towards a consistent, easily understood, safety risk based determination of significant change. See IV.B.(3) – Other Threshold Models Discussed Paragraph
- **DO Procedures Manual:** The WG recommends further discussion on the necessary level of detail for inclusion in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual. See IV.C.(1) – DO and Organization Control System (OCS)
- **SMS as a requirement of DO:** The WG recommends further discussion by the ARC on the subject of SMS being directly tied to DOs. See IV.C.(4) – Safety Management System
- **Supplier Oversight “Pooling”:** The DO WG recommends that DO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities, in a manner similar to what is currently done by manufacturing facilities. See IV.D.(1) – General Requirements
- **Speciality Service Providers (SSP):** The DO WG recommends that the FAA give priority to developing a means for recognizing an accreditation system for SSPs. See IV.D.(3) – The Need for Speciality Service Providers
- **Business Structure Variation:** The DO WG recommends further development of how business structures variations will be accommodated under the DO framework. See IV.D.(6) – Business Structure Variation
- **Form of the DO Certificate:** The DO WG recommends a certificate structure similar in nature to the European Aviation Safety Agency (EASA) Design Organization Approval (DOA) Certificate and Terms of Approval. See IV.E.(3) – Form of DO Certificate

- **DA Transfer:** The WG recommends non-DO DA transfer requirements be provided by a separate WG to the ARC. See IV.E.(4) – Transfer of Design Approvals under DO
- **Maintenance Aspects of Instructions for Continued Airworthiness (ICA):** The WG recommends that the maintenance aspects of ICA requirements also be determined by the DO. See IV.E.(8) – Flight Standards Functions
- **Environmental Compliance Determinations:** The WG recommends that the FAA propose to the Environmental Protection Agency (EPA) that the process-based approach to compliance, as established by DO program principles, is far more robust than the normal delegation process and is sufficient to ensure compliance with the environmental aspects of the 14 Code of Federal Regulations (CFR) Parts 34 and 36. See IV.E.(9) – Noise, Fuel Venting and Exhaust Emissions
- **Form for DO Transmittal of Approved Data:** DO-issued service bulletins should be a means for DOs to provide "approved data" for general use. When issued, service bulletins constitute a change in type design by the holder and convey the necessary "approved data" to implement the change by owner/operators under part 43. A new or revised form is also needed for domestic and international recognition of "approved data" created under the DO concept. The DO WG recommends that the form be similar to the FAA Forms 8110-3 and 8100-9 that are currently used to approve data in the FAA's delegation system. See IV.F.(1) - Service Bulletins and a Standardized form for DO Transmittal of Approved Data

II. BACKGROUND

II.A. Chartered Design Organization Working Group

On October 5, 2012, the FAA Administrator chartered an Aviation Rulemaking Committee (ARC) for Part 21/SMS. The ARC was tasked to recommend improvements to the effectiveness and efficiency of existing certification procedures for products and parts along with incorporating SMS in the design and manufacturing environments. The ARC was tasked with making recommendations, including proposals for rulemaking, suggested processes, policies, guidance, and any other actions the agency should take in support of its goal.

In addressing its charter, the ARC further chartered the DO WG on March 17, 2013 to assist it in developing details associated with FAA recognition of DOs in Part 21. The WG was tasked to define and address the details necessary for the FAA to recognize a DO that meets organizational and system requirements sufficient to ensure that a DO is capable of making compliance statements upon which the FAA may rely. The WG presented and discussed in-depth principles, guidance, and recommendations that the members of the committee considered relevant to the implementation of the DO concept.

The DO WG membership is listed in Appendix A. The WG charter is contained in Appendix B.

II.B. DO WG Report

This report represents the consensus position of the WG and its recommendations to the ARC for the development, scope, and operation of a DO from Industry and FAA perspectives. Dissenting opinions expressed by members against specific section concepts or recommendations are also presented within each section. Specifics relevant to SMS and Oversight requirements were assigned to other ARC WGs.

This report is intended to be a thorough presentation of background material to be considered by the ARC in making its recommendations to the FAA regarding the requirements, privileges, and responsibilities of a FAA recognized DO. Taken in its entirety, it constitutes the WG recommendations detailing the guiding principles, concepts, and attributes necessary to prepare regulatory language for the drafting of a Notice of Proposed Rulemaking (NPRM). The WG recommends that proposed regulations, preamble language, and guidance material should be discussed as a follow-on activity to mature the information provided in this report.

A glossary of terms and a list of acronyms used in this report are contained in Appendix C and Appendix D, respectively.

II.C. What is DO?

A DO is a regulatory-recognized organization that meets organizational and system requirements sufficient to ensure that it is capable of making compliance statements upon which the FAA may rely in support of obtaining Design Approvals (DA) under 14 Code of Federal Regulations (CFR) part 21. As such, the DO maintains and follows processes to manage its certification projects, as well as the continued airworthiness of its products.

A DO will include organizations applying for, supporting the application for, or holding Type Certificates (TC), Supplemental Type Certificates (STC), or Parts Manufacturer Approvals (PMA). Further details regarding eligibility are included in section IV.B.(3) of this report.

II.C.(1) DO Enhances Compliance, Efficiency, and Effectiveness

Moving Beyond Delegation. Under the current FAA delegation system, there are several "persons" working together to find compliance with the FAA requirements, be they individuals or delegated organizations. In a typical program, the FAA personnel

- will make some of the findings,
- will delegate some to designees or delegated organizations, and
- by using the FAA's statutory discretionary authority, may choose not to review some demonstrations by the applicant in less-safety-critical areas or where the FAA has confidence in the applicant's compliance with the regulations.

The current process of obtaining a DA places no requirement on the applicant to establish a system of documented processes and procedures to show compliance. As such, the variety in applicant capabilities makes it highly resource-intensive for the FAA to effectively deal with the certification process.

With DO, the design organization operates in accordance with their FAA-approved processes and compliance assurance system (CAS). If a non-compliance is found by the DO or by the FAA, the DO's CAS is subject to review and change, as required by its FAA-approved procedures manual. The DO is also subject to enforcement action, including civil penalty, for not following its approved procedures and for not adhering to the regulatory requirement to present an accurate statement of compliance to the Administrator for approval.

Compliance Assurance System (CAS) Enhances Compliance. Under DO, the establishment and determination of compliant designs will be made through a CAS, with appropriate internal checks and balances to ensure it is functioning properly. The WG envisions that the CAS will be composed of a design management system (DMS) and a compliance certification system (CCS), both of which are defined in greater detail in section IV.C.(3) of this report.

Organizations must have a thorough understanding of the regulatory requirements and what constitutes compliance. They must incorporate design and quality systems so that compliance is designed into the product along the path toward certification. When this occurs, every step along the path of product design and development is a step along the path toward compliance, and is not dependent on the FAA or its designees to make the compliance determination.

This system will be required under DO in order to provide a high degree of regulatory compliance assurance that is shown to be as effective as a skilled independent check. Such a system with appropriate FAA oversight increases assurance that compliance with the requirements has been established by the applicant. The FAA is able to rely on this increased assurance when making its finding for the issuance of the certificate, rather than requiring the FAA's direct involvement in making discrete findings.

Other Systems Also Enhance Compliance. In addition to the CAS, the DO is subject to requirements for a SMS and organization control system (OCS). The systematic approach to the engineering certification process, coupled with SMS and OCS enhances the organization's overall ability to consistently perform the compliance assurance functions, and to identify and correct problems that may arise. The above noted system requirements are addressed within section IV.C of this report.

Enhanced Efficiency and Effectiveness. Industry's product development and certification efficiency is paced, in part, by the FAA under the existing delegation system. Delays like certification plan approval generate additional uncertainty in program schedule and costs. DO provides greater industry control over a product delivery schedule by allowing the FAA to rely on statements of compliance by the DO. This allows the FAA to shift its focus from specific compliance findings to compliance and safety system oversight, providing the opportunity for greater capacity in the system.

Additionally, FAA approval of DO relational or supplier processes allows a DO to utilize supplier or consortium-member contributions to certification projects without data duplication.

II.C.(2) DO is Not "Self–Certification"

Under DO, all determinations of compliance within the DO certificate holder's authority will be made by the DO organization. This does not mean that DO is self-certification by Industry.

The FAA will retain the right to review, audit, and otherwise oversee the operation of the DO while the DO makes compliance determinations, as well as after the FAA has issued design and airworthiness certificates. These functions are being addressed by the Oversight WG.

Approval by the FAA of DO processes, certification bases, Means of Compliance (MOC), and continued oversight during certification activities differentiate DO from any self-certification process. This contrasts with self-certification, wherein the government would issue standards and the applicant would certify that it has met those standards when it introduces its product into service. For example, the National Highway Transportation Safety Administration (NHTSA) establishes safety standards for motor vehicles and there is no government involvement or review until after products are introduced into service.

II.D. The Role of the FAA

The role of the FAA with respect to DOs will be provided by the Oversight WG of the Part 21/SMS ARC. The Oversight WG will address DO assessment, issuance of DO certificates, ongoing DO oversight, and FAA level of project involvement (LOPI)(e.g. certification basis, approved MOC) in DO certification programs.

The DO WG expects that the FAA will be able to rely on the DO-in-good-standing's statement of compliance to issue the DA, without further showing, verification, or involvement (as noted in Section IV.F).

III. ACCOUNTABILITY FRAMEWORK

The foundation for development of the DO program, as with any design certification program developed by the FAA, must be an accountability framework that begins with Congressional statutes and is applied through FAA regulations that establish clear roles and responsibilities for both the FAA and Industry. This framework is largely derived from Title 49 and 14 CFR part 21, and addresses the roles and responsibilities of applicants, certificate holders, and the FAA. This framework includes each stakeholder's role in the certification process and continued airworthiness, as well as FAA's role in developing standards policy and guidance, and its enforcement responsibility.

The foundation of DO is an accountability framework that clearly distinguishes the roles and responsibilities of both Industry and FAA. Applicants lacking certification experience and many companies' use of numerous FAA designees have sometimes resulted in a blurred distinction between the showing of compliance by the Industry and the finding of compliance by the FAA.

The accountability framework principles, based on current regulatory requirements, are summarized below.

FAA promotes aviation safety by:	**Issuing regulations**
	Specifying the certification basis consistent with issued regulations
	Providing guidance regarding acceptable means of compliance
	Overseeing compliance
	Taking enforcement actions as necessary
	Issuing certificates and approvals after FAA finding of compliance
	Mandating corrective action as necessary
Applicants for a design approval have a regulatory obligation to:	**Use means of compliance acceptable to the FAA**
	Show that their designs are compliant
Applicants for a production approval have a regulatory obligation to:	**Establish an inspection system or a quality control system to support production efforts**
	Demonstrate that they can produce products that meet the approved design
Design Approval Holders have an ongoing regulatory obligation to:	**Maintain compliant designs with no unsafe feature**
	Report all known failures, malfunctions, and defects for their products

III.A. Accountability Considerations

In the event of an issue where the FAA is required to take action, the action would be taken based on the obligations of the involved Design Approval Holder (DAH) and DO Certificate holder, as appropriate. For example:

- If an unsafe condition is identified in an approved product and is determined to be the result of a design deficiency by the applicant's DO or by an Agent DO, the FAA would address the product issue with the DAH as is done today (e.g., Airworthiness Directive (AD) issuance, etc.). In addition, the FAA would address the design deficiency with the DO and its systems.

The WG recommends the FAA consider the DO model impact on the existing Accountability Framework, particularly with respect to how a DA applicant, DAH, and DO are related.

IV. DO GUIDING PRINCIPLES AND ATTRIBUTES

This section defines the guiding principles and system attributes that form the foundation of the DO concept. They are the framework for the WG proposal for consideration by the ARC for recommendation to the FAA in developing DO policy. These guiding principles are intertwined and must be viewed in their entirety.

The overarching objectives are:

- Define a regulatory framework by which the FAA can recognize a company's system and process capabilities for DA applicant and holder requirements.
- Leverage the capability of DOs, allowing more efficient use of FAA oversight resources.
- Consistency with the accountability framework.
- Continuous improvement in safety processes and compliance.

IV.A. Overview

The DO principles and attributes are defined in terms of overall objectives, not specific implementation. This is intended to allow flexibility in the creation of systems to address these objectives and to assure that the systems created may be of appropriate scale for the organization involved.

These principles and attributes may be applied to a range of DA applicant and holder scenarios [e.g. a small organization seeking approvals for a limited set of design modifications (defined by STC), an organization with a full line of products, including aircraft, or a small organization that holds a single TC for an aircraft no longer in production but with a significant fleet still in service]. This range of organizational sizes and responsibilities demands that the DO be scaled appropriately to the organization. It is obvious that a "one size fits all" principle is not appropriate for DO. The WG has approached this task by creating a single set of scalable requirements, with the expectation that each requirement would be assessed for effective implementation in the organization.

IV.B. DO Model and Framework

IV.B.(1) DO Model and Framework

The key entities in the proposed DO model are consistent with the Accountability Framework and consist of:

- 14 CFR part 21 DA Applicant - required to meet obligations in part 21 to apply for and obtain the DA (certificate)
- 14 CFR part 21 DAH - required to meet obligations outlined in part 21 as a DA holder
- DO Applicant
- DO Certificate Holder
- FAA – issues DA certificates once a finding of compliance has been made that the product meets the airworthiness standards of the certification basis; certifies DOs and conducts oversight of DOs

The requirements and obligations of DA Applicants and Holders under CFR Part 21 are distinct. DA Applicants seek approval of a design and are required to demonstrate that the design meets the applicable airworthiness standards, whereas DA Holders are obligated to meet “Holder” requirements for reporting, mandatory corrective actions and Continued Operational Safety (COS) activities. This has the potential to lead to different DO requirements and capabilities for different phases of the DO operations.

In considering the implementation of a DO for DA applicants, the WG identified associated potential benefits in the form of a number of desired privileges. These privileges have the advantage of balancing the addition / implementation of DO systems within the organization, as well as providing benefits to the regulator. In the case of DAHs, there are limited associated privileges for an organization and as a result the benefits of a DO from an industry perspective are much more difficult to quantify. The benefits of SMS, as a required element of a DO, have not been sufficiently quantified to be considered by this WG.

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IV.B.(1).(a) DA Applicant DO and DAH DO

The WG deliberated on whether DO should apply to DA applicants, DAHs, or both. This section provides insight into the deliberations prior to the WG reaching a consensus on the threshold applicability approach to be applied to DO (see Section IV.B.(3)). As such, it represents the considerations for DO under a mandated threshold approach.

DO for DA Applicants

The WG considered a risk-based approach to establishing requirements for a DO as a DA applicant. The model for incorporation of the DO with respect to applicants in certification process is proposed as follows:

- An applicant for a DA under 14 CFR part 21 will be required to have a DO if the DA being sought meets specific criteria (thresholds) as outlined in Section IV.B.(3)
- If an applicant does not have a DO at time of application, the applicant may:
  - Make application to the FAA for a DO, or
  - Use an "Agent" DO to act on their behalf [see section IV.D.(5)]
- The DA applicant's DO must meet the requirements and have the systems in place outlined in Section IV.C that assure that any and all statements of compliance may be relied upon by the FAA when the FAA makes its ultimate finding of compliance by the act of issuing the DA certificate.

DO for DAH

As noted previously, the privileges and obligations of a DAH are not the same as a DA Applicant. In addition, there are a number of types of DAHs, many out of production and with no active DAH to support. For example:

- DAH in production, active or non-active applicant – may require DO
- DAH out of production /some fleet, non-active applicant – low risk – No DO required

In particular, for a DAH, there are no associated identifiable DO privileges and the prirmary "benefit" of a DO is related to having an SMS that can support the Part 21 COS obligations, which would be most applicable for organizations that are DAH for products that are "above the threshold" per Section IV.B.(3) and are in production

In considering DO requirements for DA holders, the group reviewed the relationship between a DO and SMS and the need for specific DAH's to have a DO and / or an SMS. As a result, two possible options were identified with associated pros and cons. An outline of each option follows:

Option 1: DO required to apply SMS to DAH

Assumptions:
- SMS is needed for some DAH above threshold / meeting certain criteria
- DO is needed to apply SMS to DAH

Model:
- "Holder" DO will capture DAH above threshold / meeting certain criteria

- DAH DO Threshold / specific criteria is established based on risk and need to have an SMS
  - Potential additional criteria: in production / number of products in service / product risk level
- Holder DO capabilities / functions / privileges are specifically identified vs Applicant DO capabilities / functions / privileges
- Could have a Holder DO with no (embedded) Applicant DO

Rationale:
- DO provides an "operational" certificate to which SMS can be applied as a condition - no other (identified) approach to apply SMS
- Part 21 plus + 21.605-like model is not equivalent to full SMS so may not be adequate as an alternative for DAH that would be "above the threshold" from a risk perspective
- Applicant and Holder capabilities / functions / privileges are not the same and can't assume Applicant DO & SMS can/will apply to Holder aspects.

PROS :
- Having DO makes it easier to make sure SMS aspects are applied to the DAH responsibilities; No need to try to make "21.3 Plus" work for higher risk DAHs
- Makes DAH transfer scenario easier since if DO required as DAH, new DAH should also have DO
- Aligned with other authorities' approach with respect to DO for DAH and SMS (Harmonized) and facilitates bilateral acceptance

CONS:
- Cost / benefit:
  - hard to justify to add DO and SMS to DAH (no quantifiable "benefit" to industry similar to additional Applicant DO privileges and SMS benefits not yet quantified
  - Impacts "value" of DA for transfer / sale
- Threshold:
  - Challenge to establish
  - Not exactly same as applicant – needs to be reviewed
  - Adding additional requirements and complexity to the system / reg to implement
- Could have retro-active effect if not properly implemented

<u>Option 2: DO and / or SMS for a DAH not required</u>

Assumptions:
- DO is not needed to apply SMS to DAH
- "Full" SMS not required and minimum SMS elements could be applied through some other mechanism to a DAH

- Organizations will voluntarily implement DO and SMS

Model:
- Applicant DO will capture large organizations above threshold
- DO = Design Org and there is no need for a design org as a DAH , except to do design changes, where an (applicant) DO would then be invoked.
- Part 21 plus + 21.605-like will be sufficient to cover DAH COS aspects for all types of DAHs
- A DA applicant / holder that is required to have an Applicant DO (which includes SMS) should apply the SMS to the entire DA / part 21 aspects, including holder obligations

Rationale:
- As a DAH: There are no obvious privileges or demonstrated benefits to industry to have an SMS with / without DO
- SMS cost / benefit to industry not established and difficult to justify required changes and additional processes / elements
- SMS cost/ benefit to FAA would need to be further examined and quantified

PROS:
- Cost / benefit easier
  - No need to explain lack of privileges and positive benefit for DO and / or SMS on DAH
  - Retains "value" of DA from Transfer perspective
- Abandoned / surrendered DAs:
  - Makes possibility to have another organization be DAH, since no DO/SMS applied [Maintains "value" of DA]
- No need to define DAH DO Threshold

CONS :
- If SMS is required, challenge to apply SMS since no DO. No approach yet defined to apply SMS to DAH (which is NOT an operational certificate) without a DO
- Could lead to DAH Applicants (> threshold) to immediately transfer DA to avoid DO / SMS
- Relies on reviseed 21.3 / COS regulations to be sufficient to meet intent of SMS requirements *[SMS WG / 21.3+ yet to be tasked WG]*
- Would require concept of Agent DO to be in place to allow non-DO orgs to do (above threshold) design changes
- Possible issue with respect to FAA action and non-compliance to (new) Part 21.3+/COS requirements for SMS aspects / elements linked to (product) DA versus an operational certificate (DO). Would penalize product operators, not DAH
- May not be harmonized with other authority approach and could impede bilateral product acceptance and / or validating authority SMS review of DAH

WG Consensus:
Based on the cost / benefit challenge and the possibility to apply any required SMS elements to DAHs via enhanced Part 21 requirements or alternate approaches, the group recommends Option 2 above as the model, with the additional considerations as follows:

- No specific DO threshold for DAH, as the Applicant DO will capture large organizations above threshold
- A DA applicant / holder that is required to have an Applicant DO (which includes SMS) will be required to apply the SMS to the entire DA / part 21 aspects, including DAH obligations
- Separate, yet to be tasked, WG recommendations for all DAHs will be sufficient to cover DAH COS aspects for all types of DAs (anticipated to include 21.3+, 21.605-like recommendations)
- If a DAH does not have a DO, the Holder may use an "Agent" DO to act on their behalf [see Section IV.D.(5)] for 14 CFR part 21 Applicant or Holder activities

Dissenting Opinion
One industry member of the WG dissented with the decision to recommend Option 2, with the following comments:

- If an SMS is to be applied to DA entities, the greatest benefit, from a safety enhancement perspective, is for DAHs – particularly in the area of COS activities. It seems counter-intuitive to have a DO with an SMS applied to a DA applicant, (based on a successful cost benefit analysis) yet not apply it to certain DAH above the threshold.

- It can not be assumed that all DAH are going to be "compliant" and voluntarily adopt an SMS. Experience of other authorities is, if SMS is deemed necessary, a non-mandatory (or voluntary) approach to SMS is not that effective in capturing all organizations that should have an SMS. Many organizations will pro-actively adopt the SMS and gain the benefits, but many will not.

- There is an assumption that if SMS needs to be mandated, it can be applied to DAHs via another mechanism other than an "operating certificate" such as an DO. However, no other approach has been determined (yet) by other authorities for DA entities. If the SMS is made a condition of being a DAH, and the FAA needs to take some certificate action against the organization due to SMS issues, the certificate action is against the specific design / product and impacts the operators of the product, not just the DAH.

- There is a potential risk of reduced bilateral acceptance of products that have not been designed / certified / produced under an FAA-accepted SMS and the possibility that other authorities will want to review an organization's voluntary

SMS if it is not explicitly FAA "endorsed". It is unlikely that the FAA will utilize FAA resources to "endorse" voluntary SMS. It may be possible to have third party "endorsement" but this may also be subject to lack of acceptance by other authorities and additional cost (to pay third party org)

- The overall industry perception of SMS as a burden due to the difficulty in regulator implementation approach and required cultural changes is not unwarranted, however the benefits of a having an operational and recognized SMS are not well enough understood and are currently underestimated in terms of incident / accident / liability cost avoidance.

IV.B.(2) A DO Certificate is Not a Delegation

A DO certificate is not a delegation as defined under section 44702(d) of Title 49. While it provides functions similar to those available to designees and delegated organizations, the DO's ability to perform these functions is a privilege of its DO certificate as defined under section 44704(e) of Title 49 and not delegation.

While DO is a significant regulatory change, it is only astep in the maturing relationship between the FAA and Industry related to product certification compliance determinations. The FAA is still responsible to evaluate the capability of the DO and its determinations of compliance, to monitor and audit these determinations, and to issue certificates. In addition, the ability of the Administrator to amend, modify, suspend, revoke, or otherwise alter the DO certificate, as specified in sections 44709 and 44711 of Title 49, is not affected in any way.

IV.B.(3) Eligibility and Thresholds

Eligibility

All organizations who meet the minimum requirements (see Section IV.C) are eligible to apply to become a DO. DO does not require a FAA determination of need. Nor does a DO application require previous FAA approval experience.

No Thresholds, DO is optional

One of the key aspects of the United States (US) aviation industry is the continuous innovation and ability to foster entrepreneurs to develop the next generation of safety improvements. Therefore it was important to the WG to establish a "lower overhead" path that would allow for "low risk" innovation and yet leverage the strengths of established organizations for "higher risk" designs.

Industry's recommendation is that there be no mandatory thresholds for any DA applicants or DAHs. All DOs would be optional. Benefits of this approach are that each DO applicant would be making the decision to become a DO based solely on the cost/benefit (business case) of that organization. This approach would be dependent on the benefits of the privileges outweighing the costs of implementation and maintenance of DO.

The "Mandatory Thresholds" described below could still be included, but changed from DO Required to DO Recommendedor DO expected, as guidance.

Mandatory Thresholds (if required)

In the event that the "No threshold, all DO's are optional" recommendation is not accepted. The WG developed a set of logical thresholds that could be used to minimize overhead where not required, and leveraging the strengths of DOs.

The WG explored various methods of developing thresholds to define which types of DAs would be above vs. below the threshold. The threshold structure was developed in an attempt to capture the highest-safety risk DAs, while allowing the lower-risk DAs to be handled by the current "FAA Managed" process.

The WG desired to develop thresholds that could be completely objective and evaluated without detailed analysis or interpretation. However it quickly became apparent that a more nuanced approach would be required to meet the intent of the thresholds. Various threshold models were evaluated. (See *Other Threshold Models Discussed* below for details on the other models.) Ultimately the WG settled on a Primary/Secondary (Risk Based) Threshold model as a logical approach.

Threshold Decision Tree

The decision tree (see Appendix F) is intended to be an easy-to-follow process to determine whether a project is above or below the threshold. The intent of the decision tree is only to determine if a DO is required to work the project. There are only two possible outcomes of the decision tree:

1. DO is NOT required, FAA-Managed or optional DO are acceptable
2. DO is required for Project, Develop DO (or have access to DO) w/ DA Application

Note that the projects worked with a DO and with the "FAA Managed" process would be required to meet the same airworthiness standards. DAs obtained through a DO or "FAA Managed" processes would have the same approval status and acceptance.

Existing DOs

The WG expects applicants who are already DOs to work any new project through their DO. If the DO makes application for a project beyond its existing authority, the WG would expect the DO to work with the FAA to expand its existing authority.

Primary Threshold

The primary thresholds were developed to be completely objective. See Appendix F, Figure F-1 for the primary threshold decision tree. The primary threshold is designed to be a coarse screen for those projects that would be easily identifiable as "low" or "high" risk. This section discusses some of the rationale for the decision points.

New TC applicants
Projects that present a small enough risk/population that they would not require a DO:

1. Part 31 (Manned Free Balloons),
2. Part 21.24 (primary category aircraft),
3. Part 21.25 (restricted category aircraft),
4. Part 21.27* (surplus aircraft of the Armed Forces),
5. Part 33 (engines) & Part 35 (propellers) intended for Part 21.XX Aircraft

*Rotorcraft Directorate asked to exclude rotorcraft from the Part 21.27 exemption. The reasoning behind this request was due to the high volume of safety issues and ADs being issued on the large number of rotorcraft being pulled from military surplus boneyards and applying for Restricted Category TC using 14 CFR part 21.27. These applicants are using old maintenance manuals that are inadequate and outdated. However, the local FAA offices lack the knowledge of the history with these aircraft and issue the Restricted TC. The Rotorcraft Directorate wants to require applicants for Restricted Category TC using 14 CFR part 21.27 to be or use a DO. The benefit of this would be that the DO would require the applicant to have a better engineering staff than what they currently have, and it would also have an improved COS Program. It is the opinion of this WG that this issue needs to be addressed outside of this WG.

STC, PMA and changes to TC, STC or PMA
Projects that present a small enough risk/population that they would not require a DO:

1. Part 31 (Manned Free Balloons)
2. Part 33 (engine) non-turbine
3. Part 35 (propeller) fixed pitch
4. Part 23 Small Airplane
   a. <=9 Passengers
   b. Not certificated as a commuter category or predecessor commuter category airplane (Special Federal Aviation Regulation (SFAR) 23 and SFAR 41), AND
   c. Not pressurized and certificated to fly at altitudes 24,000 ft or above

Note: The Small Airplane Directorate's primary threshold criteria are consistent with the safety continuum work associated with the concurrent Part 23 ARC.

5. One Time Only STC (and changes to a one time only STC)
   Since, by definition, One Time Only STCs apply to only one product (aircraft, engine or propeller), the risk associate with the STC will be limited to one aircraft.
   Note: Any attempt to apply a One Time STC to multiple different products should be discouraged.
6. Non-Critical PMA (and changes to Non-Critical PMA)
   Every PMA applicant has to make a safety assessment determine if a part is critical or non-critical (See FAA Order 8110.42). Therefore this is a well understood and accepted process and can be used as part of the primary threshold.

Secondary "Risk Based" Threshold

For Multiple STC and changes to TC or Multiple STC not captured by the primary thresholds, the threshold decision tree directs the applicant evaluate the secondary "Risk Based" threshold. (See Appendix F, Figure F-2.)

Note that in order for a project to be evaluated by this secondary threshold, it must have passed through the primary threshold flowchart without a "DO is required" or "DO is NOT required" determination.

As stated above, the WG desired to develop the thresholds that could be completely objective and evaluated without detailed analysis or interpretation. Since the fidelity required to get to a good determination of product safety risk was not possible with the purely objective approach, the Failure Modes Effects (FME) Assessment was chosen. (See *Other Threshold Models Discussed* below for details on the other models examined by the WG.)

Most applicants make a formal FME Assessment (or Analysis) at some point in time during the development of the design change. In most cases, this FME Assessment (or Analysis) is part of the formal application or change record. For some CFR 14 Parts and disciplines this FME Assessment (or Analysis) currently has a regulation, order and/or guidance material. Others unfortunately do not.

In the interest of making the FME Assessment as transparent and well understood as possible, the WG proposes to use the current regulations and guidance wherever possible, and recommends the various directorates work with industry to develop regulations and guidance where it is currently absent or unclear.

The secondary risk-based threshold is designed to be a more nuanced screen for those projects that would be identifiable as "low" or "high" risk. This section discusses some of the rationale for the decision points.

Existing FME Assessment regulation/guidance
As stated above, the WG desired to use existing regulation and guidance material where it is available. The following are examples of this material:

1. Part 27/29 Structures
    a. Part XX.571(b)(2) & Part XX.573(c)(2) Principal Structural Element (PSE)
    b. Part XX.602 Critical Parts
2. Part 23/25/27/29 System and Equipment
    a. Part XX.1309 Equipment, systems, and installations
3. Part 33.75 Safety analysis
4. Part 35.15 Safety analysis

The part 27/29 structures assessment is relatively simple. If the change affects a PSE or Critical Part, then "DO is required". If not, "DO is NOT required."

For the Part 23/25/27/29 System and Equipment disciplines and Part 33 and Part 35 assessments, the applicant only has to make an assessment as to the failure modes and effects. If the potential failure mode of the change would introduce a new failure mode(s) or otherwise impact the existing failure mode(s) which could result in either Hazardous or Catastrophic classification, then "DO is required." If not (i.e., the potential failure mode is Major or less), then "DO is NOT required."

Note: the regulations and guidance material provide for not only an assessment but also an analysis. The assessment provides the category of potential failures. The analysis provides the probability of occurrence for the potential failures. For the purposes of threshold determination ONLY the assessment is required.

The WG expects "below the threshold" applicants to include their FME assessment with their application/proposal for any FAA managed projects. Since this is currently done with most applications, the WG does not expect this to be an undue burden on "below the threshold" applicants.

Areas without existing FME Assessment regulation/guidance
The WG recommends encouraging the various directorates to work with industry to develop regulations and guidance for any areas where existing FME Assessment is absent, or unclear. There should be a clear delineation between "High risk" and "Low Risk", similar to the Hazardous/Catastrophic vs. Major or less that is currently used for other directorates/disciplines.

Other disciplines and Product Level Safety Assessments
The WG explored adding detailed discipline-level FME assessments and other secondary criteria. The WG recommends that the secondary threshold be limited to Product Level Safety Risk Assessments. Any "other" secondary threshold assessment should be set using the criteria of will the potential failure mode "affect

the continued safe flight and landing of the aircraft." As an example, the WG explored occupant safety assessments. While occupant safety and crash survivability are important and there are specific regulations written around these areas, they do not rise to the level of "continued safe flight and landing."

Any applicant for a STC (or change to a TC) would be expected meet all the regulatory requirements whether they use a DO or an FAA-managed approval process.

Risk of Under/Over Classification

If an applicant makes an error in the application of the secondary "Risk Based" threshold, the proposed system has a robust 'fail safe' mechanism built in.

If the applicant under classifies the FME Assessment and incorrectly determines that "DO is NOT required," then they would submit that assessment as part of their FAA-Managed project. The FAA would then have the opportunity to review the assessment and correct the error. The applicant would then be required to become a DO or to obtain access to a DO to process the application.

If the applicant over classifies the FME Assessment and incorrectly determines that "DO is required," then the applicant would (on their own) become a DO or obtain access to a DO to process the application. A fully-functioning DO would be able to detect the error and correct the FME assessment.

Optional DO

Because of the privileges associated with a DO (see section IV.E), non-DO Applicants who are operating below the thresholds may desire to become a DO. Such applicants would be treated in the same manner as any other DO/DO Applicant. (As discussed above, there is no "need determination" required to become a DO.)

Other Threshold Models Discussed

Major/Minor Change
Major vs. Minor design change would be a convenient delineation for setting a DO threshold. Unfortunately, the current state of the industry and guidance does not allow for an easy, consistent determination of Major/Minor change, nor is the Major/Minor threshold necessarily safety risk-focused. For example, adding a placard in the lavatory of a Part 25 aircraft may be classified as a Major Change if no placard currently exists in that location. The WG noted many more examples where Major/Minor change determinations have been controversial, with disagreements between FAA and industry. For these reasons the Major/Minor change was not selected for the threshold determination.

While Major/Minor determinations are out of scope of this WG, the WG recommends that the FAA and industry drive towards a consistent, easily understood, safety risk-based determination of Major/Minor change.

Significant Change
Similar to Major/Minor, Significant Change would also be a convenient delineation for setting a DO threshold. Unfortunately, the current state of the industry and guidance does not allow for an easy, consistent determination of significant change. The WG noted many examples where significant change determinations have been very controversial, with disagreements between FAA and industry. For this reason the significant change was not selected for the threshold determination.

While significant change determinations are out of scope of this WG, the WG recommends that the FAA and industry drive towards a consistent, easily understood, safety risk based determination of significant change.

Proxy Thresholds: Substitute objective thresholds (such as weight, thrust, altitude, passenger count) for the risk-based secondary threshold. Benefits of this approach are that the determination of above vs. below the threshold would become completely objective and not dependent on analysis or interpretation. Drawbacks of this approach include that some “low risk” changes will be caught by the proxy thresholds, and that some “high risk” changes could be below the threshold.

Technical Standard Order Approval (TSOA)

TSOA Applicants/Holders would not be required to have a DO. The WG identified no appreciable benefits or privileges that a TSOA Applicant/Holder would attain by becoming a DO that they do not currently have as a TSOA Holder/Applicant nor would there be a reduction in FAA resources required. Therefore TSOA Holder/Applicants were determined to be out of scope, since a simple cost-benefit evaluation was perceived as negative.

Dissenting Opinion – DO requires previous FAA approval experience

A member of the WG dissented with the eligibility statement that DO application does not require previous FAA approval experience. The dissenting opinion is that an applicant for DO should be required to demonstrate capability as a mature Organization Delegation Authorization (ODA) before being granted a DO certificate. This approach provides experience in building toward a DO certificate.

Dissenting Opinion – Secondary risk-based mandatory thresholds

A member of the WG objects to the manner in which the mandatory thresholds are established; particularly to the secondary threshold mechanism which uses an overly complicated analysis that is subjective and that makes it difficult for new market entrants to identify their regulatory obligations.

The methodology posits a primary threshold, which would be based on easily ascertained objective criteria. But it then continues to posit a secondary threshold, which would be based upon an analysis that is analogous to a failure modes and effects analysis (FMEA).

The audience for this threshold distinction won't be large and well-established companies. Their participation in the WG suggests that these sorts of companies would voluntarily obtain DO Certificates regardless of whether there is a mandate. Rather, the audience for this threshold distinction will be new market entrants seeking their first DA. These are more likely to be small businesses, with limited resources and limited experience. Such companies may not have past experience in performing FMEA, so mandating that they perform an analysis equivalent to an FMEA on their design idea just to determine whether or not they need to perform the design process under the auspices of a DO Certificate seems ill-advised.

Furthermore FMEA is typically performed in the context of an existing design. The engineer is identifying failure modes and effects based upon the design features. But the FMEA posited by this secondary analysis would not be performed by analyzing a design. Instead, it would be performed by analyzing an idea that has not yet been designed. It would need to be performed at such an early stage because it would be a vital part of the analysis that drives the prima facie question of whether the design work needs to be performed in the context of a DO Certificates. So new companies would be caught in the catch-22 of trying to perform FMEA on a part that has not yet been designed in order to compare the FMEA to the secondary threshold metrics, and being unable to perform the design work until first receiving an answer to the prima facie question of whether a DO Certificate was needed.

Finally, there is no need for a complicated mechanism for identifying whether a company needs to hold a DO Certificate. It is possible to establish an objective standard that serves as a proxy for the safety thresholds upon which the WG wants to rely.

Under the discussion of Existing DOs in this Report, the WG has asserted its intent that existing DOs would work all new projects through their existing DOs. Thus, the threshold question of whether you need a DO is an important one that has an effect on all future projects from that company – and companies may be dissuaded from pursuing complex projects if they fear that this sort of complex project would adversely affect the resource requirement for all future projects.

It is recommended to retain the primary threshold only; because the companies that would be asked to perform the risk assessment are the ones that have the least experience in performing such analyses, and the fact that they would need to predict failure modes and effects based on incomplete engineering means that they will not have adequate data upon which to make their FMEA predictions. The primary threshold adequately serves as a proxy for the safety standards that are necessary to establish the DO Certificate threshold.

It is also strongly recommended that all threshold criteria related to this new certificate (like eligibility and necessity) be established using objective standards. For example, it is objectively obvious to an applicant whether their aircraft parts concept is intended for use on a Part 25 aircraft, and thus a criteria that uses Part 25 is likely to be both objective and observationally simple.

IV.B.(4) Certificated Organization

The WG discussed what form of recognition a DO should be provided and determined that a DO should be a certificated organization. The alternative options discussed included approved, authorized, and accepted organizations. The WG agreed that a certificated organization aligned best with the accountability framework model.

Design Organization Certificate

Like any other FAA certificate, a DO certificate comes with privileges and requirements. This is similar to how an air carrier operating certificate is structured. Section 119.7 of 14 CFR indicates the kinds of authorized operations that constitute a part of the operations certificate. Similarly, the types of activities authorized under a DO certificate, including the types of covered products and services, would constitute a part of the DO certificate.

Not all DO certificate holders will have the same scope of authority.

DO Certificate. All persons who meet the minimum requirements are qualified to be issued a DO certificate. DO does not require a FAA determination of need.

The DO certificate holder has the right to retain the certificate unless the FAA takes certificate action in accordance with 49 United States Code (USC) 44709.

IV.B.(5) Applicability of Part 21 Requirements

There are several places within 14 CFR, chapter 1, subchapter C, most of them being in Part 21, where the principles embodied within the DO concept conflict with existing regulations.

The WG saw two possible avenues available to resolve those conflicts:

- Change each rule wherein a conflict occurred; or
- Place a single section within the DO requirements that contained the MOC by which the DO would comply with the conflicted rules.

In no case would the compliance objective of the conflicted rule be changed. The WG chose the latter approach consistent with the CDO ARC, as it results in all the DO requirements residing in one place within Part 21. Refer to the CDO ARC report proposed NPRM (e.g., paragraph 21.741).

It is important to recognize that the DO certificate holder, like any other applicant or certificate holder, must comply with the other requirements of 14 CFR Part 21, unless otherwise stated or otherwise excluded.

IV.B.(6) Transition Provisions

A WG subteam addressed transition provisions prior to forming the consensus opinion of the threshold applicability for a DO (i.e., no threshold). The following information is presented should a dissenting opinion that DO become a mandatory requirement be further considered.

Should a rule for mandatory DO becomes effective there should be a transition period to allow applicants time to meet the new requirements. The WG made the following assumptions about this transition period:

- All parties will act in good faith.
- The effective date of the rule will be a date one to two years after the rule's publication date.
- There will be no link or requirement between TC/STC/PMA issuance and DO certificate issuance.
- Issuance of a DO certificate should be within five years of date of DO application.
- There will be no mandated date requiring new applicants to have a DO certificate. New applicants may apply for TC/STC/PMA and a DO certificate concurrently.
- A process needs to be in place to address applications/projects that started prior to effective date of new rule, but not yet finished. This is only required if the applicant decides they want to apply for a DO certificate; otherwise all applications submitted prior to effective date of the rule may continue as FAA-assisted applications.
- For TC/STC/PMA applications, ODA will not exist. This might require a "sunset" ODA regulation.

The WG proposal DO certificate application requirements with the following progression:

- Applicants applying for a DA (TC/STC/PMA) above the threshold after the effective date of the rule AND (a) do not already hold a DO certificate OR (b) are not utilizing an agent DO will be required to:

- Submit application for a DO certificate (a plan should be submitted with the application, but a proposed procedures manual is not required at this point).
- Submit DO procedures manual to the FAA within 2 years of initial application date.
- Within 3 years of DO procedures manual submittal, the FAA should have a means to approve the manual and issue the DO certificate.

IV.C. DO Minimum Requirements

As previously discussed, a DO must have systems in place that assure any and all statements of compliance may be relied on by the FAA when making its ultimate finding of compliance by the act of issuing a certificate. That activity must occur under established minimum requirements of a DO.

An integrated and systematic approach to compliance and safety therefore encompasses several elements, including an organization, CAS and SMS. Successful execution of these elements should enable the continued growth of a compliance and safety culture within the DO. While each of the elements of the systems discussed below need to be satisfied by the DO, they may be arranged or grouped differently or encompassed within organizational systems with different names to accomplish the intended purpose.

The DO must be able to establish and show that the organization;

- possesses the required competence to determine that the certificate holder's designs meet all applicable airworthiness standards within the scope of the DO certificate,
- has procedures for assuring compliance to the airworthiness standards, and
- maintains the essential process controls to deliver repeatable and sustainable compliance.

IV.C.(1) DO and OCS

The WG does not recommend that a particular organizational structure be required; however, there are certain functional roles, aspects and elements that must be defined in the FAA-approved DO Procedures Manual. Each holder of a DO certificate must have a Procedures Manual that defines the procedures and processes to be used (i.e., OCS) which meet the requirements specifically required by the DO regulation to be in the procedures manual.

The holder of a DO certificate must follow the procedures in the manual. The manual must be in the English language and retrievable in a form acceptable to the FAA.

The DO Procedures Manual contains the DO organization's procedures for meeting its regulatory requirements. The manual must address all relevant DO requirements.

The DO Procedures Manual processes and procedures must be sufficient for the FAA to determine that regulatory compliance is properly addressed. The manual is intended to be a top level document that will guide the development of lower level processes and work instructions that the DO can develop and change as it finds necessary (i.e., without the need for FAA approval) to meet the top level requirements and objectives. While these lower level process documents will not be FAA approved, they must be cross-referenced to the procedures manual. These lower level processes and procedures are auditable by the FAA. If the DO fails to comply with any procedure contained or referenced in the procedures manual, this non-compliance could result in enforcement action. This means that all lower level processes and work instructions within the DO that are related to compliance must have a means to tie them to the FAA-approved Procedures Manual. Internal company processes and procedures that are not required to show DO regulatory compliance would not be referenced in the procedures manual and would not be auditable by FAA as part of its DO oversight.

If the FAA determines that the procedures manual lacks the detail necessary to ensure regulatory compliance, the FAA will request a change to the manual. The DO is obligated to respond to FAA's request within an agreed upon time frame. The WG recommends further discussion on the necessary level of detail for inclusion in the procedures manual and the appropriate reasons/rationale for FAA requests for changes to the procedures manual.

The procedures manual must be consistent with all issued FAA regulations and guidance related to the proper functioning of a DO. The manual may not be used by the FAA to apply policy that has not been formally implemented through a public process. The certificate holder may not use the manual for relief from any regulatory requirement or to create unique policy for its sole benefit.

The DO Procedures Manual may be in any format proposed by the DO and acceptable to the Administrator. There is no expectation that each DO procedures manual would be formatted the same.

The organizational and OCS requirements are:

(a) **Identified DO Executive.** The DO Executive is accountable for all the activities covered within the scope of the DO certificate. This executive must be identified by name and position within the company. The DO Executive may also act as the primary point of contact (POC) for the DO. The DO Procedures Manual must contain an explanation of the reporting relationships between the DO Executive and senior company management, as well as the organizational relationships within the DO.

(b) **Identified DO point(s) of contact.** The DO POC is the person(s) within the DO with whom the FAA will communicate. A formal list of POC must be maintained by the DO. The DO POC must have familiarity with the DO processes and the applicable FAA regulations consistent with the scope of the DO certificate. The DO POC must also have unencumbered, but not necessarily direct, access to the DO Executive. Additionally, defined procedures for communication between the DO and the FAA, including agreement on expectations and expediency, shall be stated.

(c) **Each DO certificate holder shall have qualified staff as appropriate to the DO privileges and obligations.** The DO is responsible for ensuring the staff in technical departments have the experience, training, and authority to be able to discharge their allocated responsibilities, and that these, together with the accommodation, facilities and equipment, are adequate to enable the staff to achieve the airworthiness objectives for the product.

Note: The intent is for the DO to preserve autonomy in defining the structure and number of staff in alignment with its business model. The intent is not to require identification by name of staff in the procedures manual, however, it is intended to provide a means to trace determinations of compliance to qualified staff. While the WG did not discuss details regarding staff qualifications, a WG member suggested DO staff qualification requirements should be addressed prior to rulemaking activity.

(d) **A process for verification of personnel qualifications.** The scope of personnel is intended to focus on those people who hold accountability for maintaining the organizational oversight of the DO and those people with prime accountability for the DMS, CCS and SMS. Personnel qualification includes essential competencies, experiance and training.

(e) **A process for verification of systemic performance of duties.** This includes procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved Procedures Manual, DMS, CCS and SMS. The procedures must include reporting of internal audit results to the manager responsible for implementing corrective and preventative actions.

(f) **A process for retaining records that are required to be produced.** This includes the identification of records that must be retained, the method and means of storage and retrieval, control and access privilege, and retention period. These records typically comprise DO Procedures Manual approvals (including changes to), DA records, approval of design changes, internal audit records and CCS records.

(g) **A process for identifying which certification projects require an application, for establishing details of the project list, and for how often this information should be provided to the FAA.** (Refer to Section IV.C (4))

(h) **A process for notifying the FAA if circumstances prevent the DO from meeting the DO obligations.** Notification is not required if the circumstances have been anticipated and mitigated. This process includes agreed expectations pertaining to communication and notification protocols between the organization and the FAA regarding identification and investigation of potential (or actual) non-compliance.

(i) **The process, timetable and authority for obtaining and agreeing on changes to the DO Procedures Manual, DMS, CAS, and SMS.**

IV.C.(2) Compliance Assurance System

The DO applicant must demonstrate that it has established and is able to maintain a regulatory CAS for:

- the control and management of the DA(s),
- design changes of products and articles covered by the scope of the certificate, and
- any production activities associated with those DAs.

The CAS should result in assurance that the compliance determinations are correct and consistent with what would result from an independent skilled review of compliance.

The DO applicant's regulatory CAS must contain a means to provide assurance that the design and design changes of the applicant's products and articles comply with the applicable airworthiness standards. This is presented in this report as being accomplished through a DMS and a CCS, details of which are contained below.

As appropriate to compliance and safety, the compliance assurance process for the various aspects of the product or article design may include safeguards, risk-based assessments, and/or checking functions of the showings of compliance. As an example of a safeguard, a computer-aided design system could preclude designers from inadvertently selecting materials that had not been qualified by the DO as compliant with the airworthiness standards. In these instances where safeguards have been implemented or where a risk-based assessment has been accomplished, a checking or verification function may not necessarily be required.

After the issuance of the DO certificate, any changes to the CAS materially affecting compliance with the certification basis or airworthiness standards must be submitted to the FAA for approval, prior to implementation. The DO must identify to the FAA how the proposed changes to the CAS will result in continued compliance after implementation.

Assurance of compliance with the airworthiness standards, including the performance of suppliers, is of critical importance to the success of DO. As will be discussed in a later section, there are no FAA designees used by the DO. Therefore, the quality of the DO's processes for determinations of compliance and process adherence, and the robustness of the CAS are the basis for enabling the FAA to rely on the DO's statement of compliance when making its finding.

The DO CAS is comprised of two elements:

1. **Design Management System**. The DMS is the system by which a DO creates and maintains product design data. The DMS requirements are:

(a) A process for creating, and maintaining configuration and control of, design data. The establishment of a structured and controlled system for the development of design data, the control of changes to, and the assurance that the descriptive design data is current and approved is fundamental to this process.

(b) A process for retaining, retrieving, protecting and maintaining design descriptive and substantiating data. This process should also include any agreements between the DO and the FAA regarding availability of data, access and any electronic system requirements required to view the data.

(c) A process for engineering supplier control that defines how design activities performed external to the DO are controlled, validated, and assured. This also includes Inter-DO relationships (see Section IV.D.(4)).

(d) A process for creating eligible data that can be used for showing compliance when applied to a particular certification activity.

(e) A process for receiving and processing “safety” data related to approved designs.

Note: “Safety” data is meant to pertain to information relevant to identification of product safety hazards, risk analysis and mitigation, as appropriate.

(f) A process for applying relevant “safety” data to the DMS for purposes of continuous improvement.

2. **Compliance Certification System.** The CCS is the system by which a DO assures product compliance (showing of and verification of, as appropriate) to the applicable airworthiness standards. The CCS requirements are:

(a) A process for identifying and/or establishing regulatory certification basis. This process includes an assessment of the product’s intended usage and determination of the applicable airworthiness standards. The process should also include protocols for coordination with and, if required, agreement from the FAA. For changes to existing DAs, an assessment and determination of the changed product rule shall be performed. The establishment of a product’s certification basis may be a pre-decisional FAA approval based on the agreed processes defined within the DO Procedures Manual.

(b) A process for identifying regulatory changes that affect the design system. The DO must have an active means of monitoring regulatory changes that affect the product(s) for which the organization is responsible and evaluating the need for implementing changes or taking other actions. This includes any activities resulting from the issuance of an AD against a DAH’s product.

(c) A defined system that shows compliance to the applicable airworthiness standards under 14 CFR 21.20(a) and how verification of compliance will be conducted including any process for assuring independence and objectivity. The “show” responsibility is identical to that already prescribed under 14

CFR 21.20(a). However, in the DO model, the "show" and "verification" functions are intended to be accomplished within the DO.

(d) A process for using MOC that are acceptable to the FAA, including, as appropriate, a process for verification and validation of analytical tools and a process for managing testing and inspection required to support each showing of compliance. This would include conformity inspections used to support showings of compliance.

It is expected that this process will delineate between showings within well-established MOC and procedural distinctions when addressing a MOC that is new or novel.

(e) A process for declaring to the Administrator that a design is in compliance with the applicable airworthiness standards at the time that the DA is requested. This documentation fulfills the requirement under 14 CFR 21.20(b).

(f) A process for reporting other approvals such as design changes, changes to Instructions for Continued Airworthiness (ICA), and approval of repair data.

(g) A process for receiving, processing, and implementing corrective action with respect to "compliance" data related to approved designs. If during the course of regular business or as the result of a finding during any internal or externally conducted audit a non-compliance to the approved procedures or airworthiness standard is identified, the mechanism for evaluating the risk of the non-compliance and identification of any corrective actions must be defined.

DO show and verify compliance certification functions. The CCS processes must include a showing of compliance by the DO to each applicable airworthiness standard. The following principles provide guidance in this regard:

- Show and verify functions are part of the CCS.
- The show function is a demonstration of compliance to an airworthiness standard (i.e., 14 CFR 23, 25, 27, 29, 33, 35) and is comprised of substantiating data, statements, and/or other acceptable methods of demonstration (e.g., acceptable MOC).
- The verify function is an independent check, or equivalent, of the show function.
- The show and verify functions are distinct functions or activities, where appropriate. The degree of independence between the individuals performing the show and verify functions or activities should be established in the DO Procedures Manual.
- A DO determination of compliance is a showing with an independent verification function unless the DO Procedures Manual identifies a specific area where a verification is not required or where the Procedures Manual

identifies a process that allows the DO to assess risk to make decisions on whether a verification step is required. As such, a mathematical expression for a determination of compliance may be considered as the following: determination of compliance = showing of compliance + verification of compliance, as appropriate per Procedures Manual

- The showing of compliance requirement remains identical to that which exists in the current regulatory system. There is no intent to establish a changed requirement for showing of compliance for a DO.

Tools used for performing compliance activities. Where the system is dependent on the use of a tool for performing some of the processes and methods, means must be provided to ensure:

- The tool performs it required function;
- The tool and its output are being controlled under a configuration management program;
- The tool is periodically verified for its applicability with respect to the processes and methods for which it is intended to apply; and
- A record is kept of the use of the tool to accomplish the compliance activity.

IV.C.(3) Safety Management System (SMS)

The SMS requirements for a DO are to be provided in a separate report by the SMS WG of the Part 21/SMS ARC.

The DO WG anticipates the SMS to be the system for actively monitoring product safety, identifying and managing risks to product safety, and promotion of a strong safety culture throughout the organization, which would likely consist of;

- Safety policy and objectives including management commitment, responsibilities, accountabilities, key safety personnel and coordination of emergency response planning.
- Safety risk management including identification of hazards, assessment of risk and mitigation.
- Safety assurance through performance monitoring, measurement, management of change and continuous improvement.
- Safety promotion through training, education and communication

The majority of the industry represented in the WG disagrees that SMS must be directly tied to DO. While there is agreement that specific elements of SMS should be addressed by a DO (i.e., DO minimum requirements), the majority of industry believes that SMS as proposed in Part 5 should be independent from DO requirements. As the development of SMS for DO was outside the scope of this WG charter, the WG recommends further discussion by the ARC on this subject.

IV.C.(4) DO Project Applications and Activity Reporting

[Note: This section is consistent with the CDO ARC report of May 2008.]

The WG believes there are many projects that the DO certificate holder may complete without having to notify the FAA, since the DO will be making all determinations of compliance in accordance with its FAA-approved Procedures Manual. There are other projects that the FAA must be immediately aware of as they require the FAA to validate the existing type certification basis or establish a new one.

Part 21 already specifies when an application must be made to the FAA. This includes applications for TC, STC, and PMA. The WG concluded that the existing required applications could be used to discriminate between those projects that required notification of the FAA and those that did not. If the project would require an application under Part 21, then the FAA must be notified when the project is initiated. Such projects would be any new DA, amended TCs requiring a new model designation, new STCs, and any project that would be expected to have a revised type certification basis under section 21.101. Any change that does not rise to this level will be handled by the DO under their approved Procedures Manual.

The WG discussed other DO activities that would not require an application. The WG concluded that in all cases the FAA must be provided access to a record of all compliance activities being performed by the DO. This could be a paper record but in most cases it is expected to be electronic. Such a system of records would include activities such as major and minor changes to an existing design as well as repair approvals. The WG envisions a constantly updated database that may be accessed by the FAA as it desires. This database would need to contain the type of information that the FAA currently uses to measure the significance of a project, similar to the data collected through its Certification Project Notification (CPN) process. The database should also address whether or not the type certification basis may need to be revised, and the scope of FAA LOPI. This complete project listing would provide the FAA with information regarding the DO's activities and would help guide FAA oversight of the DO.

The details of the project list, how often it should be provided to the FAA, and how the FAA would be notified of projects requiring an application are some of the matters that should be discussed with the FAA and included in the Procedures Manual.

IV.D. DO Relationships and Supplier Control

IV.D.(1) General Requirements

An applicant for, or holder of, a DA has sole responsibility for proper control of all its suppliers, be they suppliers of engineering services, manufacturing of pre-production parts, special process, etc., or any other part of its compliance responsibilities. Should there be any deficiency or non-compliance on the part of a supplier, even if it is a supplier of compliance determinations, products, parts or appliances, the FAA holds the applicant or holder of the design certificate responsible to correct the deficiency. This long-standing principle remains for the DAH even if the DAH is also the holder of a DO certificate.

The DO must qualify its engineering suppliers, provide oversight, and define the process by which suppliers function within the DO system. This means that a DO may authorize suppliers to make determinations of compliance only after the DO has evaluated the supplier's system and determined that the supplier is qualified to act in that capacity for the DO. This does not mean that the suppliers must adopt the DO's system of processes, but it does mean that the DO must determine that the system of processes to be used by the suppliers are acceptable and meet the DO's requirements.

To fulfill its supplier management responsibilities, a DO must have as part of its system a process by which it will determine the appropriate level of oversight required for its suppliers. The DO would need to consider such things as:

- the criticality of the design,
- its experience with the supplier,
- the supplier's standing as a FAA-approved DO or as a holder of other FAA DAs or delegations,
- additional compliance determinations to be made during integration testing of the design, and
- any other appropriate factors.

The WG recommends that DO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities, in a manner similar to what is currently done by manufacturing facilities. As an example, several companies buying avionics components from a single supplier may cooperate in the surveillance of that supplier by allowing one of the companies to conduct the audit and the other companies to use the results as if they conducted the audit themselves. To gain the credit for such pooling of audit requirements, it is essential that the supplier processes be consistent across all companies, or that the company auditing the supplier assess all the requirements of those companies wishing to share the benefits of the single-party audit.

In selecting suppliers, the DO must consider that, for both engineering and production suppliers, there must be means for FAA to gain access to the facility for the purposes of DO oversight.

IV.D.(2) Oversight of Foreign Suppliers

Oversight of foreign suppliers is required whether or not a bilateral agreement exists between the FAA and the country in which a foreign supplier is located. A DO may authorize foreign suppliers to make determinations of compliance only after the DO has evaluated the suppliers' systems and determined that they are qualified to act in that capacity under the DO processes.

To fulfill its supplier management responsibilities, a DO may also propose as part of its quality system a foreign supplier oversight process for its design services supplier, just as companies do today for parts suppliers under Advisory Circular (AC) 21-1B, "Production Certificates." This process could be based on using an approved organization as a supplier to its DO, for example, a contract with an European Aviation Safety Agency (EASA) Design Organization Approval (DOA) holder in good standing. In doing so, it must be recognized that the foreign civil aviation authority (CAA) may not be performing any oversight of that activity if it does not lead to an approval under the CAA authority. If representatives of an EASA DOA, for example, are authorized by the DO to make compliance determinations, those determinations must be acceptable and meet the DO's requirements.

The DO remains fully responsible for all compliance determinations made by the foreign supplier holding an organizational approval from its cognizant CAA, just as it is for all other compliance determinations. However, in its supplier oversight function, the DO may take credit for the surveillance of the supplier by its CAA. That credit would result in a reduced need for oversight by the DO, and the foreign supplier oversight process should be defined within the supplier surveillance portion of the DO Procedures Manual. The DO, for example, could review periodic reports from audits performed by the supplier CAA or establish some other means of tracking supplier performance. The DO would need to consider the criticality of the design, experience with the supplier, and other factors in determining the degree of oversight necessary, as it does with all supplier oversight. The DO oversight methodology applied to foreign suppliers having capabilities recognized by their respective CAA would be evaluated as part of the FAA's oversight function. Additionally, the DO supplier oversight process could include a qualified third-party organization (such as Bureau Veritas).

IV.D.(3) The Need for Specialty Service Providers

For the design and production companies in the aviation system, the FAA has been moving away from a system of approvals that is based on the use of individual designees, and towards organizational delegations that are based upon demonstrated and approved processes within a company. This is especially true for those seeking or holding original DA certificates. The DO concept further propagates this trend.

At the same time, many companies in the aviation community are becoming very specialized in their ability to perform unique technical services. In certain highly technical areas, the number of qualified organizations that can perform specialized services has been reduced to a critical few. The designers and producers of approved products and articles rely on these specialty services to supplement their capabilities. The CDO ARC recognized a need to create a new process wherein these specialty companies are recognized for their capability, and that capability can be used to supplement DO (and ODA) compliance activities, as well as those of other applicants. The CDO ARC chose to call these companies "Specialty Service Providers" (SSP).

The WG recommends that the FAA give priority to developing a means for recognizing an accreditation system for these SSPs. This concept could encompass technical specialties ranging from the more complicated [such as flammability, dynamic seats, icing, electromagnetic interference, and high-intensity radiated fields] to the more routine specialties [such as materials testing, non-destructive inspection processes, and environmental testing of components]. These are but a few examples of the scope of activities that could be included under this concept.

The WG charter does not authorize the committee to develop the details of such a concept or offer specific proposals to the FAA on this subject. However, the WG agrees with the CDO ARC on the following initial principles and details for the FAA's consideration. The WG recommends that this CDO ARC concept be developed by Industry with the direct participation of the FAA because of the variety of issues that must be addressed and the need to create Industry consensus standards.

- The SSP could perform compliance with Industry consensus standards acceptable to the FAA and DO as evidence of compliance with specific airworthiness standards, resulting in a determination of compliance.
- The possibility of third party approval and oversight of SSPs should be considered.
- The data developed by SSPs must be directly usable by all applicants without further verification of the data's integrity.
- The FAA should pursue international acceptance of the SSP system.

- While SSPs may have individuals who are designees of the Administrator, such individuals do not exercise delegation in the course of a DO project as a SSP.
- Persons using SSPs must do so under their supplier control system. The amount of supplier oversight conducted by the user of these services can take into consideration the accreditation of these SSPs.
- The continued compliance responsibility of applicants who use SSPs is not reduced by the fact that the SSPs are recognized by the FAA for their expertise. The TC, PMA approval, or part approval holders still have the total responsibility for initial and continued compliance of the DAs they hold, and the resolution of all COS issues.

The WG recognizes that there are different methods that may be used to implement the SSP concept, and that the concept is not of necessity tied to implementation of DO. Regardless of the method of implementation, the WG recommends that the SSP system be made available to the aviation community.

IV.D.(4) Inter-DO Relationships and Responsibilities as Design Partners

Inter-DO relationships will be controlled by a supplier interface document (see section IV.F). This interface document will allow the supplier DO to utilize its own procedures and processes within its scope of authority as a DO. The applicant DO will identify how supplied data (and potentially determinations of compliance) will be assessed for integration and applicability to the product.

IV.D.(5) Agent DO

The WG discussed the creation and recognition of a DO that has been contracted to act on behalf of a DA applicant. The WG refers to such a DO as an Agent DO. An Agent DO may or may not hold a DA and must meet the minimum DO requirements specified within this report. The Agent DO provides an avenue for an interested DA applicant to utilize the professional DO services that the applicant either does not have or does not have the financial ability to create. The use of an Agent DO promotes consistency in design activity (safety enhancement), an accountable design organization (responsibility), and may reduce the necessary aviation system assessment and oversight resources. The WG believes the Agent DO role fills a critical need in the DO model where DO thresholds impact an applicant's ability to create needed designs or design changes, particularly with respect to small business applications.

The WG provides the following text from EASA 21.A.2 to consider, as a similar application of the Agent DO concept.

21.A.2 Undertaking by another person than the applicant for, or holder of, a certificate
The actions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part or appliance under this Section may be undertaken on its behalf by any other natural or legal person, provided the holder of, or applicant for, that certificate can show that it has made an agreement with the other person such as to ensure that the holder's obligations are and will be properly discharged.

IV.D.(6) Business Structure Variation

The WG recognized that additional business structures may exist where a DO is part of a business structure in which companies are not in a traditional supplier relationship. An example of such a business structure is a consortium, where each company is an equal business partner and is not considered a supplier to the other. In some cases one business partner is US-based while the other is foreign-based. Also the consortium company may or may not be US-based. As such, neither company has complete oversight, in the supplier sense, of the other company. Each business partner wants recognition of their respective DO in a certification project. Such is the situation, in any business structure, where one company does not have full supplier oversight responsibilities over another company.

Industry members of the WG currently have such business structures with US-based companies and foreign-based companies. As the aviation business continues to grow globally, Industry members foresee continued growth of such business structures to mitigate associated business risks and leverage various strengths of different companies.

The WG discussed the notion that a US-based DO, when the consortium company is foreign-based, should be able to manage the integration responsibilities for the FAA portion of a certification project, including the project statement of compliance to the applicable airworthiness standards knowing that the US-based DO may not possess or have access to all project descriptive and/or substantiating data. This is a result of the need to protect proprietary methods and information within each respective company. Completion of all the required determinations of compliance must be documented to support the project statement of compliance.

The WG also discussed the notion that a consortium may consist of two US-based DO's. Industry recognizes there is one applicant and certificate holder for each TC; that has historically been the consortium company. The FAA has worked with consortium companies to execute shared-responsibility agreements between the members, which are acceptable to the FAA. That has allowed each consortium member to autonomously execute its role independent of the other consortium members, including findings of compliance under FAA delegation, thus protecting its proprietary data. A similar FAA-accepted working agreement could describe how those autonomously performed design and compliance determination processes under DO are integrated into a single type design, a single TC, and a single continued airworthiness process.

The WG believes further discussion is needed between the FAA and Industry to develop how this would be accomplished. Therefore, the WG recommends further development of how such business structures will be accommodated under the proposed DO framework. Input from industry, especially those who presently have consortium programs, should be considered further.

IV.E. Scope, Limitations, and Privileges of DO Certificates

There are many variations in design and production organizations and their products throughout the aviation system. They range from organizations dealing with a full line of products, like transport airplanes, high-tech general aviation aircraft, helicopters, and high-bypass engines, to PMA holders with a more narrow focus. In some cases, the FAA compliance approvals for the activities of these organizations are made either directly by FAA resources, or by using individual or organizational delegation approvals from the FAA. Repair stations may have ODA authorizations or their own company designees, or may contract with consultant designees to perform DA functions. This describes but a few of the organizations that make a business of engaging in design and production certification activities.

The challenges and benefits of the DO concept are outlined in Section II. In addition to the ability for FAA to implement SMS, the safety benefits of a more complete corporate focus on compliance and safety can further permeate the Industry if these organizations are required to obtain DO certificates. For this reason, the criteria for obtaining and holding a DO certificate must be such that they can be tailored to the size and functions of the specific DO certificate holder.

As has always been the case, Industry is responsible for compliance with the regulations; this will not change under the DO concept of operation. The rigor associated with that compliance is contained within the FAA-approved DO Procedures Manual, and it must be tailored to the size of the organization and the complexity of the items that the DO certificate holder designs and / or produces.

A total "culture of compliance" must exist within each DO company, but how that culture is established will likely differ for each DO certificate holder. The key is to define criteria against which all potential DO certificate holders will be measured, but recognize that there will be variables in how the criteria are met based on different types and sizes of companies and associated regulatory obligations.

IV.E.(1) FAA Limitations on the DO Certificate

A DO certificate may cover type certification activities, supplemental type certification activities, and activities leading to the issuance of PMAs, as well as activities associated with a production approval. For a particular DO, the FAA may limit the scope of activities that might be accomplished by that DO.

Type Certificates. For type certification activities, it would be rare that a certificate holder would be able to perform all the responsibilities necessary for demonstrating compliance for all products that are eligible to receive a TC. For this reason, the FAA may restrict a DO certificate to only products covered by a specific part of the airworthiness/design requirements, such as 14 CFR part 23 (small airplanes), 25 (large airplanes), 27 (small rotorcraft), 29 (large rotorcraft), 31 (balloons), 33 (engines), or 35 (propellers).

The FAA may further limit the scope of DO certificate activities within a given regulatory part. For instance, a manufacturer might only have the experience necessary to properly comply with DO requirements for small transport airplanes under 14 CFR Part 25 airplanes, but not large transport airplanes; or for reciprocating engines under 14 CFR Part 33, but not large turbofan engines. The FAA may use other parameters it determines to be necessary to further limit the scope of a DO certificate. The intent is to allow the widest scope of certificate for which the applicant has been able to demonstrate its capability to comply with the relevant design and airworthiness requirements.

Supplemental Type Certificates. In the case of STCs, the scope would also likely be defined in more narrow terms. For example, the scope might be limited by the products that a particular airline operates, or by technical discipline and subpart (Part 23 structures, for instance), or by the complexity of the product (large turbofan engines, for instance), or by other generic parameters the FAA determines to be appropriate.

PMA. In the case of PMA the scope would likely be tailored to each certificate holder.

Determining the Appropriate Scope of a DO. When determining an appropriate scope for a DO certificate, the FAA must ensure that the certificate holder has, and will continue to maintain, the capability to meet all the requirements of the subpart within the scope of its certificate.

As part of this determination, the FAA may consider providing multiple DO certificates in unusual situations for applicants with substantially decentralized organizations, or who have a wide range of products or capabilities. When evaluating whether a single certificate or multiple certificates is most appropriate, the FAA would consider the organizational structure of the applicant, interactions of remote or co-located design and production facilities, and the use of common processes and procedures.

The scope of any DO certificate will be clearly defined so that all persons, including other civil aviation authorities (CAA), will understand the scope of authority for FAA-approved data granted under that certificate.

Transfer of a DO Certificate. A DO certificate holder cannot transfer the DO certificate.

IV.E.(2) Scope of DO Certificate Privileges Must Be "Functionally Complete"

The DO certificate privileges must be functionally complete, which means they must cover all activities that would have to be undertaken in order to fully complete a DA project within its scope of a DO's authority. The DO holder's competence and capabilities must also be functionally complete in order to certify compliance with the applicable airworthiness safety standards within the scope of its authority. Those include:

- **All certification activities leading to the issuance of an original or amended design approval**, including design, airworthiness, manufacturing, and maintenance and operations activities as they relate to a DA. This includes; engineering inspection, analysis and tests; flight tests; ICA, aircraft flight manuals, etc.
- **All determinations of compliance**, including those that involve a subjective evaluation.
- **Continued airworthiness activities,** including changes to those approved designs for product improvements or safety enhancements, such as those contained in service bulletins, or repair data.
- **Manufacturing and airworthiness activities**, such as the pre-production manufacturing of parts, components, and subassemblies; and conformity of test articles and products, and their airworthiness certification for flight test.
- **The development and testing of designs and processes** for possible inclusion in future approved designs (i.e., "eligible data").
- **Any other activities leading to the development of data** necessary for the FAA to determine compliance with the requirements issued by those countries from which validation is sought and with which the FAA has a bilateral airworthiness agreement covering that compliance activity.

  [Note: While not a privilege of the DO certificate, the FAA may wish to grant the DO holder the additional privilege of making compliance determinations to CAA requirements.]

IV.E.(3) Form of a DO Certificate

Examples of EASA DOA Certificates and Terms of Approval were reviewed and discussed in assessing application to DOs. The WG recommends a structure similar in nature for a FAA DO Certificate. This would provide consistency between the FAA Certificate and CAA Certificates.

IV.E.(4) Transfer of Design Approvals under DO

A TC/STC issued after the effective date of regulation (e.g., under the DO framework) is transferable provided the following requirements are met:

(a) The transferor of the TC/STC makes a statement, in writing, to the FAA that they are providing all descriptive data and providing, or making available all substantiating data to the transferee. This statement must describe the conditions under which the substantiating data is made available to the transferee if the data will not be provided (i.e., contractual agreement).

A TC/STC issued prior to the effective date of regulation is transferable provided the descriptive data and substantiating data the transferor has, or has access to, is provided to the transferee. The WG recognized that existing TC/STC holders may or may not have the descriptive data and/or substantiating data and imposing a regulatory restriction on the transfer would negatively impact the asset value.

The WG recommends non-DO DA transfer requirements be provided by a separate WG to the ARC.

IV.E.(4).(a) PMA Specific Design Approvals under DO

Due to the unique combined design and production nature of a PMA, PMA is not eligible for transfer.

IV.E.(5) The Generation of "Eligible Data"

Under a DO certificate, compliance is an intended by-product of an FAA-approved DO system properly functioning under its Procedures Manual, which includes a formal internal audit and oversight process. For the compliance determination for a particular part or component to be complete, it is essential that a certification basis be established for the product on which it is to be installed or for the article itself. Another essential element is that a type or article design be fully defined so that the interaction of products, parts, and components may be assessed, since that interaction may establish additional certification needs.

It is common for a company, within its normal engineering and production system to develop products, parts, components, and processes for future use in certification programs. In the case of a DO certificate holder, if that development is accomplished under the approved DO system, then that development could be eligible for inclusion in subsequent designs, except for the establishment of a product final certification basis and complete product or article definition. It would be inappropriate to consider such development activity as meeting the standards for complete compliance determination because those two elements would be missing. It is appropriate, however, to give credit for any compliance activities accomplished under a DO. The WG refers to this as "eligible data."

"Eligible" data are data developed under the processes of an approved DO system, given a specified, but not necessarily final, certification basis and product type design or article design.

To use "eligible" data, the DO holder must assess the data's compliance against the final type certification basis of the product or article and final type design or article design, respectively, in which it is to be used. It would not be necessary to repeat the compliance activities, provided those activities were appropriate for the final product or article and its certification basis.

The creation of "eligible" data is a concept that is intended for use internal to the DO. No approval or compliance determination can be conferred upon the data if the data are provided for use outside the DO.

IV.E.(6) Voluntary Disclosure Privileges

The FAA has several active voluntary disclosure programs for air carrier, production approval holders and organizations that have an ODA, among others. These programs are designed to encourage the reporting of product and process deficiencies so they can be corrected before unsafe conditions occur. The programs also apply to discovered deviations from FAA-approved procedures manuals and inadvertent regulatory violations. If the deficiencies or non-compliance activities reported were not intentional or criminal in nature, the FAA will refrain from using the disclosures as the basis for any civil penalty, as long as the certificate holder takes swift action to correct the deficiencies discovered.

As stated on the FAA's Voluntary Safety Programs Branch website:

> *"... the FAA believes that aviation safety is well served by providing incentives for certificate holders to correct their own instances of non-compliance and to invest more resources in efforts to preclude their recurrence. The FAA's policy of forgoing civil penalty actions when a certificate holder meets the requirements of this program, is designed to encourage compliance with the FAA's regulations, foster safe operating practices, and promote the development of internal evaluation programs."*

Although the DO is a new type of certificate, the WG concludes that the information presented above remains equally applicable for a DO, and the FAA voluntary disclosure policy should be extended to DO certificate holders. Activities under a production approval are already covered by FAA voluntary disclosure policy.

The FAA voluntary disclosure reporting program is presented in AC 00-58A**.** Under the section entitled "Purpose" there is an important exception that must be recognized. The AC states, in part:

> *"The procedures and practices outlined in this AC cannot be applied to those persons who are required to report failures, malfunctions, and defects under 14 CFR Part 21, section 21.3, and do not make those reports in the timeframe required by the regulation."*

This exception to the program is in recognition of a determination made by the FAA that, since there is a regulatory requirement to report under §21.3, the voluntary disclosure of a failure to report cannot relieve the certificate holder from any enforcement that might be based on that failure to report. This exception still appears to be appropriate for a DO certificate holder under the same defined

IV.E.(7) Manufacturing and Production Functions Under DO

There are two types of manufacturing and production functions that need to be addressed with respect to a DO and a production organization:

- Those pre-production manufacturing functions associated with obtaining a DA, and
- Those associated with a production approval (i.e., post-design approval production).

The intention is to allow a DO to utilize its existing FAA-approved production system during pre-production manufacturing functions associated with obtaining a DA. If the organization, within its scope of its design authority, chooses to use their approved production quality system, then it must use the DO procedures manual processes for any of the following:

- Conformity inspection
- Determining conformity of parts and test articles
- Determining conformity of test setup
- Determining conformity of installations

For DOs performing pre-production manufacturing as part of its scope of activities, in addition to the above, the DO Procedures Manual must also contain procedures for:

- Controlling documents and data associated with pre-production manufacturing
- Ensuring that each supplier furnished product, part or appliance conforms to its design.
- Controlling manufacturing processes to ensure conformity to its design.
- Conducting inspections and tests.
- Ensuring calibration and control of all inspection, measuring, and test equipment.
- Documenting the inspection and test status of products, parts, and appliances supplied or manufactured to the design.
- Ensuring that discarded articles are rendered unusable.
- Implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the design or non-compliance with the approved DO Procedures Manual.
- Preventing damage and deterioration of each product, part, and appliance during handling, storage, preservation, packaging, and delivery.
- Identifying, storing, protecting, retrieving, and retaining quality records.
- Planning, conducting, and documenting internal audits to ensure compliance with the approved DO Procedures Manual.

With respect to post-design approval production, the production approval requirements remain the same.

The DO processes would also support the FAA's issuance of special airworthiness certificates in the experimental category for the purpose of research and development or show compliance.

While the WG intended to further discuss the manufacturing and production functions to include the combined design and production organizations (i.e., one certificate comprising design and production), the WG was limited to the pre-production concepts noted above due to schedule constraints. Further discussion would be required to propose a recommendation on additional privileges that may be available for a combined Design Production Organization (DPO).

IV.E.(8) Flight Standards Functions

Section 21.17(a)(1) requires an applicant for a TC to show that its product meets “the applicable requirements of this subchapter that are in effect on the date of application for that certificate.” Part 21 resides in 14 CFR chapter 1, subchapter C, titled "Aircraft." This subchapter covers Parts 21 through 59, which includes the type certification airworthiness standards found in Parts 23-35. The operating rules applicable to these same type certificated aircraft are found in subchapters F and G, which include Parts 91 through 139.

While a TC may legally be awarded without the product complying with appropriate operating requirements, the practice has been to provide an initial operational evaluation of aircraft during the type certification program. That operational evaluation is carried out by the Flight Standards Aircraft Evaluation Group (AEG) that has the responsibility for the particular product being type certificated. The AEG performs or coordinates the following activities associated with the type certification of products, which are discussed in FAA Order 8900.1:

- ICA – Review and find acceptable the maintenance aspects of the ICA which are required under 14 CFR §21.50, and §XX.1529 in the respective aircraft certification standards.
- Flight Operations Evaluation Board (FOEB) – The primary tasks are the development and revision of the master minimum equipment list (MMEL).
- Flight Standardization Board (FSB) – The primary responsibilities are to determine the requirements for pilot type ratings, to develop minimum training recommendations, and to ensure initial flight crewmember competency.
- Maintenance Review Board (MRB) – Establish the minimum maintenance and inspection requirements for transport category aircraft, engines, propellers, and auxiliary power units. Participate in industry steering committee meetings to review the Maintenance Steering Group (MSG)-3 analyses.
- Participate in type certification board and flight manual review board activities.

During type certification, all determinations of compliance to the airworthiness requirements in Parts 23-35 are made by the DO certificate holder, with appropriate FAA oversight. Since compliance with the ICA requirement in §XX.1529, §31.82, §33.4, and §35.4 are to be determined by the DO certificate holder, the WG recommends that the maintenance aspects of those requirements also be determined by the DO. The DO procedures manual would have to contain appropriate procedures that ensure the maintenance aspects of the ICA are properly addressed, consistent with §21.50 and FAA Flight Standards' regulatory guidance.

The WG believes that the formulation and execution of the FOEB, FSB, and MRB should continue as Flight Standards AEG functions, with support from the DO certificate holder. All determinations of compliance to airworthiness standards associated with those boards would be made by the DO certificate holder consistent with its Procedures Manual. Some additional responsibilities associated with the operation of those boards might be assigned to a DO certificate holder, under Flight

Standards policy, after experience is gained. This would necessitate a revision to the DO Procedures Manual.

AEG participation in type certification board and flight manual review board activities would continue to the degree that the FAA Aircraft Certification Service participates in those functions. For new TCs and amended TCs requiring a model change there would be a review by the type certification boards, but it is expected that most major changes would be conducted under DO procedures and would not require board review. This is because the type boards are identified in an FAA order and the DO certificate holder is free to propose its own procedures in lieu of those identified in existing FAA orders.

For a DO, there would not be a flight manual review board as the sole responsibility for determining compliance for the flight manual would reside with the DO certificate holder. Any operational regulations and associated Flight Standards guidance with respect to flight manuals would be complied with through processes and procedures defined in the DO Procedures Manual.

IV.E.(9) Noise, Fuel Venting, and Exhaust Emissions

While Congress has granted the FAA full statutory authority over the airworthiness certification of civil aviation products in the US, the Environmental Protection Agency (EPA) actually guides FAA requirements with respect to noise, fuel venting, and exhaust emissions (14 CFR Parts 34 and 36).

Under the current system, FAA Order 1050.1E sets policies and procedures and assigns responsibilities for ensuring that the FAA complies with environmental procedures as required by the National Environmental Policy Act under the direction of the Council on Environmental Quality. The Order contains examples of actions that normally require an environmental assessment, including noise and emission requirements.

In addition, The Noise Control Act of 1972 requires the FAA to make findings, not withstanding any delegation to companies, other private persons, CAAs, or any procedures for type certificating foreign-manufactured aircraft. The FAA's Office of Environment and Energy (AEE) delegates the authority to make these types of findings to the appropriate FAA Certification Directorate, depending on the type of aircraft involved. That Directorate may not re-delegate the authority and the FAA must base its finding on actual examination of each type design. Individual delegations have been granted by the FAA but they are only for recommending approval, and not finding compliance.

While the WG recognizes the distinction between the airworthiness requirements of 14 CFR and the noise, fuel venting, and emissions requirements, the WG believes that a DO could be found to have the necessary capabilities and expertise to make compliance determinations with respect to the environmental requirements contained in 14 CFR Parts 34 and 36. Specific noise, fuel venting, and emissions processes would be developed within the DO compliance, safety, and quality systems to ensure proper compliance determinations. This is in keeping with the WG's principle of a DO making 100% of the compliance determinations.

The WG recommends that the FAA propose to the EPA that the process-based approach to compliance, as established by DO program principles, is far more robust than the normal delegation process and is sufficient to ensure compliance with the environmental aspects of the 14 CFR Parts 34 and 36. The WG believes this to be consistent with the recommendations set forth by the FAA in response to section 312 of the FAA Modernization and Reform Act of 2012, which recommends "expanding delegation capability to include support for all certification airworthiness standards when appropriate; particularly low-risk or routine activities such [as] those related to noise and emissions tests and ICA."

IV.E.(10) Establishing a Certification Basis

An applicant for a DA may propose a certification basis to the FAA and the FAA establishes the certification basis. With regard to design changes under DO, the WG discussed that the FAA could establish a certification basis by utilizingwithin limited boundaries contained within the DO approved procedures manual. This is considered a FAA pre-decisional approval process provided to the DO. Projects that fall within the approved boundaries would be performed under the domain of the DO without additional FAA input. Industry has identified such pre-decisional approval as being critical to the success of DOs.

IV.E.(11) Changed Product Rule

The derivative type certification requirements, which apply to TCs and STCs, specify the need for FAA to make a determination of the appropriateness of the original type certification basis. This is sometimes referred to as the "changed product rule requirements." As a general rule, those projects would be subject to FAA LOPI, and it is expected that a DO would notify the FAA when it undertakes such projects.

As the FAA gains more confidence in specific DO certificate holders, it may be willing to rely on specific DO approved processes to assist the FAA in making its determinations under the changed product rule.

IV. F. DO Approval of Data

The DO privileges associated with approval of data discussed below are made in consideration of a 14 CFR part 21 accountability framework policy initiative which the FAA has indicated it is currently pursuing for FAA managed certification projects. The FAA has advised that the policy will be formalized in Order 8110.4D and in future changes to Orders 8110.37 and 8100.15. The new policy will clarify that discrete substantiating or descriptive data generated in support of a part 21 certification project do not need to be discretely 'approved'. While the WG accepts the FAA's intent to return to the basic foundations of part 21, the WG believes that this specific change alters an accepted paradigm and practice that has been established over several decades within FAA policy. However, if the FAA continues to pursue this new policy, the WG strongly believes that whether a project is managed by the FAA with designees or by a DO, the status of any data, irrespective of the part 21 process that produced it, should be the same. Should the FAA not pursue this policy change, the FAA must ensure that the DO regulation includes the privilege of making discrete 'compliance determinations' that result in data that 'are' or 'are equivalent' to "FAA-approved" and that the data is internationally recognized within the scope of bilateral agreements.

Data Supporting a Design Approval under Part 21

Current practice has facilitated "FAA approval" of discrete 'substantiating data' as well as discrete 'descriptive data' that ultimately makes up the type design. However, part 21 contains no requirement for "approval" of these discrete data separate from issuing the TC (ref: 14 CFR 21.41 where the TC is defined to include the type design, any operating limitations, the certificate data sheet, the certification basis, and any other conditions or limitations). The 'substantiating data' is the documentation related to the applicant's 'showing', while the 'descriptive data' defines the type design that needs to be determined 'compliant' to the CFRs and ultimately approved when the FAA issues a DA. The WG concurs with the FAA that making this clear would eliminate the perceived value and pedigree many currently attach to data and the assumption that the reason data has value is because the FAA has labeled it "FAA approved".

The significance of getting back to the basics of part 21 is relevant to all discrete data 'showings'. However, it will become even more relevant as the FAA begins to implement risk-based decision making and when it chooses not to be involved in certain aspects of a certification project. In such cases, it would not be logical to require the FAA to status discrete data "showings" when it has chosen not to be involved in making a discrete "finding" of compliance. Doing so wrongly implies that all data need to be statused by the FAA, which implies some level of FAA involvement, even when the FAA has already determined not to be involved in a given aspect of a certification program.

The WG acknowledges that independent of how any data was used in the past, it remains the applicant's responsibility to 'show' compliance even when such data is used to support subsequent part 21 projects. The WG understands that the FAA intends to clarify this in future type certification policy to further reinforce the accountability framework concepts related to design certification. This should include revisions to its 8110-3 and 8110-9 forms to distinguish between when the form is being used for a part 21 project and when it is supporting a part 43 maintenance or other operational requirement associated with an existing DA.

While not the case for part 43 maintenance actions, which will be discussed later, and unlike today's practice, the data produced for the purposes of showing compliance under part 21 needs no label or pedigree designating it as "approved" by the FAA. Instead, the 'descriptive' and 'substantiating' data will only be designated as "found to have shown compliance to the airworthiness standards by the FAA" or "determined compliant to the airworthiness standards by a DO." In either case, only when the FAA issues its DA will it make the single "finding" required by part 21 and in so doing "approve" the 'descriptive data' that defines the complete type design.

Data Supporting Major Design Changes under Part 21

Part 21 currently contains provisions for FAA approval of both major and minor design changes. In promulgating the DO regulation, once a type design is held by a DO, the DO must have the privilege to make all necessary "determinations of compliance" associated with any change and also "approve" the 'descriptive data' by incorporating the change into its type design. While existing statutory law (Title 49, Section 44702) allows only the FAA to issue a certificate, there is no restriction preventing the FAA from allowing a DO to make changes to an existing TC as a privilege of its DO certificate (i.e., DO is not a delegation). In exercising this privilege, the DO will "approve" the 'descriptive data' associated with any design change once it incorporates the change in accordance with its approved procedures. This privilege should be given with respect to any type of DA held by a DO, including PMAs (which are not addressed in Title 49). This privilege should also be given to a DO that is contracted to act as an agent of the applicant to manage its type design. In a supplier role, a DO may provide 'determinations of compliance' that support a design change, however, as a supplier a DO cannot 'approve' design changes since it is not the custodian of the type design.

In promulgating this privilege, the existing part 21 regulations regarding major changes will need to be changed. For major changes, the current regulations *require* that 1) an application be made, 2) the regulations under 21.101 be considered, and 3) the "person" obtain either a STC or an amendment to the TC. There is no alternative process that allows this to happen without the FAA. Today, only the FAA or its designee can address the certification basis or issue an amended TC or STC. Therefore, today the approval of the major change is an FAA activity. In the case of 21.101 the function is inherently governmental and will require the

FAA to be involved. However, the WG foresees that the FAA could facilitate its involvement through a “pre-decisional” process that is part of the DO procedures manual. The DO could follow such a process to ensure that the FAA is properly engaged on certification basis decisions that are outside what is allowed by the pre-decisional process. In this way the DO is not held up and forced to wait on the FAA for the majority of its project activity.

Data Supporting Part 43 Maintenance or any Operational Requirement

While DO “determinations of compliance” associated with seeking a DA or supporting a minor or major change do not need to result in discretely “approved data”, a DO must have the authority to make “determinations of compliance” that result in the creation of “approved data” when required to support part 43 maintenance or any operational requirement associated with an existing type design. In such cases, the data may or may not be part of the approved type design. For example, when a DAH issues a service bulletin, the data is conveyed as a change to the type design. However, a holder (or even the FAA) can provide data to support a unique repair or alteration for an individual owner/operator, an action which does not result in a change to the type design.

The WG contends that the “approved data” required by part 65 for use in part 43 is the approved ‘descriptive data’ and any other “technical data” required to perform the maintenance. (This includes any drawings, material specifications, process specifications, procedures, and other data describing an approved repair or alteration). The WG contends that part 43 does not require any ‘substantiating data’ used to ‘show’ compliance to be approved directly by the FAA. Thus, the DO’s authority to approve data in support of part 43 maintenance applies only to the ‘descriptive data’ (i.e., not the ‘substantiating data’) associated with the DAs it holds. This means that, at its discretion and without any action by the FAA, the DO may create “approved data” to support repairs and alterations by third party owner/operators for DAs held by the DO (or with respect to any other DA for which the DO is authorized to provide data for maintenance under its scope of authority).

As a result of its discussions, the WG sees three possible regulatory options for the FAA to consider in addressing DO “approved data” to support major changes and to support maintenance:

Option 1 – DO has authority to create “FAA approved data”: This option assumes the DO will be authorized to create "FAA-Approved Data” in a manner that does not include delegation. In the FAA's current system, all type design data “approved” by the FAA for use in the global aviation system have been referred to as “FAA-approved.” This option continues with that approach.

For decades 14 CFR §21.95 ("Approval of minor changes in type design") has allowed minor changes to a type design to be “approved under a method acceptable to the Administrator before submitting to the Administrator any substantiating or descriptive data." Additionally, in 14 CFR part 1, the term "approved" is defined as *approved by the Administrator, unless used with reference to another person*. Since section 21.95 makes no reference to another person, the regulation allows for the creation of FAA-approved data without the data being submitted to the FAA or reviewed by the FAA. The FAA-approved data are created when the TC holder executes the "method acceptable to the Administrator."

While section 21.95 applies only to minor changes to a TC, the WG believes that this existing approach can be applied to major type design changes determined to be compliant by a DO (i.e., DO creation of FAA-approved data before any substantiating or descriptive data are submitted to the FAA). The DO regulatory requirements, along with the processes and procedures contained in an FAA-approved DO Procedures Manual, must be sufficiently thorough for the FAA to approve the data resulting from them prior to it being submitted to the FAA. As with minor type design changes, the FAA may review any 'compliance determinations' and supporting data after it has been determined to be compliant by the DO.

Under this concept a DO is not approving data on behalf of the FAA, because a DO is not a delegation. Once the FAA-approved DO process for making a compliance determination has been properly executed, the 'descriptive data' are FAA-approved.

<u>Option 2 – DO has authority to create "DO-approved data" equivalent to "FAA-approved data"</u>: This option would facilitate recognition of "DO-approved data". It would require a change to 14 CFR Part 1, where the term "approved" is defined as *approved by the Administrator, unless used with reference to another person*. The regulation would need to be changed to include other entities entrusted by the administrator to "approve". Under this option, the WG would recommend the definition be revised to: *approved by the Administrator or under the authority of a certificate granted by the administrator, unless used with reference to another person*. In granting this privilege to each DO, it is essential that the FAA affirm to its international airworthiness partners that such DO data is equivalent to being "FAA-approved."

<u>Option 3 – Create a different term for DO "approved data"</u>: This would require a change to parts 65, 121, 135 and 145 instead of part 43 to make it clear that it can be used.

While it may seem easy to simply permit certificate holders to issue "approved" data, this seemingly easy function would actually be far more difficult to reconcile with current regulatory practice than it appears at first glance. The FAA Chief Counsel's office has already met with the WG to explain that the word "approved" is currently defined to encompass inherently governmental tasks, and that office has expressed reservations at permitting a certificate holder to issue approved data. The word "approved" is also a difficult word to redefine in this situation because it used in a variety of different contexts in the FAA regulations to reflect things that are approved by the Administrator, and this use imposes certain constraints on the ability to make changes in the use of the term.

Options 1 and 2 are trying to affect a very specific use of the term "approved" (a subset of the ways that it is used) – the use of the term in the context of data upon which maintenance providers may rely in the case of major repairs and major alterations. Rather than trying to craft language thath does not adversely affect the other uses of the term “approved,” it might be preferable to adopt a different adjective to describe the data that is appropriate for use to support major repairs and major alterations. In order to effect this change, one could define a new term (“purple data” and “eligible data” have been used as placeholders by the WG, but any adjective not already in use in the regulations could be acceptable). The data included under the definition of this adjective would include both FAA approved data and DO-approved data (it would need to be defined in section 1.1 of the regulations to have global impact on all FAA Parts of the regulations). Then, the requirements for approved data currently found in Parts 65, 121, 135, and 145 could simply be updated to reflect the new adjective.

Some positive aspects of this proposed change include (1) it would accomplish the goal of permitting DOs to issues data upon which the maintenance community could rely in a manner that is nearly identical to current practice, except with limited FAA involvement (limited to FAA-chosen LOPI), (2) it would be consistent with existing statutory authority, (3) it would limit the possibility of unintended consequences (impact on other uses in the regulations of the term “approved”), and (4) It would also avoid potential delegation to the public of inherently governmental functions. The negative aspect of this proposal would be the potential need to update international executive agreements (like the maintenance-acceptance provisions of the bilateral agreement with Canada) in order to reflect the new terminology; however this impact would likely apply also to expanded use of the term “approved,” due to the fact that we would be changing the inherent definition of a term upon which the bilaterals rely, which may cause our trading partners to want to revisit the affected bilateral agreements, anyway.

While any of the above three options would be acceptable to industry, the FAA members of the WG indicated that option 3 is likely the most viable option for supporting part 43 maintenance without the use of delegation (an action which was achieved in the past through recognition of SFAR-36 organizations). The FAA expressed concern regarding whether it was statutorily possible to grant DOs the privilege of approving major changes to the DAs under part 21, as Industry prefers. Current FAA thinking is that some form of delegation would be required. The FAA members of the WG acknowledge that, in order to work within the DO construct, any delegation would essentially be performing an administrative function in making its statutorily-required finding. In this role, the delegation would perform the following administrative actions prior to certificate issuance or approving a type design change:

- Verify the FAA’s planned project LOPI is complete without open issues,

- Verify that the statement of compliance was issued by a DO representative authorized to make the statement, and
- There is no knowledge of any non-compliance or unsafe condition conveyed by FAA or DO personnel involved in the project. (Note: This is intended to be a yes or no answer without conducting research.)

In summary, the WG identified three key privileges that a DO must be granted with regard to how it documents its compliance decisions and dispositions data. In all cases the data would require no further 'showing' in regard to the applicability and acceptance of its intended use:

1. New Part 21 Design Approvals -- Make "determinations of compliance" related to the DAs it is seeking to hold under part 21 and similarly to make them as either a supplier to another DO or as an agent contracted to manage a certification project for an applicant seeking a DA, when authorized through a formal interface agreement.
2. Part 21 Type Design Changes --- Make 'determinations of compliance' related to both major and minor changes to the DAs it holds under part 21, or for those it has been contracted as an agent for another holder evidenced by a formal interface agreement, and to also "approve" those type design changes. (Note: in a supplier role, a DO does not 'approve' design changes since it is not the custodian of the type design.)
3. Maintenance and Operations -- Create and distribute "approved data" to support part 43 maintenance or any operational requirement associated with a DA it holds, and similarly with regard to third party DAs (i.e., not held by the DO), but where the data approval is executed within the DO's FAA-authorized scope of authority.

Dissenting Opinion – Approved Data

A member of the WG does not agree with the opinion expressed above, related to data considered to be approved by the FAA. A WG member agrees that the type design, as defined in §21.31, is not only found to comply to applicable airworthiness requirements but is considered to be approved by the FAA, with the issuance of a DA. Thus, the issue is with the FAA desire to not call the substantiating data "approved data."

Section 44704 of Title 49 U.S.C. requires the Administrator to issue a TC (including STC) when a finding is made that the product "meets the regulations and minimum standards prescribed under section 44701(a) of this title." FAA policy has extended this basic premise to all DAs. Those minimum standards include the airworthiness requirements found in 14 CFR. The only way the FAA can make that finding is by reviewing, to whatever degree it deems appropriate, the substantiating data submitted by the applicant to show compliance with applicable airworthiness standards. This statutory requirement is implemented in 14 CFR Part 21. Thus, all substantiating data must be found to comply by the FAA. It would be proper to refer to this data as "data found to comply."

For many decades the FAA has called that "found-to-comply" data "approved data." The words "approved data" have been common place within the U.S. aviation system and have been recognized as having significance by international authorities. Any change to this entrenched concept in U.S. aviation, and the enormous task of reeducating FAA employees, U.S. industry, ICAO, and other airworthiness authorities, should only be undertaken after the FAA has presented a good cause argument for that change. In all of the discussions of this issue within the WG, FAA has never defined the problem they are trying to correct or the new message they are trying to convey by no longer allowing substantiating data to be called "approved data."

A WG member has been unable to identify any process or other action the FAA undertakes to create "approved data" from "data found to comply." A WG member company designees cannot recall any training from the FAA that defines an action they must undertake once they have found data to be compliant, in order for them to check the box on the DER approval form saying the data is approved. A WG member has not been able to find any instructions in DER guidance material that describes any action a designee needs to take to create approved data, other than simply checking the box on the form. Based on that absence of direction and years of history working with the FAA on type certification programs, a WG member believes that "approved" is merely a shorthand way of referring to "data found to comply."

While it could be argued from the above discussions that there is nothing changed about the data itself by not calling it "approved," a WG member fails to see the need for the FAA to change several orders and reeducate the entire international aviation community on why it is not calling substantiating data approved, when in fact the character of the data has not change. A WG member would rather see valuable FAA resources used for more productive purposes, such as continued airworthiness oversight and eliminating design project sequencing. Also, with the FAA calling the type design "approved data" yet not using the same term with respect to substantiating data, it is only natural for some people to conclude that substantiating data has a somewhat lesser safety pedigree in the eyes of the FAA, no matter what the FAA does to combat such a position. To remove the words "FAA approved" will likely be seen as a change in safety or airworthiness status of the data.

IV.F.(1) Service Bulletins and a Standardized form for DO Transmittal of Approved Data

DO-issued service bulletins should be a means for DOs to provide "approved data" (reference approved data option discussions in IV.F) for general use. When issued, service bulletins constitute a change in type design by the holder and convey the necessary “approved data” to implement the change by owner/operators under part 43.

A new or revised form is also needed for domestic and international recognition of “approved data” created under the DO concept. The WG recommends that the form be similar to the FAA Forms 8110-3 and 8100-9 that are currently used to approve data in the FAA’s delegation system. The form should be titled to recognize the source of the data approval and should be traceable to the originator. In addition, there should be no provisions for recommending approval of data. Thus, "approved" is the only statement that can be made about the data.

The new or revised form should contain the same basic information as the Forms 8110-3 and 8100-9 with respect to the compliance data and purpose of the approval. The form should also address both the date the determination of compliance was made as well as the date the form was signed.

The WG believes that allowing FAA designees and DOs to use the same form to be the preferred option. This would help reinforce the equivalency of the data when executed by a DO. The FAA should also consider whether electronic formats would be acceptable for transmitting this type of information to owner/operators.

IV.F.(2) DO Use of Previously Approved Data

The concept of previously approved ‘substantiating’ or ‘descriptive’ data implies that the data has an established pedigree with an FAA approval that makes the data more valuable than data without such a pedigree. However, no inference can be made with respect to the applicability of such data to another DA project unless a “determination of compliance” has been made by the DO. This does not mean that the data has to be regenerated, recalculated or retested by the DO, but no relief regarding the part 21 showing is implied with respect to the new project based on how it was used in the past. The DO will still have to assess the data to determine its applicability to the new project and to make a “determination of compliance” to the cert basis of the new certification project.

In addition, when a DO incorporates a TC’d or Technical Standard Order (TSO) component into its type design, it is only required to show that its type design is compliant with the installation of that component. There is no requirement for the installer to ‘look behind’ the design or compliance status of the component itself. A similar approach can be taken with STCs and PMA parts when they are installed by owner/operators. However, if a DO desires to make an STC or PMA part directly a part of the type design on which it is being installed, then the DO will need to obtain, or have access to, both the ‘substantiating’ and ‘descriptive’ data associated with the STC in order to make its ‘determination of compliance’. Drawing this distinction in no way prevents a TC holder from installing an STC in its production line, but in such cases the STC is not a part of the DO’s type design, but rather a change to that design, installed at the time it is manufactured, but held by another entity.

IV.F.(3) Use of FAA's Delegation System

One of the basic principles developed for DO is that the FAA makes no discrete 'findings' of compliance. Design organizations are issued a DO certificate because they have a demonstrated engineering capability and commitment to compliance. This enables the FAA, using its discretionary authority, not to direct its resources to making numerous discrete compliance 'findings'. Instead, it can rely upon the DO's statement of compliance in making its overall compliance 'finding' when issuing a TC or other DA.

Since the FAA is making no discrete compliance 'findings', there is no basis for allowing the use of engineering designees, either within the DO itself or at its partners/suppliers. Designees are authorized only to perform tasks the FAA itself would otherwise perform. Since the FAA is not making any discrete 'findings' of compliance under the DO concept, there is nothing to delegate. Thus, the advantage to Industry of being able to make all 'determinations of compliance' is that the DO is not dependent upon the existing delegation system.

This does not mean that DOs cannot use individuals and companies that also hold FAA delegations, but those designees would be acting solely as a design supplier resource to the DO and any compliance determinations made by such suppliers must be conducted under a system determined acceptable by the DO. They are not acting as representatives of the FAA Administrator.

IV.F.(4) DO Recognition and Use of Design Suppliers with FAA Credentials (including other DOs)

A DO may take the status of an FAA designee or another DO into consideration when determining the appropriate method and level of supplier oversight it needs to perform. That oversight must be defined within the DO supplier procedures and must include both the qualification of that supplier and periodic oversight. In conducting its oversight of the supplier, the 'project DO' may include as one of its considerations the fact that the supplier is a designee of the FAA, but it must recognize that the FAA will not be conducting oversight on any non-delegation activity. If the supplier is another DO, the FAA will perform oversight of the 'supplier DO', but this does not relieve the 'project DO' of performing oversight.

Irrespective of the FAA credentials of a particular supplier, the 'project DO' must, under its CAS and SMS processes, assess and find acceptable the compliance and safety risk associated with its degree of reliance on this type of supplier. The ‘project DO’ must also be satisfied that these organizations or individuals are performing as expected, and must be aware of any FAA corrective action related to their performance. The ‘project DO’ could achieve this awareness by contractually requiring the designee or ‘supplier DO’ to provide records of any FAA corrective action, such as designee counseling letters or audit records.

A formal supplier interface agreement must exist between a ‘project DO’ and every ‘supplier DO’ providing it with ‘determinations of compliance’. The interface document should address the scope of what the ‘supplier DO’ may accomplish for the ‘project DO.’ The document may authorize the ‘supplier DO’ to follow its existing DO procedures when making “determinations of compliance” associated with the ‘project DO’s’ certification plan. The presence of a supplier interface document in no way relieves the ‘project DO’ from its showing compliance responsibility as an applicant.

V. CHANGE MANAGEMENT PLAN

This section is intended to contain a change management plan which may include industry and regulatory awareness initiatives; industry and regulatory training, coordination with other regulatory authorities (including potential changes to bilateral agreements), and a transition period. As of the original release of this report, a change management plan was not prepared in lieu of completing the development of the DO concepts contained in the prior sections. Further action is recommended to develop a change management plan as intended.

Appendix A. DO Working Group Members

NAME	**ORGANIZATION**
Industry Representatives:	
Beck, Tony	IS&S
Chick, Mike	Duncan Aviation
Desrosier, Walter	GAMA
Diamant Boustead, Jodi	Pratt & Whitney, Canada
Dickstein, Jason	MARPA
Dionne, Paul	Sikorsky
Fernandez, Felipe Eudes Pontes	Embraer
Grove, Robert	Garmin
Haerr, Mike	Rolls Royce
Hill, Paul	GE Aircraft Engines
Hubbs, Chris	Rockwell Collins
Linder, Ben (WG Chair)	Boeing
Markham, Pat	HEICO
Piotrowski, Dennis	BFLAC
Rogozinski, Tom	Honeywell
Trosis, Rick	Gulfstream
FAA Representatives:	
Cloutier, Paul	AFS-340
Collins, Michael	Labor - NATCA
Cook, Bob	AIR-200
Deutschman, Jason	ASW-150
DiPaolo, Tomaso	Labor - NATCA
Geddie, Scott	AIR-140
Jambor, Jacqueline	ACE-112
Janco, Tony	AFS-304
Law, Doug	AIR-120
Linegang, Michael	AIR-120
Quiles, Carlos	AFS-340
Foreign Civil Aviation Authority Representatives:	
Ferguson, Bob	Transport Canada
Hall, Julian	EASA
Labor Representatives:	
Collins, Michael	NATCA
DiPaolo, Tomaso	NATCA

Appendix B.
DO WG Charter

Part 21/SMS ARC
Charter for the Organizational Working Group

1 Scope and Boundaries

a. The Working Group (WG) shall define a Design Organization recognized by the FAA that meets organizational and system requirements sufficient to ensure that the Design Organization is capable of making compliance determinations upon which the FAA may rely.

1. To accomplish this, the WG will produce a Report that recommends those elements listed under section 3.2 (Deliverables).
2. The Report will propose to affect U.S. FAA regulations only, specifically 14 C.F.R. Part 21.
3. The Report will propose changes within the boundaries of existing U.S. statutory law.

b. The WG's efforts will assume that the Design Organization framework will include no delegations (although it will impose no limits on the FAA that would interfere with future decisions by the FAA to delegate).

c. Discussion of whether it is appropriate to amend the regulations to reflect the need for a design organization shall be out of scope (the ARC may debate the propriety of the proposed amendment).

2 Assumptions and Guidance

2.1 Assumptions

a. Under the current FAA regulations:

1. The FAA issues design approvals.
2. The FAA may delegate the examination, testing and inspection necessary to issue a certificate, and the FAA may delegate the issuance of a specific certificate.
3. There is no need to have a design organization as a condition of applying for or holding any FAA design approval.

b. The FAA would like to have design organization regulations, so that the FAA may impose conditions directly on the organizations that hold design approvals. Such conditions may include a requirement to have a safety management system, and shall likely include obligations such as those found in existing 14 C.F.R. [illegible].

c. Each Design Organization shall be required to have some sort of system to manage safety (see section 2.4 WG Integration).

d. Each Design Organization must have some sort of Continued Operational Safety responsibility, and the elements of this will be identified and developed as part of the WG process.

e. The minimum requirements for Design Organization management systems will be linked to the appropriate FAA Safety Management Systems requirements.

f. The proposed regulation shall anticipate that Design Organizations with full privileges would make determinations of compliance for 100% of the showings necessary to issue a certificate or approval.

g. The proposed regulation shall anticipate that Design Organizations with full privileges would have the privilege of issuing a certificate or approval.

h. The FAA will develop an oversight method to interface with (oversee) the design organization and will establish an oversight model (as developed by the Oversight WG).

i. The FAA shall retain the ability to have whatever levels of involvement the FAA finds appropriate based on the FAA's own risk-based resource targeting process and tools (or other processes, tools or methods chosen by the FAA).

j. Implementation: Establish the transition plan of today's FAA system to the recommended/revised system necessary for part 21 changes. Robust change management will be crucial to implementing the revised part 21. Transition plan should include criteria/toll gates, timeline/metrics, etc.

[illegible] 1

2.2 Guidance

a. The FAA is comfortable with the idea of a system in which third-party or other-party auditors conduct compliance audits of Design Organizations, and in which the FAA may review the results of such audits to supplement the FAA's oversight (without delegating the responsibility for ongoing oversight).

b. The WG may want to refer to the FAA production certificate regulations as a model for how to lay out design organization certification standards. For example, 14 CFR 21.137 lays out quality system requirements, and an analogous regulation in the Design Organization regulations might lay out the management system elements for the management system manual.

c. The WG may want to refer to the TCCA Design Organization regulations for guidance.

d. The WG may want to refer to the EASA Design Organization Authorization regulations for guidance.

e. The ARC feels that design organizations are appropriate for those who wish to hold the following design approvals: TC, STC, PMA and TSOA.

3 Tasking

3.1 Relevant Questions

a. Core Questions. Answers to these questions are meant to drive thoughts about the elements that must be considered when developing the proposed regulations. The WG's Report need not include the answers to all of these questions, but it should be based upon the answers (to the extent that the answers are relevant or useful, they may be included in the Report). The initial questions include:

1. The ARC has agreed that design organizations are appropriate for holders of the following design approvals: TC, STC, PMA and TSOA. Who is a design approval applicant and at what stage in the process does such an applicant fit into the design organization?
2. What is the purpose of a design organization? Are there societal benefits? Safety benefits? Will such organizations save government resources? Are there different purposes for different holders?
3. What privileges should be afforded to design organizations? If there are different sorts of design organizations, then how do the privileges of each differ?
4. What are the management processes that a Design Organization should have to ensure it meets its responsibilities and effectively exercises its privileges?
5. What sort of different design organizations should exist? Should there be three levels: a minimum level for first-time applicants, a normal level for ongoing enterprises and a higher level for organizations whose management processes suggest that hazards are managed in a way that minimizes the FAA's necessary level of involvement (along the lines of the CPO discussion)?

b. Additional Questions. These should provide development and drafting discussions but will not have special meetings specifically dedicated to these questions. These questions should be used as a tool for assessing the final Report, which should satisfactorily address these questions:

1. If a design approval holder needs to have a design organization, then at what stage should it have the design organization? At what point might a potential design approval applicant benefit from having a design organization? When do the benefits outweigh the costs? Before initial application? Before the approval or certificate is issued? Does the entity need to maintain the design organization as a condition of retaining the approval or certificate? If there are multiple levels of design organization recognition, then is there a minimum level necessary to retain certain approvals or certificates?
2. Which design approval holders need to have a design organization? Do some design approval holders NOT need a design organization? For example, do applicants for field approvals need design organizations?
3. How will Safety Management Systems be integrated into the design organizations?
4. What explicit [illegible] will exist for the privileges and benefits [illegible]?

OrganizationalWGCharter [illegible] 2

5. How will we ensure that the Design Organization is sufficiently flexible to permit a diversity from small businesses to multi-national corporations?
6. What transitional structure would be appropriate to achieve the privilege and responsibility plans?

3.2 Deliverables

a. The WG shall deliver a proposed regulatory change that (if promulgated) would integrate design organizations into the existing 14 C.F.R. Part 21 scheme of the United States. The regulations shall include:

1. One or more design organization models
   (a) Defining criteria for organizations
   (b) Objective qualifications to obtain each level of design organization recognition
   (c) Continuing obligations/responsibilities to maintain each level of design organization recognition
   (d) Privileges associated with each level of design organization recognition
2. Limitations or alternative processes for those who do not obtain design organization recognition
3. A transition provision
4. Metrics for determining success of the change management system associated with the transition provision

b. The WG shall deliver a proposed change management plan. The change management plan will likely be a broad template that needs to be completed by the FAA with additional details. The change management plan may include:

1. Industry awareness initiatives, including media and trade organization involvement
2. Regulatory awareness initiatives, including media and labor organization involvement
3. Industry training
4. Regulatory training
5. Coordination with other authorities (including possible changes to bilateral agreements)
6. A transition period

3.3 Milestones and Dates

Date	Action	Expected Deliverable
April 5, 2013	Live WG Meeting: What are the expected benefits and purposes of a Design Organization? What must Design Organizations do in order to achieve the expected benefits and purposes?	List of purposes and benefits of a design organization. List of responsibilities associated with design organizations that would support the purposes and benefits. WG project plan with key tasks and milestones and associated dates.
April 8-12, 2013	WG Members to develop lists of privileges	Lists of privileges submitted to the Chair by COB April 12 (Chair will share before April 19 meeting)
April 19, 2013	Telephonic WG Meeting: What privileges should Design Organizations exercise in order to effectively meet their responsibilities?	List of privileges associated with design organizations that would correlate to the responsibilities.

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Date	Action	Expected Deliverable
April 30, 2013	Telephonic WG Meeting: What management systems should Design Organizations have in order to effectively meet their responsibilities and exercise their privileges?	List of expected management processes
May 14, 2013	Telephonic WG Meeting: Who is a design approval applicant?	Confirmation that the focus of design organizations will be TC, PMA, TSOA and STC Working Definition: "design approval applicant" for purposes of the Design Organization Regulations
May 16, 2013	"Tiger Team" Live Meeting: Assemble a first draft outline of the regulatory framework	Establish an outline of where the Design Organization would fit within the regulations leaving "blanks" for filling in the work of the SMS WG Outline the responsibilities and privileges of the Design Organization Share with WG, AIR and AIR-100
June 3-21	WG: Review the Design Organization Outline	Members submit comments on Design Organization Outline by June 21
Approximately June 25	Chair / Delegates Brief FAA AIR-100, AIR-200 and AFS-800 on Design Organization Outline (may be delegated to FAA representatives on the team)	Obtain FAA AIR-100, AIR-200 and AFS-300 Comments on Design Organization Outline
June 27	WG Live Meeting: Discuss Design Organization Outline	Review Comments and finalize on Design Organization Outline
July 2013	Chair / Delegate Meets with SMS WG Chair Chair / Delegate Meets with Oversight WG Chair	Coordination with SMS WG Coordination with Oversight WG
July 16, 2013	ARC meeting	ARC comments on Organization Outline
July 17-18, 2013	"Tiger Team" Live Meeting: Draft Design Organization Report based on Outline and WG Comments	Draft of Proposal
August 2013	WG Live Meeting: Discuss Draft Design Organization Report	Edited Draft of Proposal
September 2013	Chair / Delegates Meet with FAA AIR-100, AIR-200 and AFS-300 to Brief them on DRAFT Design Organization Report (may be delegated to FAA representatives on the team)	Obtain FAA initial thoughts on DRAFT Design Organization Report
September 2013	Chair / Delegate Meets with SMS WG	SMS language in draft Report

Organization WG Charter DRAFT [illegible]

Part 21/SMS ARC
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Date	Action	Expected Deliverable
	Chair to discuss coordination of Report language	
September 2013	Chair/Delegate Meets with Oversight WG Chair to discuss transition plan coordination Chair/Delegate Meets with Cost-Benefit WG Chair to support Cost-Benefit WG efforts	Coordination with Oversight WG. Outline of transition plan highlights Coordination with Cost-Benefit WG to provide data to them
September 17, 2013	ARC meeting	ARC review/comments on draft Report
September 18-19 2013	WG Live Meeting: Discuss transition plan for the Design Organization Report	Transition Plan Outline
Early October 2013	Tiger Team Live Meeting: Develop a transition plan for the Design Organization Report from the WG outline	Transition Plan
November 2013	WG Live Meeting to edit and finalize Design Organization Report	Design Organization Report
December 10, 2013	Final Report Due ARC meeting	Final Report Due ARC review of final report

3.4 WG Integration

a. Allocation of expected benefits and expected costs of the proposed regulation to support the work of the Cost-Benefit Analysis WG.

b. Integration of Safety Management System requirements into Design Manufacturing Organization with the [illegible] WG.

c. Oversight WG will address the criteria for Level of Involvement with the Design and Manufacturing Organization.

4 References

a. [illegible] ARC Report

b. EASA DOA/[illegible] Presentation

c. TCCA Level of Involvement Presentation

5 WG Lead(s) and Members

[illegible]

Appendix C. Glossary of Terms

ACCOUNTABILITY FRAMEWORK: An established set of responsibilities and commitments of the FAA and Industry.

AGENT DO: A DO that has been contracted by a DA applicant to manage a certification project.

APPROVED DATA: Descriptive data approved by FAA employees, its designees, or in accordance with Part 1.

AUDIT: Formal scheduled review by the FAA or the DO of the DO's processes, projects, and compliance with DO regulatory requirements, as determined by the FAA or the DO internal audit function. It is expected to include some review of compliance findings on closed projects. For the FAA, audit is a part of FAA's Certificate Management function.

DO EXECUTIVE: The company individual directly responsible for ensuring that the DO meets all of its regulatory responsibilities.

DO POINT(s) OF CONTACT: The individual(s) within the DO responsible for all communications with the FAA.

CERTIFICATE MANAGEMENT: FAA actions to monitor the DO certificate holder and to determine the holder's compliance with the provisions of its certificate(s).

COMPLIANCE ASSURANCE SYSTEM (CAS): DO holder's system for maintaining design configuration control and ensuring that it complies with the applicable regulations.

COMPLIANCE FINDING: FAA decision (either directly or through a designee) that compliance has been shown with the applicable airworthiness standards.

CULTURE OF COMPLIANCE: Knowledge, beliefs, attitudes, and behaviors of an organization that are focused on ensuring regulatory compliance within all its activities.

DESCRIPTIVE DATA: Data that defines the type design that needs to be determined compliant to the applicable airworthiness standards. The descriptive data is what is approved by the FAA when a DA certificate is issued.

DETERMINATION OF COMPLIANCE: A decision made by the DO that compliance has been shown and verified with the applicable airworthiness standards. It may also be a decision made by the DO that data previously used as part of another project are applicable to the design of the new product, part, or appliance for which it is to be used, including the applicable certification or approval basis.

ELIGIBLE DATA: Data developed under an assumed, but not FAA-established, certification basis, and product type design if appropriate.

FINDING OF COMPLIANCE: FAA decision that the applicable regulatory requirements/airworthiness standards have been met. Statutorily required action to issue a certificate.

PROJECT DO: The DO responsible for overall integration of a specific certification project. The project DO ensures all determinations of compliance are complete and may be the DA applicant or may act on behalf of a DA applicant (i.e., contracted as an agent DO).

SAFETY CULTURE: The product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to an organization's safety programs.

SAFETY MANAGEMENT: The act of understanding and making decisions and taking actions to lower risk, inherent in all human activity, to acceptable levels.

SAFETY MANAGEMENT SYSTEM: An integrated collection of processes, procedures, and programs that ensures a formalized and proactive approach to system safety through risk management. Risk analysis and assessment are required for all changes to identify safety impacts. The SMS is a closed-loop system, ensuring all changes are documented and all problems or issues are tracked to conclusion. When properly implemented, an SMS establishes a safety philosophy or culture that permeates the entire organization in the monitoring and continuous improvement of safety.

SCOPE OF AUTHORITY: A combination of explicit statements of the DO Certificate and Terms of Approval that identify the capability of the DO and to which category of aircraft (e.g., large airplanes, commuter airplanes, etc.) and products that the DO is approved to conduct its operations.

SENIOR COMPANY MANAGEMENT: Those in the company management chain above the DO Executive who are accountable for the actions of the DO.

SHOWING OF COMPLIANCE: An applicant's demonstration of compliance to an airworthiness standard (i.e., 14 CFR 23, 25, 27, 29, 33, 35) and is comprised of substantiating data, statements, and/or other acceptable methods of demonstration (e.g., acceptable MOC).

STATEMENT OF COMPLIANCE: A statement from the DO to the Administrator certifying that compliance with the applicable airworthiness standards for the project has been determined in accordance with the procedures listed in its FAA-approved DO Procedures Manual. With this statement, the DO is indicating that the project is complete and ready for the FAA to issue the certificate or DA.

SUBSTANTIATING DATA: Documentation related to a DA applicant's showing of compliance to the applicable airworthiness standards.

SUPPLIER DO: A separate DO entity in its own right that provides engineering data to a project DO. The supplied data supports the project DO's certification project.

VERIFICATION OF COMPLIANCE: An independent check, or equivalent, of the showing of compliance leading to a DO determination of compliance.

Appendix D. List of Acronyms

AC	Advisory Circular
AD	Airworthiness Directive
AEE	FAA Office of Environment and Energy
AEG	Aircraft Evaluation Group
ARC	Aviation Rulemaking Committee
CAA	Civil Aviation Authority of another country
CAS	Compliance Assurance System
CCS	Compliance Certification System
CDO	Certified Design Organization
CFR	Code of Federal Regulations
COS	Continued Operational Safety
CPN	Certification Project Notification
DO	Design Organization
DA	Design Approval
DAH	Design Approval Holder
DMS	Design Management System
DOA	Design Organization Approval
DPO	Design Production Organization
EASA	European Aviation Safety Agency
ELOS	Equivalent Level of Safety
EPA	Environmental Protection Agency
FAA	Federal Aviation Administration
FME	Failure Modes Effects
FMEA	Failure Modes and Effects Analysis
FOEB	Flight Operations Evaluation Board
FSB	Flight Standardization Board
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
IP	Issue Paper
LOPI	Level of Project Involvement

MOC	Means of Compliance
MRB	Maintenance Review Board
NHTSA	National Highway Transportation Safety Administration
NPRM	Notice of Proposed Rulemaking
OCS	Organization Control System
ODA	Organization Designation Authorization
PMA	Parts Manufacturer Approval
POC	Point(s) of Contact
PSE	Principal Structural Element
SC	Special Condition
SFAR	Special Federal Aviation Regulation
SMS	Safety Management System
SSP	Specialty Service Provider
STC	Supplemental Type Certificate
TC	Type Certificate
TSO	Technical Standard Order
TSOA	Technical Standard Order Approval
US	United States
USC	United States Code
WG	Working Group

Appendix E. DO Challenges, Benefits and Concerns

The WG began discussions by identifying various challenges, benefits, and concerns with the existing system and the move to a DO model. The following challenges, benefits and concerns were identified as a reference for the issues that might need to be addressed. It merely represents a starting point for the WG that led to the WG report. The WG report contains the final product, without a revision to the initial discussion topics captured in this Appendix. This Appendix is intended to serve only as a reference to the initial thoughts. Note that these initial thoughts may have been captured prior to full participation of the WG members listed in Appendix A.

General

- **Challenge 1**: Meeting SMS requirements established by International Civil Aviation Organization (ICAO). A regulatory SMS for design activity cannot be implemented without regulatory recognition of a design organization. SMS cannot be applied to a FAA-delegated organization.
  - **Benefit:** A DO model would enable implementation of SMS by FAA on design organizations as required by ICAO and FAA requirements, such that no differences would be filed with ICAO.
  - **Concern**. The benefits of the DO model will not be commensurate with or greater than the potential regulatory SMS burden imposed on the design organization.

FAA

- **Challenge 2:** Any applicant, regardless of qualifications, may apply for a DA under existing requirements. The FAA is experiencing a significant increase in the number of STC applications by persons who do not currently hold a DA and are unfamiliar with applicant and holder responsibilities.
  - **Benefit:** DO approval/certification/oversight would give the FAA a mechanism to require minimum applicant and holder qualifications.
  - **Concern**. The DO model may not be flexible enough to support small business operations, the establishment of new companies, and a range of capability levels appropriate to the range of aviation products being designed, especially new or novel designs.
- **Challenge 3:** Existing practices rely heavily on the "show/find" actions occurring at the end of the design process, regardless of any compliance design processes that may exist.
  - **Benefit:** DO approval/certification/oversight would give the FAA a mechanism to require compliance assurance within the design processes.

- **Concern:** FAA approval of the DO manual may be used to restrict a DO from choosing where to place an emphasis in compliance processes (e.g., some companies may wish to emphasize early processes for assuring compliance, while others may rely more heavily on late-term processes for verifying compliance).

- **Challenge 4:** FAA currently expends significant resources making discrete compliance findings related to specific products and supporting DAs. Future federal budget expectations do not allow for growth in the federal workforce, so growth of the aviation industry requires a different approach.

  - **Benefit:** DO approval/certification/oversight would give the FAA a mechanism to focus on the system used for compliance assurance and aviation system safety. Additionally, the DO model provides the opportunity for greater capacity in the system.

  - **Concern**: Because the FAA does not fully utilize its ability to rely on ODA to remove itself from discrete compliance findings, FAA and ODA holders do not receive the perceived benefits associated with the scope of the ODA. Similarly, DO implementation may have similar issues and a reduced benefit relative to the notion of a fully-delegated ODA.

- **Challenge 5:** Once a DA has been issued, the only mandatory actions FAA can take to address aircraft design compliance or safety issues is to issue ADs against products or continued airworthiness actions as defined in 14 CFR part 26. ADs do not address root cause (i.e., DAH practices that may have created an unsafe condition). Other than under ODA, the FAA cannot take certificate action against non-compliant DAH practices without affecting the eligibility of products manufactured by that holder for operation. In other words, FAA certificate action has significant downstream effects that may be considered inappropriate.

  - **Benefit 1:** DO approval/certification/oversight creates an accountable organization which may be held responsible for mandatory action to address safety issues.

  - **Concern 1**: It is unclear how a DO addresses this challenge differently or better than an ODA.

  - **Benefit 2:** DO approval/certification/oversight opens up new opportunities for implementing safety improvements that do not rise to the level of an unsafe condition.

  - **Concern 2:** FAA may use the opportunity of DO approval and oversight to mandate perceived improvements that are above and beyond actual regulatory requirements.

  - **Benefit 3:** DOs reinforce both a safe culture within a company and the accountability framework addressed in Part 21 and encourage a reactive compliance culture to become a proactive compliance culture.

Industry:

- **Challenge 6:** Industry control of development and certification schedules is difficult. Delays in certification plan approval and Issue Paper (IP) closure generate additional uncertainty on program schedule and costs. DA applicants cannot currently rely on internal capabilities for determining compliance (i.e., applicant compliance capabilities on any given project are always subject to question by the FAA and FAA inquiries result in product delivery schedule impacts). Currently, for a new airplane TC, Special Conditions (SC), Equivalent Level of Safety (ELOS), and specific agreed MOC are generated. In some cases IPs may take as much as two to three years to close. Delays in IP closures (Stage 4) generate uncertainty on program schedule and cost.
    - **Benefit:** DO would give an applicant greater control over product delivery schedule. Moving the FAA from specific compliance findings to actual governmental actions is in the direction of best use of FAA resources to achieve safer products.
    - **Concern**: The FAA may be reluctant to rely on applicant capabilities (see Challenge 9). Additionally, agreement on the MOC may still delay projects.
- **Challenge 7:** Accountable applicants are currently unable to rely on the acceptability of supplier or consortium-member contributions to certification.
    - **Benefit:** DO would give the accountable applicant an independent mechanism to assure the validity of supplier or consortium-member's contributions to aircraft certification.
    - **Concern**: Supplier DOs and consortiums with member company DOs may confuse the accountability picture. A single point of accountability is still needed. Accountability still needs to be clearly attributable to the appropriate applicant organization.
    - **Concern**: The FAA will likely not have adequate resources to oversee multiple suppliers or complex consortiums. As such, product applicants must be responsible for suppliers.
- **Challenge 8:** ODA places limitations on the flexibility of a company's processes.
    - **Benefit:** DO should afford greater flexibility in company processes for assuring compliance.

Other tangential challenges:

- **Challenge 9:** FAA culture is hesitant to fully rely on applicant accountability for certificate issuance.
    - **Benefit:** DO certification and oversight would provide the FAA both a pre-design-approval and post-design-approval opportunity to assess the knowledge, capabilities and practices of aircraft certification design organizations.

- **Concern**: The DO model may not be fully utilized by the FAA. The limit of this WG's ability to affect this is to provide a recommendation to FAA management regarding the benefits and need for the DO model. Significant cultural changes within the FAA and industry will be required to fully realize DO benefits.

- **Challenge 10:** No requirements currently exist for STC applicants to assess the compatibility of their designs with other STCs.

  - **Benefit:** DOs could be qualified for the privilege of supporting compatibility assessments for integration of multiple STCs.

  - **Concern:** Requirements for this privilege have not yet been identified. This may be out of scope for this WG.

- **Challenge 11:** Industry has significant concern over the lack of consistency in FAA LOPI decisions. There are three significant areas where LOPI decision are inconsistent:
  1) FAA involvement in compliance activities not related to safety critical areas;
  2) FAA involvement in activities where the applicant has full competence to make compliance determination; and
  3) FAA involvement at the level of approving documents such as test plans or results.

  Industry members believe these are neither the proper nor efficient means of FAA involvement.

  - **Benefit:** DO would provide a better model for the FAA to recognize capabilities and establish a consistent risk-based LOPI framework.

  - **Concern:** This may be out of scope for this WG.

Appendix F.
DO Threshold Decision Tree

Figure F-1 – Primary Threshold Determination

Figure F-2 – Secondary Threshold Determination

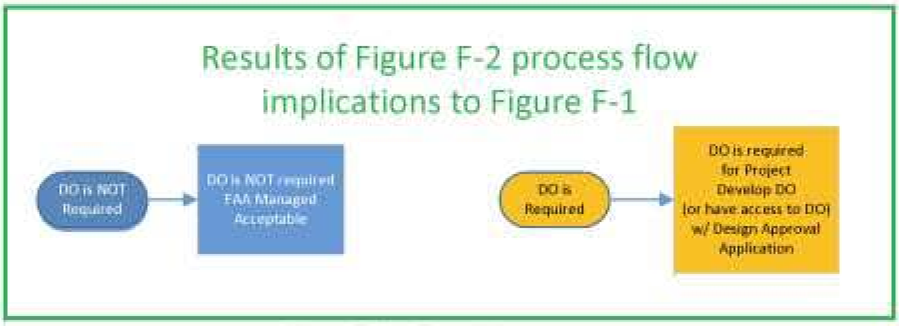

Figure F-3 – Result Assessment

APPENDIX G—SAFETY MANAGEMENT SYSTEMS WORKING GROUP REPORT

21ARC Working Document – Not for Distribution

FAA Part 21 / Safety Management Systems

Aviation Rulemaking Committee

(Part 21 / SMS-ARC)

Safety Management Systems Working Group Report

January 17, 2014

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SECTION 1.0 Executive Summary

1.1 Safety Management System Working Group (SMS WG) Overview

The Safety Management System Working Group (SMS WG) was chartered by the Part 21/SMS Aviation Rulemaking Committee (ARC) to provide recommendations and guidance to the Federal Aviation Administration (FAA) for development and implementation of SMS rulemaking applicable to organizations involved in the Design and Manufacturing (D&M) of aviation products and articles. The charter included several taskings each of which have been addressed by the SMS WG. SMS WG membership included individuals with expertise in SMS representing organizations for the design and manufacture of aviation products, articles, and replacement parts, association representatives on behalf of general aviation, and contributors from the FAA along with observers from European Aviation Safety Agency (EASA), Transport Canada Civil Aviation (TCCA), and National Civil Aviation Agency - Brazil (ANAC). Nine meetings were held in 2013 and 2014 during which the SMS WG addressed the taskings and developed recommendations.

1.2 Summary of Recommendations

The following is a summary listing of SMS WG recommendations in response to the charter and associated taskings:

- **14 CFR Incorporation:** The SMS WG has determined that the SMS requirements in the proposed 14 Code of Federal Regulations (CFR) Part 5 (Docket Number: FAA-2009-0671) (hereafter referred to as "Part 5"), with consideration given to D&M sector comments for recommended changes contained in the Docket, are appropriate for D&M organizations. In addition, the SMS WG evaluated §5.27 (Coordination of Emergency Response Planning) and determined it is not necessary for D&M organizations. Therefore, we recommend that FAA modify 14 CFR Part 21 (hereafter referred to as "Part 21") to make Part 5, excluding §5.27, the SMS requirements for organizations meeting the applicability threshold. (Refer to section 4.2)

- **Applicability:** The SMS WG recommends that the FAA develop an applicability threshold that requires SMS for organizations that:

  - Design or manufacture products (i.e., aircraft, engines, propellers) or,
  - Design or manufacture articles whose failure could directly prevent continued safe flight and landing; or
  - Make design changes to a product, through a Supplemental Type Certificate (STC), failure of which could directly prevent continued safe flight and landing.

  This recommendation is not intended to discourage voluntary implementation of SMS for organizations producing articles with criticality falling below the applicability threshold. (Refer to section 4.3)

- **Scalability:** Scalability of SMS has been addressed through the applicability threshold. Therefore, the SMS WG recommends that all Part 5 SMS components / elements (with the exception of §5.27) be applied for those design and/or manufacturing organizations

that meet the applicability threshold.
(Refer to section 4.3)

- **Policy and Guidance Material:** The SMS WG developed SMS regulatory material and a basis for preamble, policy, and guidance material, as provided in this report; however, we determined that more work was necessary to produce supporting guidance material. We recommend that the SMS WG continue to develop supporting guidance material with an objective to complete the task by October 2014 by providing an addendum to this report.
(Refer to section 4.4)

- **SMS Concept of Operations:** The SMS WG has developed a Concept of Operations (CONOPS) which describes the intent of the Part 5 SMS framework (Safety Policy, Safety Risk Management, Safety Assurance, and Safety Promotion) for D&M organizations as it applies to each life cycle phase (design and certification, production and airworthiness certification, and continued airworthiness) of a product or article. We recommend that the CONOPS form the basis for the development of preamble, policy, and guidance material. The SMS WG also recommends that, as described in the CONOPS, existing processes and procedures be considered as meeting the intent of Part 5.
(Refer to section 4.5)

- **14 CFR 21.3 for SMS:** The SMS WG has determined that §21.3 (Reporting of Failures, Malfunctions, or Defects) should be updated. We recommend the FAA task an ARC sub-team to develop recommendations to minimize or eliminate redundant and inconsistent reporting, record keeping, and risk assessment requirements for organizations with an SMS. Additionally, the sub-team should address appropriate reporting requirements and systems to enable the FAA to exercise its oversight and system level risk management responsibilities.
(Refer to section 4.7)

1.3 Additional Recommendations

The following is a summary list of additional SMS WG recommendations which were not directly tied to the charter or taskings:

- **Acceptable Safety Risk Determination:** The SMS WG recommends FAA establish WGs to develop risk acceptance criteria for products and articles. Advisory Circular (AC) 39-8 provides one example of a risk acceptance criteria that has been developed [for Transport category engines and Auxiliary Power Units (APUs)] in conjunction with the D&M industry and is mutually accepted by FAA and industry (§5.55).
(Refer to section 5.1)

- **Availability of Data for Safety Risk Management (SRM):** The SMS WG recommends that the FAA develop an approach to make fleet data already provided to the FAA (hours, flights, reported failures, malfunctions, and defects and service difficulty reports) readily available to D&M organizations, in support of executing SRM (§5.71).
(Refer to section 5.2)

SECTION 2.0 SMS WG Charter / Membership / Taskings

The Part 21 / SMS-ARC developed a draft charter, membership, and tasking list for the SMS WG. These were further developed by the SMS WG and submitted to the full ARC for approval. Summaries of the charter, membership, taskings, and meeting schedules are provided in the following sections.

2.1 SMS WG Charter

The SMS WG was chartered (refer to Appendix A) by the Part 21 / SMS-ARC to develop a report which provides comments and recommendations for developing and implementing SMS regulatory requirements in a D&M environment. Key charter deliverables include the following:

- Recommendations for rulemaking, suggested processes, policies, and guidance to align Part 21 with the SMS requirements documented in Part 5.
- Identification and assessment of any differences between the recently adopted SMS requirements in International Civil Aviation Organization (ICAO) Annex 19 and Part 5.
- Evaluation of options and provide recommendations to the FAA on the optimum solution for the application of SMS to D&M organizations.
- Recommendation as to which Design Approval Holder (DAH) and Production Approval Holder (PAH) organizations should have SMS requirements applied to them. This recommendation should include the scalability of SMS to D&M organizations based on their size, complexity, and safety risk introduced by their products.

2.2 SMS WG Membership

The SMS WG membership (refer to Appendix B) is comprised of a diverse group of individuals with expertise in SMS and related subject matter areas representing organizations regulated under Part 21 for the D&M of type certificated aircraft and engines, approved avionics articles and systems, association representatives on behalf of general aviation and modification and replacement part manufacturers, contributors from the FAA Aircraft Certification Service, and observers from EASA, TCCA, and ANAC.

2.3 SMS WG Taskings

The SMS WG was tasked by the Part 21 / SMS-ARC to complete Tasks 1 through 8 as shown in sections 4.1 through 4.6. The SMS WG added Task 9 during the course of our meetings. The nine tasks are summarized as follows:

1. Perform a regulatory gap analysis between the SMS requirements defined in Part 5, ICAO Annex 19, and Part 21.
2. Develop, evaluate options, and make a recommendation(s), for incorporation of SMS into 14 CFR for D&M organizations.
3. Provide a recommendation as to which D&M approval holder organizations should have SMS requirements applied to them.

4. Produce preamble, regulatory, and guidance material for SMS application to D&M organizations, include an "operational" definition of a hazard throughout the life cycle of a product in SRM.
5. Provide guidance that accounts for scalability of SMS to D&M organizations based on their size, complexity, and safety risk introduced by their products.
6. Define the end state (roles, relationships, and responsibilities) for SMS in a D&M organization considering design, certification, production, and in-service support.
7. Perform a review of "strategic" safety decisions that are required to be made during the design, certification, and production phases throughout the life cycle of the product.
8. Coordinate SMS WG activities with Part 21 ARC and supporting WGs [Oversight, Cost-Benefit-Analysis (CBA), and Organizational].
9. Provide a recommendation as to what §21.3 should look like for a D&M organization with a SMS.

2.4 SMS WG Meetings

The SMS WG conducted nine meetings in 2013 and 2014 to address the charter and associated taskings. These meetings were held on the dates and locations identified in the following paragraph and represented over 100 hours of detailed discussion. WG members attended either in person or by phone with web link.

1. Kickoff Meeting: April 4-5, 2013; Washington, DC
2. WG Meeting: April 30-May 1, 2013; Phoenix, AZ
3. WG Meeting: June 11-12, 2013; Seattle, WA
4. WG Meeting: July 17-18, 2013; Washington, DC
5. WG Meeting: August 13-14, 2013; Wichita, KS
6. WG Meeting: September 18-19, 2013; Washington, DC
7. WG Meeting: October 30-31, 2013; Hartford, CT
8. WG Meeting: December 10-11, 2013; Washington, DC
9. Final Meeting: January 13-15, 2014; Phoenix, AZ

SECTION 3.0 Key Assumptions

The SMS WG has documented the following assumptions which were key to our discussions and recommendations.

1. The SMS requirements considered by the SMS WG are as written in Part 5 (including consideration of the D&M sector comments in response to the Notice of Proposed Rulemaking (NPRM) [Docket No. FAA–2009–0671; Notice No. 10–15]).

   NOTE: If this assumption is shown to be invalid, the recommendations of the SMS WG should be reviewed by industry against the new Part 5.

2. The Organizational WG will set the applicability requirements for D&M organizations.
3. SMS is a management system that is described by assigned responsibilities and the functional relationship of those responsible for safety to management and other organizational components.
4. The Organizational WG will recommend that approved D&M organizations be given a certificate. This will allow Part 5 to remain applicable to a certificate holder.
5. The definition of a "hazard" is a condition that could foreseeably cause or contribute to an aircraft accident. Reference Order 8040.4A for the definition of an aircraft accident.
6. The FAA inspector workforce will need to possess a high level of knowledge and understanding of SMS fundamentals to evaluate an applicant's SMS in a context of performance-based requirements. For example, evaluating initial SMS application and conducting SMS audits requires that inspectors be able to assess whether an organization's processes simultaneously satisfy multiple regulatory requirements, e.g., Part 5, Part 21 and Part 183.
7. The SMS requirements as written in Part 5 represent "performance-based" requirements. FAA oversight of an approval or certificate holder will be primarily focused on the existence and function of SMS processes, rather than the discrete outputs of those processes.
8. From an SMS perspective, there are three phases to the life cycle of a product or article that need to be addressed: design and certification, production and airworthiness certification, and continued airworthiness.

SECTION 4.0 Responses and Recommendations to Taskings and Charter

4.1 Task 1: Regulatory Gap Assessment

Task 1 required the SMS WG to perform a regulatory gap analysis between the SMS requirements in Part 5, ICAO Annex 19, and Part 21.

4.1.1 Task 1: SMS WG Response

The SMS WG completed a detailed gap assessment between Part 5, ICAO Annex 19, and Part 21 (see Appendix C). The assessment was conducted for three D&M life cycle phases: design and certification, production and airworthiness certification, and continued airworthiness (in-service). The SMS WG determined that Part 5 contains all of the SMS components and elements addressed by ICAO Annex 19. The objective of the gap assessment was to determine which elements of Part 5 "are covered"/"are not covered" by Part 21.

The ICAO SMS framework has four main components: Safety Policy, Safety Risk Management (SRM), Safety Assurance (SA), and Safety Promotion; which is consistent with the FAA's (proposed) Part 5 SMS regulations that have been structured around these four components as:

- Subpart B – Safety Policy
- Subpart C – Safety Risk Management (SRM)
- Subpart D – Safety Assurance (SA)
- Subpart E – Safety Promotion

Part 5 also includes Subpart A (*General*) which includes *Applicability*, *General requirements* and *Definitions* and Subpart F (*SMS Documentation and recordkeeping*), which, in the ICAO Framework is included as part of Safety Policy.

A summary of the results from the gap assessment is provided in Table 1. The colors in Table 1 indicate the following:

- Green: Part 21 fully addresses the Part 5 element.
- Yellow: Part 21 partially addresses the Part 5 element.
- Red: Part 21 does not address the Part 5 element.

There are no green entries in Table 1, which indicates that Part 21 does not fully address any of the SMS elements in Part 5. This result was expected since Part 21 addresses certification procedures for products and articles and does not mention SMS, SMS Framework [i.e., Safety Policy, SRM, SA, Safety Promotion], or associated documentation and record keeping requirements.

The Part 21 coverage for each Part 5 subpart is discussed in the following sections.

Table 1: Gap Assessment Summary
Does Part 21 Currently Address SMS Requirements in Defined Part 5?

SUBPART A – GENERAL	DESIGN AND CERTIFICATION	PRODUCTION AND AIRWORTHINESS CERTIFICATION	CONTINUED AIRWORTHINESS	COMMENTS
5.1 Applicability				Part 21 does not mention or define any SMS requirements.
5.3 General Requirements				
5.5 Definitions				
SUBPART B – SAFETY POLICY	**DESIGN AND CERTIFICATION**	**PRODUCTION AND AIRWORTHINESS CERTIFICATION**	**CONTINUED AIRWORTHINESS**	**COMMENTS**
5.21 Safety Policy				Part 21 does not require a safety policy, designate safety accountabilities or responsibilities, or require emergency response planning.
5.23 Safety Accountability and Authority				
5.25 Designation and Responsibilities of Required Safety Management Personnel				
5.27 Coordination of Emergency Response Planning				
SUBPART C – SAFETY RISK MANAGEMENT	**DESIGN AND CERTIFICATION**	**PRODUCTION AND INITIAL AIRWORTHINESS**	**IN-SERVICE**	**COMMENTS**
5.51 Applicability	Product			Part 21 certification process addresses the intent of SRM through the certification process for products. Quality system partially addresses SRM; however, there is no mention of SRM for in-service issues. Organization Designation Authorization (ODA) (see §183.63) does require in-service monitoring of products, but not SRM.
	[illegible]			
5.53 System Analysis and Hazard Identification	Product			
	[illegible]			
5.55 Safety Risk Assessment and Control	Product			
	[illegible]			
SUBPART D – SAFETY ASSURANCE	**DESIGN AND CERTIFICATION**	**PRODUCTION AND INITIAL AIRWORTHINESS**	**IN-SERVICE**	**COMMENTS**
5.71 Safety Performance Monitoring and Measurement				Part 21 certification process and quality system partially addresses SA. Several SA requirements related to SMS are not addressed. ODA (see §183.63) does require in-service monitoring of products.
5.73 Safety Performance Assessment				
5.75 Continuous Improvement				
SUBPART E – SAFETY PROMOTION	**DESIGN AND CERTIFICATION**	**PRODUCTION AND INITIAL AIRWORTHINESS**	**IN-SERVICE**	**COMMENTS**
5.91 Competencies and Training				Part 21 does not require SMS or required training and communication.
5.93 Safety Communication				
SUBPART F – SMS DOCUMENTATION AND RECORDKEEPING	**DESIGN AND CERTIFICATION**	**PRODUCTION AND INITIAL AIRWORTHINESS**	**IN-SERVICE**	**COMMENTS**
5.95 SMS Documentation				Part 21 does not require SMS or required documentation and records.
5.97 SMS Records				

LEGEND

FULLY COVERS | PARTIALLY COVERS | DOES NOT COVER

21ARC Working Document – Not for Distribution

4.1.1.1 Subpart A: General

Subpart A contains three elements: §5.1 (*Applicability*), §5.3 (*General requirements*), and §5.5 (*Definitions*). None of these elements are addressed in Part 21 for any of the D&M life cycle phases.

Element §5.1 specifically discusses 14 CFR Part 119 certificate holders and 14 CFR Part 121 operators. Modification of this element will be required to include Part 21 design and production organization certificate holders.

4.1.1.2 Subpart B: Safety Policy

Subpart B contains four elements: §5.21 (*Safety policy*), §5.23 (*Safety accountability and authority*), §5.25 (*Designation and responsibilities of required safety management personnel*), and §5.27 (*Coordination of emergency response planning*). None of these elements are addressed in Part 21 for any of the D&M life cycle phases.

4.1.1.3 Subpart C: SRM

Subpart C contains three elements §5.51 (*Applicability*), §5.53 (*System analysis and hazard identification*), and §5.55 (*Safety risk assessment and control*). These elements are discussed in the following sections for the three life cycle phases.

4.1.1.3.1 Design and Certification Life Cycle Phase

The SMS WG decided to evaluate the design and certification life cycle phase for both products and organizations. This allowed a more detailed assessment between Part 5 and Part 21.

1. For products, Part 21 partially addresses SRM through compliance with the airworthiness standards (for design and certification). In general, the airworthiness standards are based on a known hazard and prescribe required design features and characteristics to mitigate the risk posed by the hazard. In addition, some aspects of SRM are addressed through §183.63 for organizations with an ODA.
2. For organizations, Part 21 does not require any of the SRM elements during the design and certification life cycle phase.

4.1.1.3.2 Production and Airworthiness Certification Life Cycle Phase

Part 21 partially addresses the SRM requirements for the production and airworthiness certification life cycle phase through the quality system. The key SMS activities during production are to build conforming products which are in a condition for safe operation. A quality system currently addresses many elements to ensure that safe and conforming parts are produced.

Some examples of how the quality system partially addresses SRM during this life cycle phase include §21.137(m) which requires that the PAH have procedures to receive and process feedback on failures, malfunctions, and defects. In addition, §21.137(n) requires procedures for identifying, analyzing, and initiating appropriate corrective action for quality escapes. These two regulations partially address the SRM requirements to identify, assess, and control the risk of potential hazards which could be introduced during this life cycle phase.

4.1.1.3.3 Continued Airworthiness Life Cycle Phase

Part 21 does not address SRM for the continued airworthiness life cycle phase with the potential exception of 21.137(m) which does mention in-service feedback, but does not address risk management explicitly. Given this limited coverage, the SMS WG determined that there is no coverage for this life cycle phase.

4.1.1.4 Subpart D: Safety Assurance

Subpart D contains three elements: §5.71 (*Safety performance monitoring and measurement*), §5.73 (*Safety performance assessment*), and §5.75 (*Continuous improvement*).

During the design and certification life cycle phase, §5.71 is partially addressed through compliance with the airworthiness standards. The remaining SA elements (i.e., §5.73, §5.75) are not addressed.

The quality system partially addresses the SA requirements for the production and airworthiness certification life cycle phase through procedures focused on producing conforming and safe products and articles.

During the in-service life cycle phase, §5.71 is partially addressed through §21.3 reporting and the quality management system. The remaining SA elements (§5.73 and §5.75) are not addressed.

4.1.1.5 Subpart E: Safety Promotion

Subpart E contains two elements §5.91 (*Competencies and training*) and §5.93 (*Safety communication*). None of these elements are addressed in Part 21 for any of the D&M life cycle phases.

4.1.1.6 Subpart F: SMS Documentation and Recordkeeping

Subpart F contains two elements §5.95 (*SMS documentation*) and §5.97 (*SMS records*). None of these elements are addressed in Part 21 for any of the D&M life cycle phases.

There are significant document and recordkeeping requirements in a quality system which address several elements of a SMS. The SMS WG rated this section red (i.e., not covered), since a quality system does not require SMS recordkeeping.

4.1.2 Task 1: SMS WG Conclusion

The SMS WG determined that Part 21 partially addresses the SRM and SA elements of Part 5 through compliance with airworthiness standards (for products) and the quality system. Elements of SRM and SA relating to the organization and the organization's processes are not specifically addressed in Part 21.

The SMS WG further identified that Part 5 is written to be applicable to a 14 CFR Part 119 certificate holder's organization and requires an update to incorporate Part 21 D&M organizations.

4.2 Task 2: Incorporation of SMS into 14 CFR

Task 2 required the SMS WG to develop, evaluate options, and make a recommendation for incorporation of SMS into 14 CFR for D&M organizations.

4.2.1 Task 2: SMS WG Response

The SMS WG used a decision-making approach to identify and evaluate options for incorporation of SMS into 14 CFR. The approach involved the following basic elements:

1. Identify criteria to be used for evaluation of options;
2. Assign a weighting or level of importance for each criteria;
3. Identify available options;
4. Assess advantages and disadvantages of each option; and
5. Score each option against the weighted criteria.

4.2.1.1 Identification and Weighting of Evaluation Criteria

Criteria were weighted using a scale of 1 to 10, with 10 being the most "important" relative to the other criteria. The following criteria were identified as being appropriate for consideration:

1. The option selected should be consistent with international equivalency of regulations and State obligations with regard to ICAO Annex 19, with emphasis on equivalency between States and efficiency within D&M organizations.
(Weighting = 10)
2. The option selected should be readily acceptable to the FAA, with emphasis on facilitation of FAA oversight of D&M organizations.
(Weighting = 9)
3. The option selected should allow for simple and practical application of SMS requirements across appropriate Part 21 provisions, with emphasis on ease of understanding "what has to be done" within a regulated SMS.
(Weighting = 8)
4. The option selected should accommodate applicability to organizations holding multiple approvals, with emphasis on efficiency of regulated SMS within D&M organizations, especially in avoiding any requirement for multiple regulated SMS within an organization.
(Weighting = 7)
5. The option selected should facilitate scalability and flexibility of SMS, with emphasis on ability to apply regulated SMS to different size organizations.
(Weighting = 5)
6. The option selected should facilitate consistency of application to sub-tier suppliers of D&M organizations, with emphasis on minimizing negative impact of flow-down requirements on the efficiency of a regulated SMS.
(Weighting = 1)

4.2.1.2 Options

The SMS WG considered four basic options:

1. **Option 1:** Extract portions of Part 5 applicable to D&M organizations and insert where appropriate in Part 21 to establish SMS requirements for D&M without reference to Part 5.
2. **Option 2:** Establish recognition of SMS elements already existing in FAA regulations, with modification of Part 5 to allow an option to implement the "missing" elements via certification or acceptance through a voluntary SMS implementation program acceptable to the FAA.
3. **Option 3:** Modify Part 21 by addition of a new Subpart for SMS requirements, tailored for D&M organizations by copying applicable Part 5 provisions to the new subpart.
4. **Option 4:** Adopt Part 5 in its entirety as applicable to D&M organizations, with modification to Part 21 only as necessary to incorporate reference to Part 5.

4.2.1.3 Evaluation of Options

1. **Option 1**: To the extent that Part 5 provisions are applicable to D&M, the SMS WG considered it would be redundant to duplicate those provisions in Part 21. Duplicative requirements might create difficulty for the FAA in maintaining consistency between the two parts. A set of extracted requirements likely would result in a regulated SMS for D&M being different from SMS for other kinds of organizations. Such differences might make it difficult to achieve equivalency of regulation between the US and other States, and efficient oversight by the FAA. With separated and different SMS provisions, this option would not avoid potential for an organization holding multiple certificates to be required to have multiple SMS, and would not contribute to effective scalability and flexibility of SMS. This option was evaluated as not achieving any of the criteria, and was scored as "zero."
   Therefore, the SMS WG removed Option 1 from consideration.
2. **Option 2**: Creation of a certification process to cover SMS elements "missing" from existing regulations, including any that exist outside of Part 21, would present considerable burden for FAA in its oversight responsibilities. Use of a voluntary standard would require that the FAA evaluate what likely would be multiple competing commercial SMS programs to determine acceptability, and would require FAA oversight of such multiple programs. It is unclear whether or how voluntary SMS implementation programs might contribute to equivalency of international regulations. This option was evaluated as not achieving any of the criteria, and was scored as "zero."
   Therefore, the SMS WG removed Option 2 from consideration.
3. **Option 3**: In this approach, requirements for applicability to Part 21 approval holders would be established in the new subpart. A new subpart would provide a vehicle for ready tailoring of SMS requirements for D&M organization, and thereby also readily accomplish appropriately scaled and flexible application of requirements. Such alignment of SMS requirements to Part 21 would facilitate straightforward implementation and compliance by D&M organizations, and efficient oversight by the FAA. With tailored SMS requirements concentrated in a new subpart, there would be low risk of any Part 21 SMS changes inadvertently inducing SMS conflict in another industry segment or

requiring change to Part 5. This approach would provide for a clear definition of "what has to be done" within Part 21 for the various certificate types.

A new Subpart for Part 21 would be advantageous only if Part 5 were determined not to be appropriate for D&M organizations. As a result of the gap analysis discussed in section 4.1, the WG determined that Part 5 is appropriate for D&M organization, with modification of §5.1 (*Applicability*), and §5.5 (*Definitions*). Consequently, addition of a new subpart to Part 21 would create redundant SMS requirements having potential for the difficulties noted for Option 1.

Therefore, the SMS WG removed Option 3 from consideration.

4. **Option 4**: The WG determined that Part 5 is appropriate for D&M organizations, with modification of §5.1 (*Applicability*) and §5.5 (*Definitions*). When accompanied by policy and guidance material (recommended by the SMS WG elsewhere in this report to be developed) describing SMS application for D&M organizations, use of Part 5 would minimize need for revision. Part 21 would need revision only to the extent necessary to refer to Part 5 for SMS requirements. The SMS WG considers that adoption of Part 5 is likely to best promote straightforward implementation by affected organizations and oversight by the FAA. Part 5 contains all of the SMS components and elements addressed by ICAO Annex 19, thereby maximizing US equivalency of regulations. Option 4 would require minimal changes to both Part 5 and Part 21, provides for straightforward implementation and compliance by D&M organizations, and efficient and standardized oversight by the FAA.

   Therefore, the SMS WG selected Option 4 as the preferred option.

4.2.1.4 Discussion of Selected Option

The SMS WG response for Tasks 3 and 5 provides a recommendation for applicability and scalability. Further, the SMS WG anticipates as noted in section 3.0 that the Organizational WG will define applicability requirements for D&M organizations, and will recommend that such approved organization be given a certificate. If those recommendations are adopted, Part 5 references to "the certificate holder" would remain valid for affected D&M organizations.

Notwithstanding the incorporation considerations discussed above, the SMS WG considers that §5.1 should be clarified with regard to the specified deadlines. Per §5.1(a), a certificate holder "must have" a SMS "that meets the requirements of this part and is acceptable to the Administrator by [3 years after the effective date of final rule]." and §5.1(b) specifies a certificate holder "must submit" an implementation plan "for approval" no later than six months after the effective date of the final rule.

A certificate holder must be able to understand the process of determining acceptability, track the progress of the submission, and respond to comments and questions in order to "have" an acceptable SMS by the deadline. The SMS WG recommends that the FAA clarify the activities and timing expected between submission of an implementation plan by a certificate holder and a determination that the certificate holder's SMS is "acceptable." Examples of needed clarification include a definition of "have an acceptable SMS," explanation of the relationship between "approval" of the submitted implementation plan and "acceptance" of the holder's SMS. Additionally, the specified dates should account for an application made after the effective date of the final rule.

To facilitate appropriate management of the approval process, the SMS WG recommends that the specified deadlines be referenced to approvals rather than to the effective date of the final rule. For example, once the implementation plan is submitted for approval, the next logical step would be approval of the plan. At that point, the certificate holder would have a basis for proceeding with implementation, eventually arriving at a point of "having" an acceptable SMS. Under such a concept, only the deadline for plan submittal would be appropriate to be tied to the effective date of the final rule.

A certificate holder must be able to understand the process of determining acceptability, track the progress of the submission, and respond to comments and questions in order to "have" an acceptable SMS by the deadline. Clarification of the respective deadlines may require development of specific policy and guidance material.

Section 3.0, Key Assumptions, includes an assumption that the definition of "hazard" is a condition that could foreseeably cause or contribute to an aircraft accident. The SMS WG recommends that Part 5, §5.5 Definitions, be changed to incorporate that definition. The change is necessary in order to appropriately focus attention during SMS implementation by an organization and during oversight by the FAA. Conditions that, for example, affect occupational health and safety, environmental protection, and security are not appropriate to be included in hazard identification requirements for a regulated aviation SMS for D&M.

The following changes would be required for Part 5:

- §5.1 (*Applicability*): Change §5.1(a) to include design and/or manufacturing organization approvals under Part 21, or make reference to "certificate holders."
- §5.1 (*Applicability*): Clarify the activities and timing expected between submission of an implementation plan by a certificate holder and a determination that the certificate holder's SMS is "acceptable."
- §5.1 (*Applicability*): Change 5.1(a) to refer to a period of time following approval of an implementation plan, rather than the effective date of the final rule, as the deadline to "have" an SMS.
- §5.5 (*Definitions*): Change the definition of "hazard" to refer to a condition that could foreseeably cause or contribute to an aircraft accident.

4.2.2 Task 2: §5.27 Coordination of Emergency Response Planning

4.2.2.1 Definition and Context of "Emergency"

According to The American Heritage Dictionary of the English Language, Fourth Edition, the definition of "emergency" is, "A serious situation or occurrence that happens unexpectedly and demands immediate action."

In the Supplementary Information of Notice of Proposed Rulemaking, No. 10-15 (Docket No. FAA-2009-0671), the FAA describes emergency response planning as, "...provides the basis for a systematic approach to managing the organization's operations in the aftermath of a significant unplanned event or during an ongoing emergency situation. The overall objective is the safe continuation of operations and the return to normal operations as soon as possible."

As noted in section 3.0 of this report, the SMS WG anticipates that a regulated SMS will address hazards that could foreseeably cause or contribute to an aircraft accident. Therefore, "coordination of emergency response planning" refers to planning for activities that take place within a limited period of time during which an aircraft operational emergency situation exists. It includes the period of time required to re-establish "normal" operations following the emergency.

4.2.2.2 Discussion of Emergency Response Planning

The SMS WG considers that situations or events (e.g., natural disaster, hostile attack of facilities, fire) that result in interruption of the business activities of a design and/or manufacturing organization are distantly removed from contribution to an aircraft accident. This is true as well for situations or events that might affect an organization's ability to provide continuing airworthiness support for a product or article. Therefore, such business interruptions do not constitute an "emergency" for which "emergency response planning" is appropriate in the context of a regulated SMS.

Generally, aircraft operational emergency situations may be relevant to design and/or manufacturing organizations in three ways:

1. The product(s) or article(s) of the organization are installed, maintained, and/or operated by another entity,
2. The organization itself conducts aviation operations, or
3. There is a need to interface with another organization during that organization's emergency response activities.

4.2.2.2.1 Products or Articles Installed, Maintained, and/or Operated by Other Entities

With regard to the operations of other entities, involvement of D&M organizations is primarily limited to airworthiness activities following an emergency situation (e.g., a design organization may need to consider whether accident investigation findings indicate a need for airworthiness action). Those activities are part of existing regulatory responsibilities of [e.g., a Type Certificate (TC) holder complying with §21.99, and are normal activities for such an organization]. Therefore, those activities, even if they occur after an aircraft accident, do not constitute "emergency response" on the part of D&M organizations.

4.2.2.2.2 Flight Operations by a D&M Organization

A variety of aviation operations may be conducted by a design and/or manufacturing organization. A design and/or manufacturing organization may conduct any, all, or none of the following kinds of operations:

- Corporate transportation.
- Sales and demonstration.
- Ferry flights.
- Air shows and displays.
- Arial photography.
- Engineering flight test (including ground tests).
- Production flight test.

Typically, such operations are conducted in accordance with 14 CFR Part 91. The SMS WG understands that Part 91 operations are not to be subject to SMS requirements. Corporate transportation flights, sales demonstration flights, ferry flights, air shows, and aerial photography flights are typical of flying operations that might be undertaken by virtually any Part 91 operator. There is therefore no basis for any requirement that a design or manufacturing organization prepare emergency response planning for such operations. The WG recognizes that engineering and production flight test operations conducted for the purpose of Part 21 activities encompass a broad range of hazards that are unique to such operations. Nevertheless, such operations are not appropriate to be subjected to §5.27 for D&M organizations for the following reasons:

- Production flight test operations normally occur within the confines of a quality management system. The products and articles under test normally are subjected to numerous inspections during assembly, and before and after flight. Thus, these operations already are conducted in a manner that significantly exceeds safety requirements for Part 91 operations. Additional requirements for coordination of emergency planning are not warranted.
- Engineering flight test operations conducted with the participation of FAA personnel or designees generally are required to be subjected to risk management as specified in FAA Order 4040.26B, Aircraft Certification Service Flight Test Risk Management Program. Among the specified requirements are project planning, descriptions of emergency procedures to be accomplished, reporting of significant events, and an accident response plan. Many, if not most, organizations that conduct engineering flight test operations apply the risk management process(es) equally to their operations that do not involve FAA personnel. Thus, these operations already typically are conducted in a manner that significantly exceeds safety requirements for Part 91 operations. Additional requirements for coordination of emergency planning are not warranted.
- Any airworthiness issues that might arise during production or engineering flight test, even an issue that might affect in-service aircraft, are dealt with using the same process(es) used to deal with airworthiness issues otherwise discovered during the normal course of business. Therefore, the exercise of those processes does not constitute "emergency response" for which coordination of planning would be required.

4.2.2.2.3 *Coordination with Other Organizations*

The coordination of emergency response planning, as noted in §5.27(c) applies to coordination of a "certificate holder's emergency response plans" with the plans of "other organizations it must interface with during the provision of its services." For the reasons described above, there should be no requirement for a D&M organization to develop an emergency response plan as part of its regulated SMS. Thus, any requirement to coordinate such a plan with another organization is moot. There may conceivably be situations where an organization that does engage in emergency response activities might benefit from information provided by a D&M organization. Examples might include an Airport Rescue Fire Fighting unit for accident first response activities, or an accident investigation authority for investigation activities. The SMS WG considers that provision of such information is not within the meaning of an "emergency response plan" that a D&M organization must coordinate. Further, provision of such information does not constitute "interface with" another organization that "must" be accomplished during the provision of a design and/or manufacturing organization's services.

4.2.3 Task 2: SMS WG Recommendation

The WG concludes that §5.27 requirements should not apply to design and/or manufacturing organizations. Consequently, §5.21(a)(6) also should not apply to design and/or manufacturing organizations.

The SMS WG recommends:

1. That Part 5 be made applicable to certain D&M organizations:
   - §5.1 (*Applicability*). Change §5.1(a) to include design and/or manufacturing organization approvals under Part 21, or make reference to "certificate holders."
   - §5.1 (*Applicability*). Clarify the activities and timing expected between submission of an implementation plan by a certificate holder and a determination that the certificate holder's SMS is "acceptable."
   - §5.1 (*Applicability*). Change 5.1(a) to refer to a period of time following approval of an implementation plan, rather than the effective date of the final rule, as the deadline to "have" an SMS.
   - §5.5 (*Definitions*). Change the definition of "hazard" to refer to a condition that could foreseeably cause or contribute to an aircraft accident.
2. That Part 21 be modified to refer to Part 5 as SMS requirements for D&M organizations meeting the applicability threshold. The specific changes to Part 21 will depend upon the manner in which the Organizational WG recommendations are implemented.
3. That §5.27 and §5.21(a)(6) should not apply to D&M organizations.

4.3 Tasks 3 and 5: SMS Applicability, Scalability, and Flexibility

Task 3 required the SMS WG to provide a recommendation as to which D&M approval holder organizations should have SMS requirements applied to them. Task 5 is related to Task 3 and required the SMS WG to provide guidance that accounts for scalability and flexibility of SMS to D&M organizations based on their size, complexity, and safety risk introduced by their products. The SMS WG decided to combine Tasks 3 and 5 into a single response.

4.3.1 Tasks 3 and 5: SMS WG Response

4.3.1.1 Applicability

ICAO Annex 19 currently requires SMS for aircraft TC and Production Certificate (PC) holders and is planning to expand the requirement to engine and propeller TC and PC holders in the future. The SMS WG agrees with the future ICAO requirement and concluded that SMS should be applied to all TC and PC holders for aircraft, engines, and propellers.

The next step in the SMS applicability decision-making process addressed Parts Manufacturer Approval (PMA), Technical Standard Order Authorization (TSOA) and STC holders. The SMS WG evaluated several criteria, but determined that safety risk introduced by the holder's products/articles was the key criteria that should be used to determine whether SMS should be applied to a PMA, TSOA, or STC holder.

The WG noted past FAA precedence with the current requirement under Order 8110.42 Chapter 5 paragraph (d) that requires a PMA applicant to conduct a safety assessment to establish if a part is critical or non-critical. Consideration was also given to the Aircraft Certification Service Category Parts List (Revision G dated 8/18/09)[1] which categorizes parts from Category I to III, with I being most critical. This was overlaid with the FAA's Certificate Management Information System (CMIS)[2] which defines criticality from Level 1 to 5, with 5 being most critical. Using these criterion, the WG rated Category I / Level 5 parts as having the largest importance for the SMS applicability evaluation. A description of these levels is provided in Table 2 which has been excerpted from the FAA 2012 Manufacturers Safety Management System Pilot Project Report for Design and Manufacturing Organizations.

Therefore, from an aviation safety perspective the SMS WG determined that SMS should be applied to PMA, TSOA, and STC parts, products and articles that are considered critical. Critical is defined as *parts, products and articles thereof whose failure could directly prevent continued safe flight and landing*, which corresponds to Category I or Level 5.

Table 2: Criticality of Products Produced by Production Approval Holders

LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	LEVEL 5
A product or part(s) thereof whose failure would have LITTLE TO NO effect on continued safe flight and landing of the aircraft	A product or part(s) thereof whose failure would not prevent continued safe flight and landing; resulting consequences COULD reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.	A product or part(s) thereof whose failure would not prevent continued safe flight and landing; resulting consequences WOULD reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures	A product or part(s) thereof whose failure COULD, IF OTHER CONDITIONS EXISTED, prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.	A product or part(s) thereof whose failure COULD DIRECTLY prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.
CPL CAT III		CPL CAT III		CPL CAT I

4.3.1.2 Scalability and Flexibility

Scalability: The SMS WG determined that SMS needs to be applied in full (with the exception of §5.27) to all D&M organizations meeting the applicability threshold. This applicability threshold also addresses scalability in that the SMS WG does not see benefit in applying scaled (i.e., partial) SMS requirements. Considering the level of activities already associated with certifying a critical PMA part or an equivalent Category 1 or Level 5 part or article under a TSOA or STC, the SMS WG does not believe scalability of SMS will be a concern for affected D&M organizations. The SMS WG feels that an organization that is capable of designing,

[1] AIRCRAFT CERTIFICATION SERVICE CATEGORY PARTS LIST can be found on the FAA website and was previously part of the now canceled Order 8120.2 and is still referred to in AC 43-18 "Fabrication of Aircraft Parts by Maintenance Personnel" and AC 21-43 "Production Under 14 CFR Part 21, Subparts F, G, K, and O".
[2] CMIS is the system used by FAA manufacturing inspection offices to prioritize oversight activities.

certifying and performing continued airworthiness of a critical part or article should be capable of implementing an SMS similar to a TC or PC holder.

Flexibility: The SMS WG recognizes that SMS application will need to be flexible based on the size and complexity of the D&M organization. For example, in a small organization, the accountable executive and SMS management representative may be the same person. The SMS WG plans to take this into account when developing SMS guidance material as part of our Task 4 recommendation based on the ARC's recommendation for applicability of SMS.

4.3.1.3 Additional Discussion Points

FAA Oversight Resource Demand: A consideration in the application of SMS to STC, TSOA and PMA companies will be the resource demand to provide oversight by the FAA. The Part 21 / SMS ARC Oversight and CBA WGs will need to evaluate if applying SMS to STC, TSOA or PMA is the most efficient application of FAA resources to address safety, meaning would the FAA resources have a greater impact to safety if the FAA resources were applied to other areas than SMS oversight of the STC, TSOA or PMA companies.

STC Holders: STC holders do not currently have an organizational requirement or a requirement for a quality management system. Therefore, a greater impact could be incurred by some STC companies to implement SMS. Similar to companies that own TCs and have continued airworthiness responsibilities, but may not produce the type certificated product, some STC companies are only design and engineering and do not manufacture or sell parts. The impact to these companies and the connection with the manufacturer and installer of the STC along with the FAA oversight will need to be evaluated by the Oversight and CBA WGs.

Voluntary Implementation of SMS: The SMS WG identified potential value through voluntary SMS implementation for parts or articles below the critical threshold. Additional privileges would need to be realized for companies that voluntarily implemented SMS. A potential option would be to have an industry SMS program that would accredit the PMA, STC, and TSOA company's SMS. Future consideration will be required to develop an industry accreditation program. Additional privileges could be avoidance of sequencing and more expeditious project reviews. An example of an industry accreditation program would be the quality management system Aerospace Standard (AS) AS9100 developed by International Aerospace Quality Group (IAQG) released by the SAE International and the Aerospace and Defense Industries Association of Europe – Standardization (ASD-STAN).

4.3.2 Tasks 3 and 5: SMS WG Recommendation

Applicability: The SMS WG recommends that FAA develop an applicability threshold that requires SMS for organizations that:

- Design or manufacture products (i.e., aircraft, engines, propellers);
- Design or manufacture articles whose failure could directly prevent continued safe flight and landing; or
- Make design changes to a product, through a Supplemental Type Certificate (STC), failure of which could directly prevent continued safe flight and landing.

This recommendation is not intended to discourage voluntary implementation of SMS for organizations producing articles with criticality falling below the applicability threshold.

Scalability. Scalability of SMS has been addressed through the applicability threshold. Therefore, the SMS WG recommends that all components / elements (with the exception of §5.27) of SMS be applied for those design and /or manufacturing organizations that meet the applicability threshold.

4.4 Task 4: Recommended Preamble, Policy, and Guidance Material

Task 4 required the SMS WG to produce recommended preamble, policy, and guidance material to support SMS application to D&M organizations. This effort also included development of an "operational" definition of a hazard throughout the life cycle of a product in SRM.

4.4.1 Task 4: SMS WG Response

The SMS WG developed SMS regulatory material and a basis for preamble, policy, and guidance material as provided in this report. However, we determined that more work was necessary to produce detailed guidance material. The SMS WG believes it is important that this guidance material be developed before FAA rulemaking begins, and that the current SMS WG be involved in the development. It also is noted that the guidance material will be dependent on the outputs from, and be used by, the Organizational and Oversight WGs.

Specific guidance that requires further development includes:

- How safety objectives are established
- Evaluating the performance of an organization's SMS
- Development of an "operational" definition of a hazard throughout the life cycle of a product
- Acceptable criteria for the effectiveness of the safety risk controls at a system level
- Process that the D&M organization implements to meet §5.55(b) and the extent to which the FAA is engaged
- Flexibility in applying SMS to the D&M organization

4.4.1.1 Safety Performance Assessment and Effectiveness

Part 5 (§5.73) requires that the D&M organization evaluate the performance of its SMS and the effectiveness of its SRM safety risk controls. With regards to safety risk controls, there will typically be hundreds of risk controls for a product and it is unnecessary and an ineffective use of safety resources to evaluate the effectiveness of each individual safety risk control. Articles and STCs can also have a significant number of safety risk controls. A more effective approach is to evaluate the product or article at a system level, for example, engine inflight shutdown rate provides a system level assessment of an engine's reliability and the risk of loss of critical thrust on an ETOPS flight. Appropriate, acceptable system level evaluation criteria are needed to effectively and efficiently evaluate the safety risk controls of a product or article.

Additionally, guidance is needed regarding an organization's safety objective and how its SMS performance is evaluated against those safety objectives. Section 5.1 defines a safety objective as a measurable goal or desirable outcome related to aviation safety. While zero accidents is a desirable safety objective it does not provide a useful timely criteria for evaluating the performance of an organization's SMS. Additionally, the goal of SMS is to improve safety by managing risk with the understanding that risk is always present and cannot be completely eliminated. Consensus on criteria and guidance for determining safety objectives and SMS performance against those safety objectives will also facilitate efficient process oversight of the D&M SMS.

4.4.2 Task 4: SMS WG Recommendation

The SMS WG recommends that we continue our efforts in 2014 to develop SMS policy and guidance material and provide as an addendum to this report.

4.5 Task 6 and 7: CONOPS for SMS

Task 6 required the SMS WG to define the end state (roles, relationships, and responsibilities) for SMS in a D&M organization considering design and certification, production and airworthiness certification, and continued airworthiness. Task 7 is related to Task 6 and requires the SMS WG to perform a review of "strategic" safety decisions that are required to be made during the design and certification, production and airworthiness certification, and continued airworthiness life cycles of the product. The SMS WG decided to combine Tasks 6 and 7 into a single response.

4.5.1 CONOPS Summary

The SMS WG has developed a CONOPS which describes the intent of the SMS framework (i.e. Safety Policy, Safety Risk Management, Safety Assurance, Safety Promotion) for D&M organizations as it applies to each life cycle phase (design and certification, production and airworthiness certification, and continued airworthiness) of a product or article. The CONOPS focuses primarily on SMS framework components SRM and SA, Part 5 Subparts C and D respectively. Safety Policy and Safety Promotion, Part 5 Subparts B and E together are intended to foster and promote a healthy "Safety Culture,"[1] which is a necessary enabler of SMS. Subparts B and E, do not exist in current regulations for D&M organizations and will need to be implemented to provide a regulatory basis for enabling enhancement to a D&M's safety culture.

The CONOPS defines how the existing applicable certification procedures or airworthiness regulations (e.g., 14 CFR §21.17, §21.101, §21.137, §33.75, §25.1309), and their associated policy and guidance (FAA Orders and ACs) satisfy the intent of Part 5 Subparts C and D. The CONOPS also identifies where the existing regulations do not fully meet the intent of Part 5, and what the additional intent of the Part 5 regulation is. Further, the CONOPS discusses how the organizational regulations required for Organizational Delegated Authority (ODA) under Part 183 Subpart D satisfy the intent of SMS framework components SRM and SA, Part 5 Subparts C and D, except that Part 183 Subpart D defines delegated responsibilities and Part 5 defines responsibilities of a certificated organization.

The procedural and airworthiness regulations that are complied with during the design and certification phase satisfy the intent of Part 5 Subparts C and D SRM and SA except that consideration of safety lessons learned from existing certified products need to be considered. During the continued airworthiness phase of a product/article life cycle, the existing Part 21 regulations do not explicitly satisfy the intent of SRM and SA. However, Continued Operational

[1] See ICAO Safety Management Manual Doc. 9859 – 3rd Edition (section 1.6) for more discussion and definition of Safety Culture

Safety (COS) programs and §183.63 satisfies the intent, although §183.63 includes requirements to notify the FAA whereas Part 5 defines responsibilities of the certificated organization.

During the production and airworthiness phase, the quality management system requirements satisfy much of the intent of Part 5 Subparts C and D SRM and SA. The primary function of a certificated production organization SRM and SA is to support COS programs by providing information regarding in-service failures, malfunctions, and defects.

We recommend that the CONOPS form the basis for the development of preamble, policy, and guidance material.

4.5.2 Task 6 and 7: SMS WG Response

SMS for D&M is an organizational requirement intended to enhance safety of products or articles with the ultimate goal of enhancing aviation safety. SMS is not intended to circumvent compliance to the applicable certification procedures or airworthiness regulations (14 CFR). Nor is SMS intended to revisit obligations or compliance with the existing applicable certification procedures or airworthiness regulations (e.g., 14 CFR §21.17, §21.101, §25.1309), or their associated FAA Orders and ACs.

The life cycle of a product or part can be logically divided into three phases:

1. Design and certification, and
2. Production and airworthiness certification, and
3. Continued airworthiness.

Current certification procedures and airworthiness regulations are divided up in accordance with these phases, except that continued airworthiness, in the current regulatory structure, is predominately an FAA function. However, with the introduction of Part 5 which contains the proposed SMS regulations applied to certificate holders, continued airworthiness also becomes an obligation of a DAH. Currently, most, if not all, DAHs have implemented voluntary COS programs for their products or parts or, if they hold an ODA, are conducting COS as part of their obligation in complying with §183.63 ("*ODA – Continuing requirements: Products, parts or appliances*").

4.5.2.1 Part 5: Four Main Elements of SMS

The ICAO SMS framework has four main components, Safety Policy, Safety Risk Management (SRM), Safety Assurance (SA), and Safety Promotion, which is consistent with the FAA's Part 5 SMS regulations that have been structured around these four components as:

- Subpart B – Safety Policy
- Subpart C – Safety Risk Management (SRM)
- Subpart D – Safety Assurance (SA)
- Subpart E – Safety Promotion

Part 5 also includes Subpart A (*General*) which includes *Applicability*, *General requirements* and *Definitions* and Subpart F (*SMS Documentation and recordkeeping*), which, in the ICAO Framework is included as part of Safety Policy.

NOTE: In the remainder of this document, the references to Subpart B, C, D, and E are considered as described in the NPRM for 14 CFR Parts 5 and 119 titled "Safety Management Systems for Certificate Holders Operating" under 14 CFR Part 121 (Docket No. FAA–2009–0671) excepted as discussed in section 3.0.

Subpart B establishes the foundation for safety management through senior management's commitment to continually improve safety and defining the methods, processes, and organizational structure needed to meet safety goals. Subparts B and E together are intended to foster and promote a healthy Safety Culture,[4] which is a necessary enabler of SMS. Again, while most, if not all, DAHs have an inherent positive safety culture, the proposed requirements defined in Subparts B and E do not exist in current regulations for DAHs and will need to be implemented to provide a regulatory basis for enhancing DAHs safety culture.

The major objective of this CONOPS is to address the intent of Subparts C (SRM) and D (SA) for the life cycle of a product or article, from an aviation safety perspective. Figure 1 through Figure 6 (contained herein), provide a graphical flowchart representation of Subparts C and D and the intent of these Subparts as they relate to the three phases of a product or article. As is discussed in the following sections, much of the intent of these Subparts is already addressed under existing regulations or by current practices to comply with the existing regulations. The discussion also identifies existing regulations as well as the additional activities that fully meet the intent of these Subparts for a DAH and/or PAH.

4.5.2.2 Subpart C: Safety Risk Management

Subpart C is comprised of three sections:

- **§5.51**: Applicability,
- **§5.53**: System analysis and hazard identification, and
- **§5.55**: Safety risk assessment and control

Specifically, these sections require:

- Identification of hazards or ineffective risk controls,
- Assessment of safety risk, and
- Development of safety risk controls.

4.5.2.2.1 Design and Type Certification

One aspect of Subpart C (§5.51) requires a safety risk determination, if a new system is implemented or a revision is made to an existing system (§5.51(a) and (b)). For DAHs designing and certifying a new or changed product or article, the intent of Subpart C [i.e., §5.51(a) - *Implementation of new systems*, and §5.51(b) - *Revision of existing system(s)*] is satisfied by the current Part 21 certification procedures (i.e., §21.17, §21.19, or §21.101), which require that the appropriate airworthiness regulations are complied with. If appropriate airworthiness regulations do not exist because the proposed design is novel or unusual, then the FAA will issue special

[4] See ICAO Safety Management Manual Doc. 9859 – 3rd Edition (section 1.6) for more discussion and definition of Safety Culture

conditions to ensure that a level of safety equivalent to that defined in the regulations is established (reference §21.16).

Airworthiness regulations are intended to define the conditions for risk controls to be developed based on known hazards. These hazards are systemic in nature and have often been defined as the result of accident/incident investigations. The intent of SRM has therefore already been performed and its outcome established in airworthiness requirements and fulfilled in certification processes. Hazards unique to a certain design are typically the topic of special conditions. As in airworthiness regulations, the process for developing special conditions meets the intent of SRM and establishes the means to manage risk to acceptable levels.

Current §21.33, §21.37, §21.39, and §21.35 require that all the necessary inspections and tests are conducted, and §21.50 ensures that the Instructions for Continued Airworthiness (ICA) are available. Additionally, even if the design meets all the airworthiness requirements and special conditions, it will not be certified if it has any feature or characteristic that makes it unsafe [reference §21.21(b)(2)].

The issuance of these regulations is evidence of how the certification procedures and airworthiness regulations have evolved over the years, and have been promulgated based on identified hazards and subsequent risk mitigations, are in essence already addressing SRM (CFR Part 5 Subpart C). Some of these rules have addressed a very specific hazard (e.g., §25.607 for fastener retention), while others are more general and allow innovation of design, provided that the hazards associated with the design are identified and appropriately mitigated (e.g., §23.1309 for system design). Additional examples are included in Appendix D.

Under Subpart C, §5.53 and §5.55 require a SRM process to perform the activities to comply with §5.51, that is, if a new system is implemented or a revision is made to an existing system. The D&M processes used to comply with Part 21 design certification procedural regulations and the airworthiness regulations (e.g., Parts 23, 25, 27, 26, 29, and 33) can meet the intent of Subpart C, §5.53 and §5.55 SRM for products or articles.

For an ODA holder, the processes required to satisfy Part 183 Subpart D (*Organization Designation Authorization*) (e.g., §183.53), considering compliance with Part 21 design certification procedural regulations and the airworthiness regulations as described in the preceding paragraph, further supports meeting the intent of §5.53 and §5.55.

For the ARC's proposed Design Organization (DO), it is expected that one of the obligations under Part 21 will be to comply with the applicable sections of Part 5, which will include compliance with §5.51, §5.53, and §5.55.

Sections §5.51, §5.53, and §5.55 require SRM for the "system," which includes not only the product or article, but the organization's operating environment, supporting processes and procedures, and personnel, equipment, and facilities (organizational/operational) required for the design or production of the product or article. In the design and certification life cycle phase, the organizational /operational hazard is the condition(s) that could foreseeably lead to a noncompliant design. For organizational / operational changes, planned or unplanned, business practices need to ensure that the changes will not lead to a non-compliant design. The intent of §5.51(c) for a DAH is addressed by 14 CFR Part 183, Subpart D (e.g., §183.53 for current ODA holders), and by the expected organizational regulations for the proposed certificated Part 21 DOs. The intent of §5.51, §5.53, and §5.55 for these organizations is depicted in Figure 6 and is meant to ensure that the organization not only produces a compliant and/or conforming product or article, but manages organizational processes and changes to these processes ensure it continues to produce a compliant and/or conforming product or article.

The intent of §5.51(d) for the design and type certification phase of the life cycle of a product or article is discussed in conjunction with the intent of Subpart D: Safety Assurance (SA).

4.5.2.2.2 Continued Airworthiness

Once a product or article has been designed, certified or approved and is in-service the continued airworthiness phase of the aviation safety life cycle begins. Most, if not all DAHs have some form of COS program which monitors reported in-service events related to the product or article certificates or approvals they hold, assesses the safety risk of those events and if necessary defines safety risk controls such that an acceptable level of risk is maintained in the fleet (reference Figure 3 and Figure 5). Monitoring of products or articles is addressed in the Subpart D: Safety Assurance, section 4.5.2.3.

In most, if not all cases, the DAH COS program satisfies the certificate or approval holder's obligations under §21.3 or the ODA holder's responsibilities under §183.63. However, under the current §21.3 regulation the DAH is only required to report, and only for thirteen specific occurrences. From a regulatory perspective §21.3 does not fully address §5.51(d), §5.53, or §5.55 identification of hazards or ineffective risk controls, safety risk assessment, and control; however, in most, if not all cases, the DAH COS program does contain processes and procedures to perform identification of hazards or ineffective risk controls, safety risk assessments, and control as depicted in Figure 3 and Figure 5. Once the COS program identifies a need for a safety risk control, the same process for §5.51(a) through (c) described above is used to implement any design or organizational safety risk controls necessary, and if the FAA determines an unsafe condition exists and will likely exist, or develop in the fleet they will issue an Airworthiness Directive (AD).

For an ODA holder, the intent of §5.51(d), §5.53, and §5.55 to have SRM processes to identify hazards or ineffective risk controls, make safety risk assessments and identify safety risk controls is satisfied by the obligations of 14 CFR Part 183, Subpart D (*Continuing requirements: Products, parts or appliances*) §183.63(c). Part 183.63(d) meets the intent of §5.51(a) through (c). If a COS program is used to satisfy §183.63(c) and (d) it also satisfies the intent of §5.51(b), (c), and (d), §5.53 and §5.55.

For the ARC's proposed DO, it is expected that one of the obligations under Part 21 will be to comply with the applicable sections of Part 5 which will include compliance with §5.51, §5.53, and §5.55. A COS program can meet the intent of §5.51, §5.53, and §5.55 provided it identifies hazards or ineffective risk controls, makes safety risk assessments and identifies safety risk controls when unacceptable risk is identified by the safety risk assessment.

As discussed in section 4.5.2.2.2, under Design and Type Certification, sections §5.51, §5.53, and §5.55 require SRM for the system which includes the organizational/operational hazards as well as the product or article hazards. In the continued airworthiness life cycle phase, the organizational / operational hazard is the condition(s) that could foreseeably lead to an uncontrolled unacceptable risk. For organizational / operational changes, planned or unplanned, business practices need to assure that the changes will not lead to an uncontrolled unacceptable risk. For a DAH, (either ODA or DO) the intent of §5.51, §5.53, and §5.55 for organizational/operational hazards can be met by assuring that the COS program continues to meet its intended function and that changes to the COS program are assessed to assure the system will continue to function properly. The intent of §5.51(c) for a DAH can be addressed by Part 183, Subpart D, §183.53(c)(14), for current ODA holders, and by the DO regulations for the proposed certificated Part 21 DOs. The intent of §5.51, §5.53, and §5.55 for COS programs is depicted in Figure 6.

4.5.2.2.3 *Production and Airworthiness Certification*

PAH organizations under Part 21 Subparts G, K, and O are authorized to produce products or articles. STCs are not addressed here because they are only a design approval and production of an STC needs to be performed under a separate authorization (e.g., a repair station authorized under Part 145). Because PAHs operating under Parts 21 Subparts G, K, or O and/or Part 183 Subpart (D) don't necessarily have design engineering expertise to conduct aviation safety risk assessments, their function for Part 5 Subpart (C) would be to support the organization's COS program by providing information on §21.3(b) and §21.137(m) and (n) quality escapes, in-service failures, malfunctions, and defects to the appropriate design organization which has the expertise to properly conduct an aviation safety risk assessment. The intent of §5.51, §5.53 and §5.55 can be met by §21.137(m) and (n), and §183.63(a) is satisfied, when this information is provided to the DAH for use in the COS program.

§5.51, §5.53, and §5.55 for PAHs are not intended to require these organizations to duplicate the design engineering expertise to conduct aviation safety risk assessments. With regards to implementation of new systems, revised systems, or development of operational procedures the intent of §5.51 is to ensuring a conformed product or article is being produced, as depicted in Figure 6.

In the production and airworthiness certification life cycle phase, the organizational / operational hazard is the condition(s) that could foreseeably lead to a nonconforming product or article with an unacceptable risk. For organizational / operational changes, planned or unplanned, business practices in accordance with §21.137, §21.146, and AC 21-43 assures that the changes will not lead to a nonconforming product or article with an unacceptable risk, as depicted in Figure 6.

4.5.2.3 *Subpart D: Safety Assurance*

Subpart D provides the process for developing procedures within the SMS that function systematically to ensure performance and effectiveness of the safety risk controls. It is comprised of three sections:

- §5.71 Safety performance monitoring and measurement;
- §5.73 Safety performance assessment; and
- §5.75 Continuous improvement.

Specifically, these sections require:

- Data to be acquired and analyzed;
- Assessments to be made of the system's performance and effectiveness of §5.55(c) [safety risk assessment and control];
- A change management process be in place;

- A means to provide feedback on new identified hazards or ineffective safety risk control to the SRM process required by §5.51(d); and
- A process to be in place to correct substandard safety performance.

4.5.2.3.1 Design and Type Certification

The intent of these sections, during the initial design and type certification phase of the product or article, is to consider the safety lessons learned from the data gathered and analyzed on existing designs for compliance with §5.71. During the initial design and type certification phase of the product or article, safety performance is indeterminate (i.e., until the product or article is put into operation its actual safety performance cannot be determined) and compliance to §5.71 [and meeting the intent of Subpart D (SA)] is by consideration of safety lessons learned into the initial design and type certification of the product or article. In addition, an evaluation of design processes based on safety lessons learned should be conducted and decisions made whether changes to the design and certification process should be enacted to avoid future unacceptable safety risk being introduced into service.

For an ODA holder, the intent of §5.71(a)(1-6) process and procedural requirements (e.g. auditing of processes and systems) can be addressed by current 14 CFR Part 183, Subpart D, assuming the SMS processes and systems are controlled under the same command media system as the ODA. For example, if the organization's processes and procedures are documented and the organization uses internal or self audit to ensure it is following its documented processes and procedures, and this system is used to satisfy 14 CFR Part 183, Subpart D §183.53(c)(5) *A process and a procedure for periodic audit by the ODA Holder of the ODA Unit and its procedures;* then it meets the intent of §5.71(a)(3).

For the ARC's proposed DO, the intent of §5.71(a)(1-6) process and procedural requirements would be part of the expected Part 21 DO certificated organization's regulations equivalent to 14 CFR Part 183, Subpart D 183.53.

Section 5.71(a)(7), which requires a confidential employee reporting system, is a new requirement not addressed by the current DAH or ODA regulations, and is intended to be in place during the initial design and type certification phase. Many large DAHs have already implemented employee-reporting systems with various structures.

Section 5.73(a)(1) through (3), require evaluating the performance of the SMS and evaluating the effectiveness of the safety risk controls. Section §5.73(a)(1) through (3) are new requirements not addressed by the current DAH or ODA regulations, and are intended to be in place during all life cycle phases of the product or article. It is recognized that processes and data to evaluate those processes may in some cases be unavailable or not fully developed. Therefore, evaluation of the safety performance against the safety objectives may be done in an incremental fashion. Additional policy and guidance material is required.

Section §5.73(a)(4), which requires identifying changes in the DAH operational environment that may introduce new hazards [i.e., change management – reference Figure 6, is a regulatory input to implement §5.51: the organization must manage changes to the organization to ensure it continues to produce a compliant and/or conformed product or article. For example, if an organization has used an Airplane-Level System Safety/Certification process like that depicted in Figure 7 to produce a compliant type design and is proposing to introduce a new process to produce a compliant type design then they would need to conduct a change management review.

to ensure the new process would still produce a compliant type design to meet the intent of §5.73(a)(4).

For an ODA holder, the intent of §5.73(a)(4) can be satisfied by 14 CFR Part 183, Subpart D §183.53 *(Procedures manual)*.

For the ARC's proposed DO, the intent of §5.73(a)(4) would be part of the Part 21 DO certificated organization's regulations equivalent to 14 CFR Part 183, Subpart D §183.53 *(Procedures manual)*.

Section 5.75 is a new requirement not addressed by the current DAH or ODA regulations, and is intended to be in place during all life cycle phases of the product or article. It is recognized that processes and data to evaluate those processes may in some cases be unavailable or not fully developed. Therefore, the continuous improvement based on the safety performance against the safety objectives may be done in an incremental fashion. Additional policy and guidance material is required.

4.5.2.3.2 Continued Airworthiness

One of the primary intents of Subpart D – Safety Assurance during the continued airworthiness phase is to monitor reported in-service and other problems and to feed the information into the organization's SRM process as depicted in Figure 3 and Figure 5. In most, if not all COS programs, monitoring of reported problems is the first step in the process. The reporting process may include in-service feedback received via the quality system program used to comply with §21.137(m) *(In-service feedback)*. The reported problems are then assessed by the organization's SRM as discussed in section 4.5.2.2 in the Subpart C, Safety Risk Management section to identify hazards or ineffective risk controls, makes safety risk assessments, and identify safety risk controls when an unsafe condition is identified. A COS program that monitors reported in-service and other (reference Figure 5) problems, failures, malfunctions, and defects per §21.137(m) or potential non-compliances meets the intent of §5.71(a)(1), (2), and (6).

For an ODA holder, the intent of §5.71(a)(1), (2) and (6) can be satisfied by 14 CFR Part 183, Subpart D §183.63(a) and (b).

For the ARC's proposed DO, one of the expected obligations under Part 21 will be to comply with the applicable sections of Part 5, which will include compliance with §5.71(a)(1), (2), and (6). A COS program that monitors reported in-service and other (reference Figure 5) problems, failures, malfunctions, and defects per §21.137(m) or potential non-compliances meets the intent of §5.71(a)(1), (2), and (6).

With regards to §5.71(a)(5), because incident and accident investigation is the purview of the NTSB (or other national agency) and controlled by their protocols, the intent is to have a process or system in place to support an incident and accident investigation, if requested by the NTSB (or other national agency).

With regard to §5.71(a)(5) for an ODA holder, as previously stated the intent of §5.71(a)(5) can be met by the same method used to satisfy 14 CFR Part 183, Subpart D §183.53(c)(5) – "*A process and a procedure for periodic audit by the ODA Holder of the ODA Unit and its procedures.*"

For the ARC's proposed DO, one of the expected obligations under Part 21 will be to comply with the applicable sections of Part 5 which will include compliance with §5.71(a)(5) which will require an audit process equivalent to that for §183.53(c)(5) or §21.137(l) *(Internal audits)*.

As previously stated section 5.71(a)(7), which requires a confidential employee reporting system, is a new requirement not addressed by the current DAH or ODA regulations, and is intended to be in place during the continued airworthiness phase as well as the other phases of the lifecycle of the product or article. However, many DAHs have implemented voluntary confidential employee reporting systems on their own.

Section 5.73(a)(1) through (3), require evaluation of the performance of the SMS and the effectiveness of the safety risk controls. The intent of §5.73(a)(1) is to ensure compliance with the risk controls established by the D&M organization. The intent of §5.73(a)(2) is to evaluate how well the SMS processes are working. The SMS process performance evaluation indicators may change over time as better measures of the health of the system are understood or as the system matures. Additionally, the SMS process performance indicators may not have an absolute value nor are they intended to indicate compliance or non-compliance to §5.73(a)(2). Normally, the SMS will be looking for trends in the performance indicators (e.g., if the indicators changes one standard deviation negatively from the norm). In this case an assessment of the SMS may be warranted to better understand the negative trend and an action plan developed to improve the functioning of the SMS.

The intent of §5.73(a)(3) is to evaluate how the product or article is performing in-service against the organization's safety objectives defined in accordance with §5.21(a). The organization is expected to develop and maintain appropriate safety related performance indicators. These indicators should be precursor indicators of incidents or accidents (e.g., high-speed refused takeoffs). It is not expected that there would be a safety performance indicator for every safety risk control, given that compliance to each airworthiness regulation is considered a risk control. However, depending on the product or article there may need to be more than a single indicator and for products it is expected that there be more than one indicator. As previously discussed with regards to §5.73(a)(2) the safety risk control performance indicators may change over time to better monitor the safety risk of the current fleet. Additionally, the safety risk control performance indicators will not have an absolute value nor are they intended to indicate compliance or non-compliance to §5.73(a)(3). Normally, the SMS will be looking for trends in the safety risk control performance indicators (e.g., if the indicators change one standard deviation negatively from the norm). In which case, an assessment of the existing safety risk control may be warranted to better understand the negative trend and an action plan developed to reduce the safety risk in the fleet.

Section 5.73(a)(1) through (3) are new requirements not addressed by the current DAH or ODA regulations, and are intended to be in place during the continued airworthiness phase as well as the other phases of the lifecycle of the product or article.

As previously stated §5.73(a)(4) requires identifying changes in the operational environment that may introduce new hazards (i.e., change management – reference Figure 6), has basically the same intent as §5.51, the organization must manage changes to the organization to ensure it continues to meet its safety objectives.

For an ODA holder, the intent of §5.73(a)(4) can be satisfied by 14 CFR Part 183, Subpart D §183.53 *(Procedures manual)*.

For the ARC's proposed DO, the intent of §5.73(a)(4) is expected to be part of the Part 21 DO certificated organization's regulations; which can be considered equivalent to Part 183, Subpart D 183.53 Procedures manual.

Section §5.73(a)(5) is an outcome of the evaluation of the performance indicators required by §5.73(a)(2) and (a)(3). If new hazards or safety issues or concerns are identified by the evaluations performed for §5.73(a)(2) and (a)(3) they are feed into the SRM process per §5.51(d).

Section §5.75 requires processes to provide ongoing improvement in the performance identified in the assessments conducted under §5.73. The intent of this requirement is to use the data from §5.73 to focus improvement where indicators identify a need for action.

4.5.2.3.3 Production and Airworthiness Certification

PAH organizations under Part 21 Subparts G, K, and O are authorized to produce products or articles. STCs are only a design approval and production of an STC needs to be performed under a separate authorization. (e.g., a repair station authorized under 14 CFR Part 145). With regards to PMA and TSOA (per Part 21 Subparts K and O), this section only describes the production aspects of the organization. The design aspects of PMA and TSOA are discussed in the design and type certification and continued airworthiness sections. Each production approval organization under Part 21 Subparts G, K and O is required to have a quality system in accordance with §21.137. FAA AC 21-43 establishes acceptable means of compliance for PAH organizations as well as quality system for §21.137. 14 CFR Part 183 Subpart D defines organizational requirements for ODA including Production Certification (PC), PMA, and TSOA functions. FAA Order 8100.15B establishes the procedures, guidance, and limitations of authority for organizations under ODA. Under §21.137(m) PAH organizations and/or §183 Subpart D PC, PMA or TSOA ODAs must have procedures for receiving and processing feedback on in-service failures, malfunctions, and defects. These procedures must include a process for assisting the DAH to address any in-service problem involving design changes; and determine if any changes to the ICA are necessary. Because the production organizations may not have to design engineering expertise to conduct SRM their primary function for SMS is to support the COS program by providing information regarding in-service failures, malfunctions, and defects. Table 3 provides a correlation showing how the existing 14 CFR Part 21 and/or the Part 183 Subpart D regulations, and guidance can meet the intent of Part 5 Subpart D regulations.

Table 3: Correlation Between Part 5 and Part 21 / 183

NPRM PART 5	PART 21.137/ AC 21-43	PART 183 SUBPART D ORDER 8100.15B	COMMENTS/NOTES
5.71(a)			
5.71(a)(1)	21.137(a), (b), (c), (d), (e), (f), (g), (h), (l), and (n) AC 21-43 ¶s 2-1 – 10, 2-11, and 2-16	183.43, 183.47, 183.53, 183.61(a)(3), (5), (7), (8), (b)(1), (2) and 183.63	For a PC, PMA, or TSOA holder the intent of §5.71(a) process and procedural requirements are met by compliance to 21.137(a), (b), (c), (d), (e), (f), (g), (h), (l), and (n). For an PC, PMA, or TSOA ODA holder, the intent of §5.71(a) process and procedural requirements are addressed by 14 CFR Part 183, Subpart D, assuming the SMS processes and systems are controlled under the same command media system as the ODA.
5.71(a)(2)	21.137(a), (b), (c), (d), (e), (f), (g), (h), (l), and (n) AC 21-43 ¶s 2-1 – 10, 2-14, and 2-16	183.53(b), (c)(5), (6), and 183.63	See comments to §5.71(a)(1). With regards to detecting operational environment changes, the intent of §5.71(a)(2) is satisfied by §183.63 and §183.53(b), (c)(5), and (6) as they relate to ensuring a conformed product or article is still being produced, as depicted in Figure 6.
5.71(a)(3)	21.137(l) AC 21-43 ¶ 2-14	183.53(c)(5), (6) Order 8100.15B ¶ 3-44	See comments to §5.71(a)(1). If the organization's processes and procedures are documented and the organization uses internal or self audit to ensure it is following its documented processes and procedures, and this system is used to satisfy 14 CFR Part 183, Subpart D, §183.53(c)(5) – "A process and a procedure for periodic audit by the ODA Holder of the ODA Unit and its procedures", then it meets the intent of §5.71(a)(3).
5.71(a)(4)	21.137(a), (b), (c), (d), (e), (f), (g), (h), (l), and (n) AC 21-43 ¶s 2-1 – 10, 2-14, and 2-16	183.53(b), (c)(5), (6), and 183.63	PAH evaluation of its SMS is within the scope of the PAH's SMS, which is primarily reporting of major in-service safety feedback or safety significant quality escapes to the DO. Major in-service safety feedback or safety significant quality escapes are those items that are potential COS items, as defined by the DO.
5.71(a)(5)	NA	NA	Because incident and accident investigation is the purview of the National Transportation Safety Board (NTSB) (or other national agency) and controlled by their protocols, the intent is to have a process or system in place to support the DO in their support of an incident and accident investigation if requested by the NTSB (or other national agency).
5.71(a)(6)	21.137(n) AC 21-43 ¶ 2-16	183.63(c) Order 8100.15B ¶ 3-18	The intent of §5.71(a)(6) is met by compliance to §21.137(n) and §183.63(c) for PC, PMA and TSOA ODA holders.
5.71(a)(7)	NA	NA	Confidential employee reporting is not required by §21.137 or 14 CFR 183 Subpart D. A PAH confidential reporting system can be combined with of the organization's existing confidential reporting provided the system can distinguish those reported items that relate to the safe operation of the product or article in the NAS.

NPRM PART 5	PART 21.137/ AC 21-43	PART 183 SUBPART D ORDER 8100.15B	COMMENTS/NOTES
§ 5.71(b)	21.137(h), (m), and (n) AC 21-43 ¶s 2-10, 2-15, and 2-16	183.63(c) Order 8100.15B ¶ 3-18	In accordance with §21.137(h), (m), and (n), AC 21-43 ¶s 2-10, 2-15, and 2-16 and §183.63(c) Order 8100.15B ¶ 3-18 the intent of §5.71(b) is addressed by a PAH having a QMS with appropriately trained authorized individuals who can make determinations of major in-service safety feedback or safety significant quality escapes such that this information is provided to the DO. Major in-service safety feedback or safety significant quality escapes are those items that are potential COS items, as defined by the DO.
§ 5.73(a)			
§ 5.73(a)(2)	21.137(l) AC 21-43 ¶ 2-15	183.53(e)(5), (6) Order 8100.15B ¶ 3-14	The intent of §5.73(a)(2) is met by compliance with either §21.137(l) or §183.53(e)(5), and (6) provided the audit includes the procedures associated with the PAH's QMS for having appropriately trained authorized individuals who can make determinations of major in-service safety feedback or safety significant quality escapes such that this information is provided to the DO.
§ 5.73(a)(3)	21.137(h), (m), and (n) AC 21-43 ¶s 2-10, 2-15, and 2-16	183.63(a), (c) Order 8100.15B ¶ 3-18	The intent of §5.73(a)(3) is met by compliance with either §21.137(h) and (m) or, §183.63(a) and (c), limited to the PAH's QMS determination and reporting of major in-service safety feedback or safety significant quality escapes to the DO.
§ 5.73(a)(4)	21.137(a), (b), (c), (d), (e), (f), (g), (h), (l) and (n) AC 21-43 ¶s 2-1 – 10, 2-14, and 2-16	183.53(b), (c)(4), 55(a), and 57(e) Order 8100.15B ¶s 3-9 and 3-12	As depicted Figure 6, the intent of §5.73(a)(4) for a PAH is ensure any changes do not result in not producing a conformed product or article in a condition for safe operation, and to perform their QMS functions as described herein.
§ 5.73(a)(5)	21.137(a), (b), (c), (d), (e), (f), (g), (h), (l), and (n) AC 21-43 ¶s 2-1 – 10, 2-14, and 2-16	183.53(b), (c)(4), 55(a), and 57(e) Order 8100.15B ¶s 3-9 and 3-12	As depicted in Figure 6, the intent of §5.73(a)(5) for a PAH is ensure any changes do not result in not producing a conformed product or article in a condition for safe operation, and to perform their QMS functions, as described herein.
§ 5.73(b)	21.137(h), (m), and (n) AC 21-43 ¶s 2-10, 2-15, and 2-16	183.63(c) Order 8100.15B ¶ 3-18	In accordance with §21.137(h), (m), and (n) and AC 21-43 ¶s 2-10, 2-15, and 2-16 and §183.63(c)/Order 8100.15B ¶ 3-18 the intent of §5.73(b) is addressed by a PAH having a QMS with appropriately trained authorized individuals, who can make determinations of major in-service safety feedback or safety significant quality escapes such that this information is provided to the DO. Major in-service safety feedback or safety significant quality escapes are those items that are potential COS items as defined by the DO.
§ 5.75	21.137(n) AC 21-43 ¶ 2-16	183.63(c) and (d) Order 8100.15B ¶ 3-18	The intent of §5.71(a)(6) is met by compliance to §21.137(n) and §183.63(c) and (d) for PC, PMA, and TSOA ODA holders.

Figure 1: Three Phases of the Life Cycle of a Product or Article

Subparts C (Safety Risk Management) & D (Safety Assurance) for Design and Type Certification

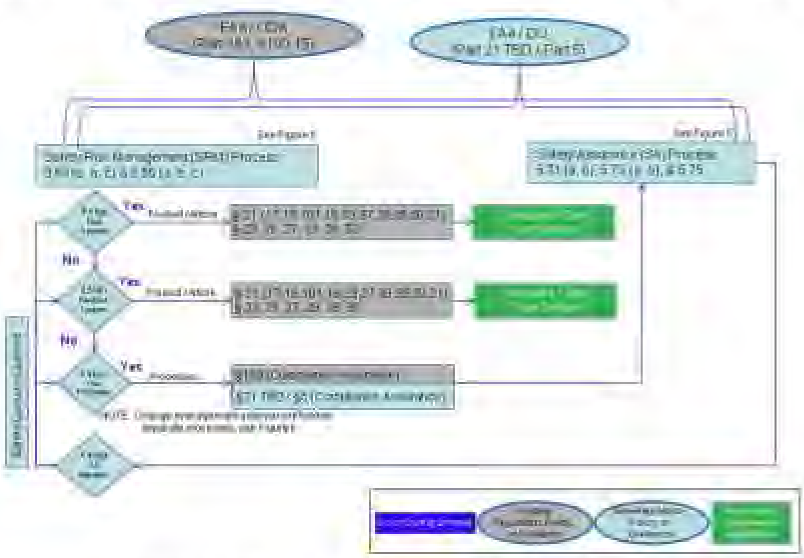

Figure 2: Intent of SMS Subpart C (SRM) and D (SA) During Design and Type Certification

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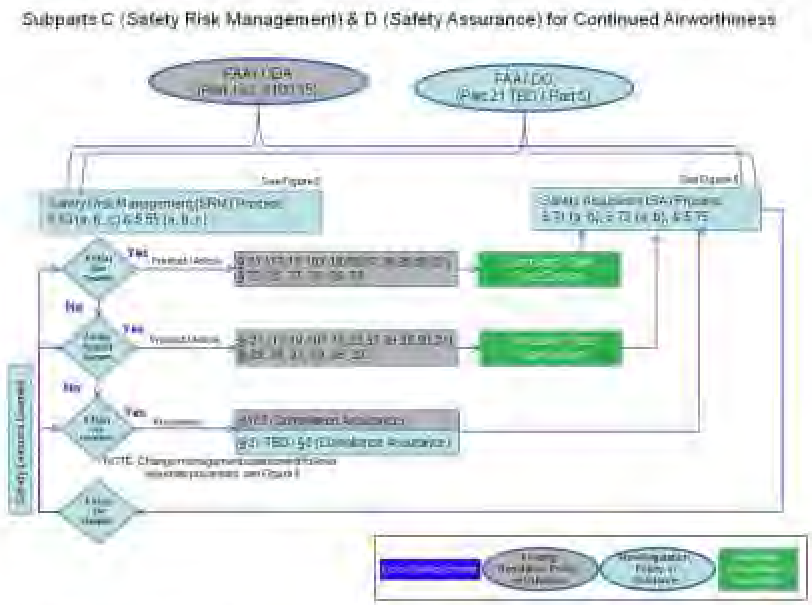

Figure 3: Intent of SMS Subpart C (SRM) and D (SA) for Continued Airworthiness

Figure 4: Intent of SMS Subpart C (SRM) and D (SA) during Production, Conformity, and Initial Airworthiness

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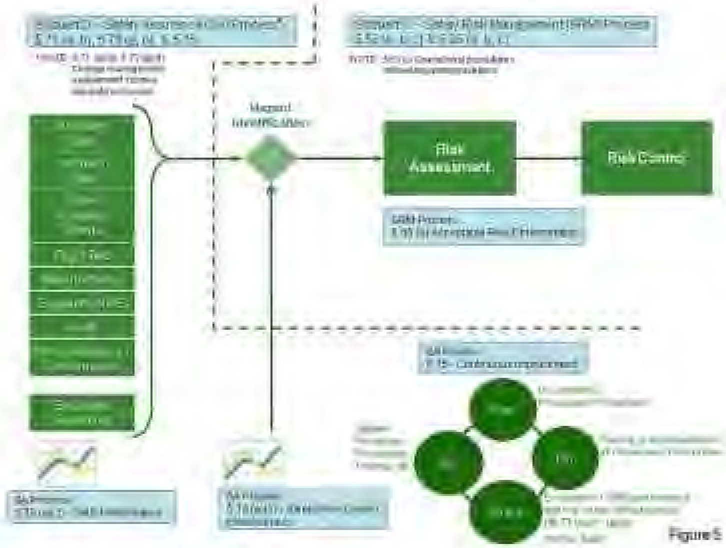

Figure 5: SMS Subparts C (SRM) and D (SA) Process Description

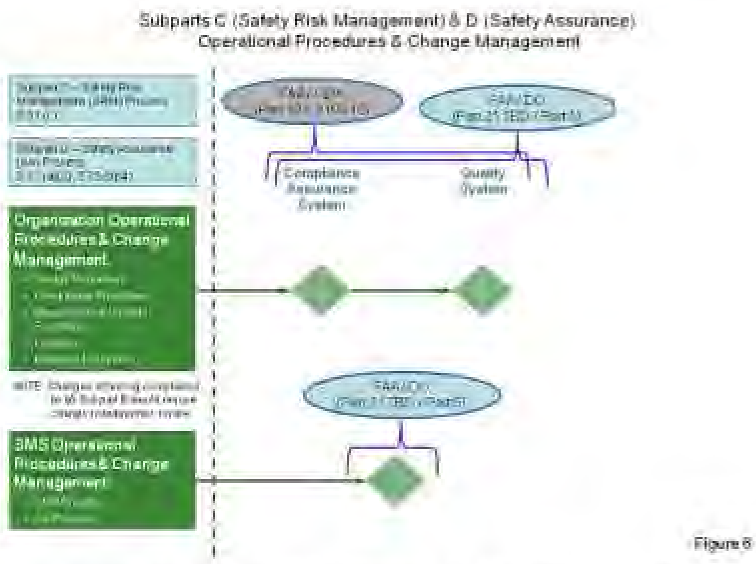

Figure 6: Intent of SMS Subparts C (SRM) and D (SA) for Operational Procedures and Change Management

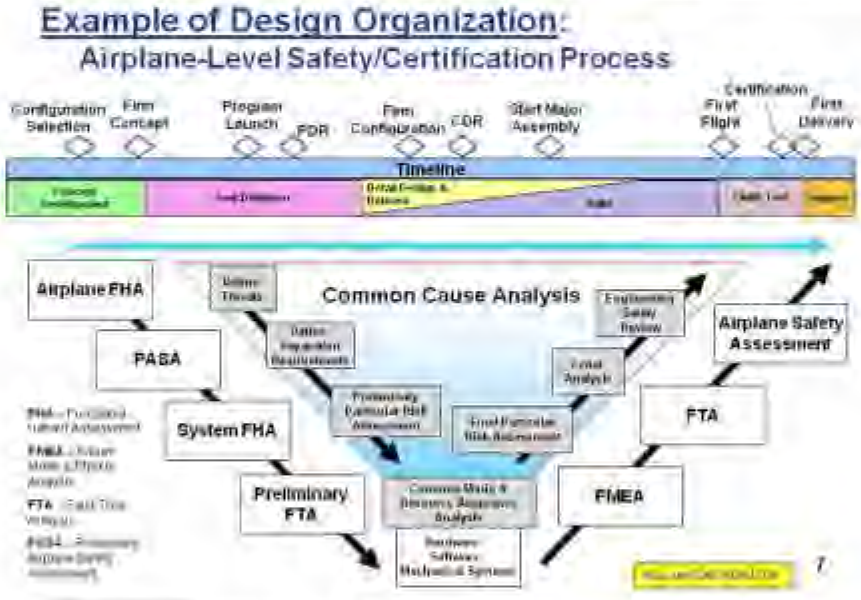

Figure 7: Example of an Airplane-Level System Safety/Certification Process

4.5.3 Tasks 6 and 7: SMS WG Recommendation

Notwithstanding the gap assessment (section 4.1) which identifies regulatory gaps between Part 21 and Part 5, the D&M community has established business practices that accomplish to varying degrees the intent of SRM and SA as part of their design, certification, production and continued airworthiness efforts although not using the SMS terminology. However, much of what has been written about SRM and SA has been from an operational sense (e.g., airline flight operations, airport air traffic operations), and limited documentation/guidance exists for how these SMS elements relate or are equivalent to what D&M organizations do as part of their compliance to the current design and certification procedures, and airworthiness regulations.

To ensure that the intent of SRM and SA, when applied to D&M, are applied in the most effective and efficient manner the SMS WG recommends that interpretations and explanations provided herein be included in any preamble, policy, or guidance material. As well, depending on the future state of delegation, approved or certificated organizations, as described herein, regulation, policy and guidance should allow an organization to use the same processes and procedures to satisfy the intent of the equivalent regulations. This approach would minimize the economic burden to industry, while maximizing the enhancement to aviation safety. The SMS WG recommends that, as described in this CONOPS, existing processes and procedures be considered as meeting the intent of Part 5.

4.6 Task 8: Coordinate SMS WG Efforts with Organizational WG, Oversight WG, and CBA WG

Task 8 required the SMS WG to coordinate our efforts between the Organizational WG, Oversight WG, and CBA WG. This effort has occurred throughout the WG activities with key coordination occurring at weekly telecoms for WG leads and also at full Part 21 / SMS ARC meetings.

Key assumptions from this coordination are provided in section 3.0 of this report.

4.7 Task 9: 14 CFR 21.3 for Organizations with an SMS

Task 9 required the SMS WG to provide a recommendation regarding what §21.3 should look like for a D&M organization with an SMS.

4.7.1 SMS WG Response

Advisory Circular (AC) 21-9A (now superseded to AC 21-9B), "Manufacturers Reporting Failures, Malfunctions, or Defects," included an explanation of the rationale for §21.3. According to the AC, "FAR 21.3 is directed to those deficiencies in the product that only the manufacturers would normally be expected to know (i.e., a design or a quality control deficiency). It is expected that compliance with FAR 21.3 will provide the earliest possible notification to the FAA of a hazardous condition, and that appropriate corrective action will be initiated by the manufacturer."

The SMS WG notes that SMS, and Part 5 in particular, introduces processes that far exceed the objectives of §21.3. Following are some points of comparison between §21.3 and Part 5:

- Absent a specific request by the FAA for more information, §21.3 requires the responsible approval holder to report only certain occurrences.
  - §5.53(c) would require processes intended to identify hazards broader in scope than §21.3, and §5.55 would require processes to assess safety risk associated with the identified hazards and to establish safety risk controls.
- There is not an explicit requirement that the approval holder establish a process or system to seek out and collect information, nor an explicit requirement to act upon a report unless requested by the FAA.
  - §5.71 would require SA processes that actively monitor and acquire data with respect to the holder's products, §5.53 would require that the holder identify hazards based on the collected data, §5.51 would require that SRM be applied to the identified hazards, §5.55 would require processes to assess safety risk associated with the identified hazards and to establish safety risk controls.

The SMS WG considers that exercise of an SMS inherently will accomplish the intent of §21.3 to a far greater extent than the regulation itself. §5.93(c) would require the certificate holder to have a means to convey safety critical information, which could include communicating information to the FAA that it needs in order to carry out its safety responsibilities. The WG recognizes that in order to accomplish effective oversight (including management of system level risk, 14 CFR 39 airworthiness directive requirements, etc.), the FAA may require that certain safety information be formally reported. Such reports and the requirement(s) for them should be established based upon Part 5, Subparts E and F.

Some approval or certificate holders are subject to the requirements of 14 CFR Part 183. §183.61 prescribes requirements for maintenance of records and reports. §183.63 requires an ODA holder to notify the FAA of a condition in a product, part, or appliance that could result in a finding of unsafe condition by the Administrator. For the same reasons as noted above for §21.3, the requirements of Part 5 meet the intent of sections §183.61 and §183.63. Thus, an ODA holder having an acceptable SMS would be subject to redundant process and notification requirements.

Many organizations that would be required to have an SMS also hold ODA and have §21.3 reporting requirements. For such an organization, there now exists high probability they would be required to have and use at least three separate processes, making separate respective reports to achieve a single common objective.

Similarly, such an organization may also be subject to other reporting redundant requirements or processes to some extent during exercise of SMS processes. Those other reporting requirements or processes might include, but not be limited to:

- §13.1, "Reports of violations of, inter alia, rules, regulations, and orders issued under the Federal Aviation Act of 1958."
- §21.139, "Location of or change to manufacturing facilities."
- §21.150, "Changes in quality system."
- §193.5, "Submission of safety information."
- §193.11, "What is the notice procedure?"
- §193.13, "What is the no-notice procedure?"

The SMS WG concludes that there is significant potential for design and/or manufacturing organizations that have an acceptable SMS to remain subject to redundant reporting requirements. Redundant requirements create the potential for inefficient and inconsistent reporting by an organization, and inefficient and ineffective oversight by the FAA. The SMS WG further concludes that the FAA should task an ARC sub-team to develop recommendations to minimize or eliminate redundant and inconsistent reporting and record keeping requirements for an SMS organization. The WG also should recommend appropriate reporting requirements and systems to enable the FAA to exercise its oversight and system level risk management responsibilities. The sub-team tasking should include consideration of any potential for redundant risk assessment requirements, such as those within ODA processes or agreements that a COS program may be used to satisfy §21.3.

4.7.2 Task 9: SMS WG Recommendation

The SMS WG recommends that the FAA task an ARC sub-team to develop recommendations to minimize or eliminate redundant and inconsistent reporting, record keeping, and risk assessment requirements for an SMS organization. Additionally, the sub-team should address appropriate reporting requirements and systems to enable the FAA to exercise its oversight and system level risk management responsibilities.

SECTION 5.0 Additional Recommendations

The SMS WG has identified the following additional recommendations based on our deliberations.

5.1 Acceptable Safety Risk

Part 5 requires that the D&M organization define a process for conducting risk assessment that allows for the determination of acceptable safety risk. The FAA would then accept the risk criteria proposed by the D&M as part of FAA acceptance of the SMS. However, there are no documented processes for determining acceptable safety risk for in-service issues on many products and articles. For example, the FAA has developed several risk assessment criteria. These include:

- AC 39-8: Transport Category Engines and APUs.
- TARAM: Transport Category Aircraft Risk Assessment Methodology.
- SARA: Small Aircraft Risk Assessment.
- RRA: Rotorcraft Risk Assessment.
- E&PD RA: Non-Transport Category Engines Risk Assessment.

Note that only AC39-8 has reached the level of maturity that it is mutually accepted by both D&M and FAA as an acceptable risk assessment criteria.

5.1.1 SMS WG Recommendation

The SMS WG recommends FAA establish WGs to develop and refine risk acceptance criteria for all types of products and articles. AC 39-8 provides one example of a risk acceptance criteria that has been developed (for transport category engines and APUs) in conjunction with D&M and is mutually accepted by FAA and industry. Agreement between the D&M and the FAA on acceptable safety risk criteria will reduce the need for the FAA to duplicate safety risk assessments conducted by the D&M. This will also facilitate efficient process oversight of the D&M SMS.

5.2 Availability of Data for SRM

The SMS WG noted that D&M organizations' ability to effectively implement SRM to address in-service risks could be constrained by the availability of in-service fleet data. The quality of SRM for in-service risks depends upon having data such as the number of hours/flights over a given time period, the number of component failures, component removals/replacements or inspections, and similar information. This is used to develop statistical models of fleet behavior, estimate failure rates, and projected numbers of future failures, recognize a failure does not necessarily denote an aircraft accident/incident in this discussion.

There is no regulatory requirement for operators to report any of this information to the TC / STC / TSOA / PMA holder or PC holder. Large D&M organizations, especially with a small number of high-volume customers, have been able to invest in a reporting infrastructure, which enables them to support a COS program. Smaller D&M organizations or those with a very large number of low volume customers may not have the same infrastructure or availability of data to conduct SRM similar to previously mentioned D&M organizations.

Since quantitative SRM can provide benefits beyond those found in qualitative SRM, enabling data flow from operators to D&M organizations may be beneficial. Possible approaches include:

- Providing data already reported to regulators back to D&M organizations in a timely and efficient way. Currently, any organization may request this data, but there is a significant time lapse between the data request and provision of the data, a subscription approach might be possible.
- Making the data already reported to regulators readily available [e.g., establishing a web interface accessing FAA Service Difficulty Reports (SDRs) database that D&M organizations could query].

5.2.1 SMS WG Recommendation

We recommend that the FAA develop an approach to make fleet data already provided to the FAA (hours, flights, reported failures, malfunctions, and defects and service difficulty reports) readily available to D&M organizations, in support of executing SRM.

SECTION 6.0 APPENDICES

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Appendix A. SMS WG Charter

A–1 Scope and Boundaries

As recommended by the ICAO FAA safety program identifies the fundamental safety management concepts and practices applicable to the implementation and oversight of SMSs for product providers. The FAA has proposed to incorporate these fundamental safety management concepts and practices into a new 14 CFR Part 5, Safety Management Systems.

The SMS WG will review the applicability of the proposed Part 5 SMS requirements within Part 21 for the D&M environment. The goal of the WG is to provide the FAA recommendations for rulemaking, suggested processes, policies, and guidance to align Part 21 with the SMS requirements documented in proposed Part 5. The WG should also identify and assess any differences between the recently adopted SMS requirements in ICAO Annex 19 and the proposed Part 5.

One option for the WG to evaluate is the integration, to the maximum extent practical, of the fundamental SMS concepts and practices into Part 21. The SMS WG will identify where and when each element of SMS can be used as a tool in the design, organization, and production processes so that once integrated, Part 21 can be considered SMS compliant. Therefore, each design and/or manufacturing organization producing a type design or product under Part 21 can be also considered to satisfy the intent of SMS in the international regulatory marketplace.

Another option is to point from Part 21 to Part 5. In consideration of this option, the WG should provide the FAA recommendations of any preamble material, guidance material, and proposed changes to Part 5 that are necessary from a D&M perspective.

The WG should evaluate these options (plus any others felt appropriate) and provide recommendations to the FAA on the optimum solution for the application of SMS to D&M organizations.

Finally, the WG should provide a recommendation to the FAA as to which D&M approval holder organizations should have SMS requirements applied to them. This recommendation should include scalability of SMS to D&M organizations based on their size, complexity, and safety risk introduced by their products.

A–2 Assumptions

1. The WG will use the SMS requirements as defined in the FAA proposed Part 5 and ICAO Annex 19 for comparison and evaluation. SMS implementation into 14 CFR is part of the broader ARC work to improve the regulatory processes and privileges for D&M.
2. Hazard is defined in accordance with FAA Order 8040.4a (Safety Risk Management Policy).

A–3 Tasking

1. Perform a regulatory gap analysis between the SMS requirements in Part 5, ICAO Annex 19, and Part 21.
2. Develop, evaluate options, and make a recommendation, for incorporation of SMS into 14 CFR for D&M organizations.

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3. Provide a recommendation as to which design and production approval holder organizations should have SMS requirements applied to them.
4. Produce recommended preamble, regulatory, and guidance material for SMS application to D&M organizations. Include an "operational" definition of a hazard throughout the life cycle of a product in SRM.
5. Provide guidance that accounts for scalability of SMS to D&M organizations based on their size, complexity, and safety risk introduced by their products.
6. Define the end state (roles, relationships, and responsibilities) for SMS in a D&M organization considering design, certification, production, and in-service support.
7. Perform a review of "strategic" safety decisions that are required to be made during the design, certification, and production phases throughout the life cycle of the product.
8. Coordinate SMS WG activities with 21 ARC and Oversight, CBA, and Organizational WGs.

A–4 *Deliverables*

1. Options, pros, cons, and recommended option for incorporation of SMS into 14 CFR for D&M organizations.
2. Recommended CONOPS for SMS (end state and potential strategic safety decisions per Tasks 6 and 7).
3. Recommendations on how to implement SMS including preamble, regulatory, and guidance material for incorporation of SMS into 14 CFR which includes applicability and scalability for D&M organizations.

A–5 Milestones and Dates

DATE	ACTION	EXPECTED DELIVERABLE
April 5th	Review and finalize Charter with SMS WG. Baseline WG on ICAO Annex 19 and Part 5 SMS requirements	Finalized SMS WG Charter, team baselined
April 30 & May 1	Phoenix WG Meeting	Review sub-team progress / update: 1. Part 5 to Part 21 gap assessment 2. ICAO Annex 19 to Part 5 gap assessment Begin team discussions on: 3. Incorporation options 4. CONOPS
June 11 & 12	Seattle WG Meeting	Finalize: 1. Gap assessment / summary Review sub-team progress / update: 2. Incorporation options 3. CONOPS Begin team discussions on: 4. Design approval holder SMS applicability 5. SMS scalability and flexibility 6. Strategic safety decisions
July 16	Present status to Part 21 / SMS ARC	1. Gap Assessment / summary 2. Incorporation options 3. CONOPS
July 17 & 18	Rosslyn WG Meeting	Finalize: 1. Recommended incorporation option 2. CONOPS Review subteam progress on: 3. Design approval holder SMS applicability 4. SMS scalability and flexibility 5. Strategic safety decisions Begin team discussions on: 6. Recommended preamble, regulatory, and guidance material
August 13 & 14	Wichita WG Meeting	Finalize: 1. Design approval holder SMS applicability 2. SMS scalability and flexibility 3. Strategic safety decisions Review sub-team progress on: 4. Recommended preamble, regulatory, and guidance material Begin team discussions on: 5. SMS WG Final Report
Sep 17	Present recommendations to Part 21 / SMS ARC	1. Gap assessment / summary 2. Incorporation options 3. CONOPS 4. Design approval holder SMS applicability 5. SMS scalability and flexibility 6. Strategic safety decisions
Sep 18 & 19	Rosslyn WG Meeting	Finalize: 1. Recommended preamble, regulatory, and guidance material Writing assignments / report outline: 2. SMS WG final report
Oct 30 & 31	Hartford WG Meeting	Draft SMS WG Report review and update
December 10 & 11	Rosslyn WG Meeting	Final report
Dec 12 & 13	21 ARC Meeting	Report out to ARC
January 13-15, 2014	Phoenix WG Meeting	Finalize report
January 17, 2014	Final Report Due	Final Report delivered to ARC

A–6 References

- ICAO Annex 19 (C-WP/13935)
- Proposed Part 5 [Docket No. FAA–2009–0671; Notice No.10–15]
- Part 21 / SMS-ARC Report
- Aircraft Certification Service (AIR) Manufacturers Safety Management System Pilot Project Report – Design and Manufacturing Organizations
- Certificated Design Organization (CDO) ARC Report

A–7 WG Lead(s) and Members

Chris Eick (SMS WG Chair, Honeywell)
Ricardo Aoyama (Embraer)
Michael Bartron (P&W)
Rafael Ximenes Borges (ANAC)
Fabio Catani (Embraer)
Peter Corbeel (EASA)
Marco Cuberos (HEICO)
Mike Deer (Bell)
Fred Etheridge (Gulfstream)
Chuck Huber (FAA)
Doug Kihm (Boeing)
Sarah Knife (GE)
Jason Lewis (BE Aerospace)
John Loehr (Cessna)
Stacy Mason (TCCA)
Claire Pelegrin (Airbus)
Ric Peri (AEA)
Rogério Possi Jr. (ANAC)
Eric Sivel (EASA)
Dean Thompson (Beechcraft)
Chris Willingham (Wencor)
Jeff Wood (Boeing)
Paul Yocera (Cessna)

Appendix B. SMS WG Membership

SEGMENT	ORGANIZATION	NAME
Association - Aircraft Electronics Association (AEA)	Aircraft Electronics Association (AEA)	Ric Peri
Association AeroSpace and Defense Industries Association of Europe (ASD)	Airbus	Claire Pelegrin
Association Modification and Replacement Parts Association (MARPA)	BE Aerospace	Jason Lewis
Association Aerospace Industries Association of Canada (AIAC)	Bell	Mike Deer
Association Aerospace Industries Association of Brazil (AIAB)	Embraer	Ricardo Anyama
Association Aerospace Industries Association of Brazil (AIAB)	Embraer	Fabio Catani
Association Modification and Replacement Parts Association (MARPA)	Heico	Marco Cuberos
Association Modification and Replacement Parts Association (MARPA)	Wencor Group	Chris Willingham
Transport	Boeing	Doug Kihm
Transport	Boeing	Jeff Wood
Transport General Aviation	Gulfstream	Fred Etheridge
General Aviation Part 23	Beechcraft	Dean Thompson
General Aviation Part 23	Cessna	Paul Vicera
General Aviation Part 23	Cessna	John Loehr
Engines	General Electric	Sarah Knife
Systems	**Honeywell**	**Chris Eick (WG Chair)**
Rotorcraft	Pratt & Whitney	Michael Burton
Federal Aviation Administration	ANM-100	Chuck Huber
Observer	European Aviation Safety Agency (EASA)	Jan Novak
Observer	Transport Canada Civil Aviation (TCCA)	Stacey Mason
Observer	National Civil Aviation Agency – Brazil (ANAC)	Rafael Ximenes Borges
Observer	National Civil Aviation Agency – Brazil (ANAC)	Rogerio Possi Junior

Appendix C. Detailed Gap Assessment between Part 21, Part 5, and ICAO Annex 19

ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SUBJECT/COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
Chapter 4 Safety Management System (SMS)	[illegible]	5.1 Applicability	[illegible]	[illegible]	[illegible]
Appendix 2 Framework for a Safety Management System (SMS)	[illegible]		[illegible]	[illegible]	
Appendix 2 Framework for a Safety Management System (SMS)	[illegible]		[illegible]	[illegible]	
Appendix 2 Framework for a Safety Management System (SMS) [illegible]	1. [illegible] 2. [illegible] 3. [illegible] 4. [illegible]	5.5 General Requirements	[illegible]	[illegible]	

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			with the requirements of Subpart D of this part; and (4) Safety promotion in accordance with the requirements of Subpart E of this part. (b) The Safety Management System must be maintained in accordance with the recordkeeping requirements in Subpart F of this part. (c) The Safety Management System must ensure compliance with the relevant regulatory standards in Chapter I of Title 14 of the Code of Federal Regulations.	commensurate with the [illegible], and are within the scope and nature of an SMS.	
Chapter 1 Definitions		5.5 Definitions	Hazard means a condition that can lead to injury, illness, or death to people; damage to or loss of a system, equipment, or property; or damage to the environment. Risk means the composite of predicted severity and likelihood of the potential effect of a hazard. Risk control means a means to reduce or eliminate the effects of hazards. Safety assurance means processes within the SMS that function systematically to ensure the performance and effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information. Safety Management System (SMS) means the formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk. Safety objective means a measurable goal or desirable outcome related to safety. Safety performance means realized or actual safety accomplishment relative to the organization's safety objectives. Safety policy means the certificate holder's documented commitment to safety, which defines its safety objectives and the accountabilities and	Part 5 adds many definitions not in ICAO (e.g., hazard, risk). Part 5 has slightly different definitions than used by ICAO (e.g., Safety Management System (SMS)).	

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 NPRM COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			responsibilities of its employees in regard to safety. Safety promotion means a combination of training and communication of safety information to support the implementation and operation of an SMS in an organization. Safety risk management means a process within the SMS composed of describing the system, identifying the hazards, and analyzing, assessing and controlling risk.		
1. Safety Policy and Objectives		Subpart B – Safety Policy			
1.1 Management Commitment and Responsibility	The service provider shall define its safety policy in accordance with international and national requirements. The safety policy shall:	5.21 Safety Policy	(a) The certificate holder must have a safety policy that includes at least the following: (b) The safety policy must be in accordance with all applicable regulatory requirements in Chapter I of Title 14 of the Code of Federal Regulations and must reflect the certificate holder's commitment to safety.		**What is Covered in Part 21:** Only as a certificate holder/ mentioned in Part 21 [illegible]. **What is Missing in Part 21:** Safety policy is not proposed; [illegible] in the context of product.
	a) reflect organizational commitment regarding safety;		(a) The certificate holder must have a safety policy that includes at least the following: (1) The safety objectives of the certificate holder. (2) A commitment of the certificate holder to fulfill the organization's safety objectives.	Part 5 requires commitment to safety objectives. Annex 19 only requires to safety commitment.	**What is Covered in Part 21:** Part 21 is focused on the [illegible] of [illegible] products. **What is Missing in Part 21:** There is not explicit [illegible] of the certificate holder's safety objectives or a commitment to fulfill them.
	b) include a clear statement about the provision of the necessary resources for the implementation of the safety policy;		(a) The certificate holder must have a safety policy that includes at least the following: (3) A clear statement about the provision of the necessary resources for the implementation of the SMS.	Part 5 is more explicit; requires provisions for implementation of SMS and just [illegible].	**What is Covered in Part 21:** It is implied in Part §21.135 (PAH) that organizations provide the required resources to meet the regulations. **What is Missing in Part 21:** Because there is no SMS mandate, or associated requirements, there are no requirements associated to resources needed for implementation of SMS.

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Part 21 / SMS Aviation Rulemaking Committee
Appendix C. Detailed Gap Assessment Between Part 21, Proposed Part 5, and ICAO Annex 19

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Revision: Original
Date: Oct 10, 2013

ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
	c) include safety reporting procedures;		(a) The certificate holder must have a safety policy that includes at least the following: (4) A safety reporting policy that defines requirements for employee reporting of safety hazards or issues.		**What is Covered in Part 21:** §21.137(i) requires [illegible] process control. §21.137(m) provides framework for collection of [illegible] feedback, including failures, malfunctions, and defects. **What is Missing in Part 21:** There is no explicit requirement [illegible] employee reporting of safety hazards or issues.
	d) clearly indicate which types of behaviours are unacceptable related to the service provider's aviation activities and include the circumstances under which disciplinary action would not apply;		(a) The certificate holder must have a safety policy that includes at least the following: (5) A policy that defines unacceptable behavior and conditions for disciplinary action.	Part 5 requires/defines when disciplinary action is [illegible], whereas Annex 19 requires when disciplinary action would not apply.	**What is Covered in Part 21:** §21.2 addresses falsification of applications, reports, and records. **What is Missing in Part 21:** There is no explicit requirement [illegible] unacceptable behavior or disciplinary actions.
	e) be signed by the accountable executive of the organization;		(c) The safety policy must be signed by the accountable executive described in §5.25.	Part 5 provides criteria for identifying the accountable executive.	**What is Covered in Part 21:** §21.135 requires the roles, responsibilities, and authority [illegible] the [illegible] management [illegible]. **What is Missing in Part 21:** The safety policy or accountable executive is not mentioned.
	f) be communicated, with visible endorsement, throughout the organization; and		(d) The safety policy must be documented and communicated throughout the certificate holder organization.	Part 5 and Annex 19 essentially equivalent.	**What is Covered in Part 21:** **What is Missing in Part 21:** The safety policy communication is not mentioned.
	g) be periodically reviewed to ensure it remains relevant and appropriate to the service provider.		(e) The safety policy must be regularly reviewed by the accountable executive to ensure it remains relevant and appropriate to the certificate holder.	Part 5 requires the safety policy be reviewed by the accountable executive.	**What is Covered in Part 21:** **What is Missing in Part 21:** The safety policy and accountable executive is not mentioned, or no associated requirements to review the policy.
1.2 Safety	The service provider shall: a) identify the accountable executive who, irrespective of other functions, has ultimate responsibility and accountability, on behalf of the organization, for the implementation and maintenance of the SMS;	5.25 Safety Accountability and Authority	(a) The certificate holder must define accountability for safety within the organization's safety policy for the following individuals:		
			(1) Accountable executive, as described in §5.25 [illegible]	Part 5 organizes accountable executive / responsibilities and accountabilities [illegible] authority [illegible] Annex 19	**What is Covered in Part 21:** **What is Missing in Part 21:** The safety policy and accountable executive is not mentioned.

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
	b) clearly defines lines of safety accountability throughout the organization, including a direct accountability for safety on the part of senior management; c) identify the accountabilities of all members of management, irrespective of other functions, as well as of employees, with respect to the safety performance of the SMS;		(2) All members of management in regard to developing, implementing, and maintaining SMS processes within their area of responsibility, including, but not limited to: (i) Hazard identification and safety risk assessment. (ii) Assuring the effectiveness of safety risk controls. (iii) Promoting safety as required in subpart E of this part. (iv) Advising the accountable executive on the performance of the SMS and on any need for improvement.	Part 5 is stronger regarding management responsibilities with respect to SMS.	**What is Covered in Part 21:** §21.135 does discuss the roles and responsibilities for the PAH management structure. **What is Missing in Part 21:** Safety policy and accountability structure is not mentioned neither are management standards.
			(3) Employees relative to the certificate holder's safety performance.	Part 5 includes non-management.	**What is Covered in Part 21:** **What is Missing in Part 21:** §21.135 does discuss the roles and responsibilities for the PAH management structure. Safety policy and [illegible] relative to the company's safety performance.
	d) document and communicate safety responsibilities, accountabilities and authorities throughout the organization; and	**§5.25 Designation and Responsibilities of Required Safety Management Personnel**	[illegible] (a) Designation of the accountable executive. The certificate holder must identify an accountable executive who, irrespective of other functions, satisfies the following: (1) Is the final authority over operations authorized to be conducted under the certificate holder's certificate(s). (2) Controls the financial resources required for the operations to be conducted under the certificate holder's certificate(s). (3) Controls the human resources required for the operations authorized to be conducted under the certificate holder's certificate(s).	Part 5 contains more explicit [illegible] for accountable executive.	**What is Covered in Part 21:** **What is Missing in Part 21:** Part 21 does not discuss the SMS accountable executive, or their associated responsibilities, accountabilities and authorities.

ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 (SMS) COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(4) Retain ultimate responsibility for the safety performance of the operations conducted under the certificate holder's certificate. (b) Responsibilities of the accountable executive. The accountable executive must accomplish the following: (1) Ensure that the SMS is properly implemented and performing in all areas of the certificate holder's organization. (2) Develop and sign the safety policy of the certificate holder. (3) Communicate the safety policy throughout the certificate holder's organization. (4) Regularly review the certificate holder's safety policy to ensure it remains relevant and appropriate to the certificate holder. (5) Regularly review the safety performance of the certificate holder's organization and direct actions necessary to address substandard safety performance in accordance with §5.75.		**What is Covered in Part 21:** **What is Missing in Part 21:** Part 21 does not designate [illegible] accountable executive [illegible]
	c) define the levels of management with authority to make decisions regarding safety risk tolerability	§23 Safety Accountability and Authority	(b) The certificate holder must identify the levels of management with the authority to make decisions regarding safety risk acceptance.	Part 5 uses [illegible] acceptance; Annex 19 uses safety risk tolerability; [illegible] are similar terms.	**What is Covered in Part 21:** §21.137 requires the organization [illegible] identify the levels of management and delegates authority for the FAA. [illegible] **What is Missing in Part 21:** Does not require the identification of the levels of management with authority to make decisions regarding safety risk acceptance.
1.2 Appointment of Key Safety Personnel	The service provider shall appoint a safety manager who is responsible for the implementation and maintenance of an effective SMS.	§25 Designation and Responsibilities of Required Safety Management Personnel	(c) Designation of a management representative. The accountable executive must designate a management representative(s) who, on behalf of the accountable executive, must be responsible for the following: (1) Facilitating hazard identification and safety risk analysis. (2) Monitoring the effectiveness of safety risk controls.	Part 5 lists implementation and management responsibilities under the accountable executive. However, Part 5 does not preclude the accountable executive from delegating this responsibility to other managers. Part 5 [illegible]	**What is Covered in Part 21:** **What is Missing in Part 21:** Part 21 does not designate the safety accountable executive, management representative, or their associated responsibilities.

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 (SMS) COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(2) Ensuring safety promotion throughout the certificate holder's organization as required in Subpart E of this part. (3) Regularly reporting to the accountable executive on the performance of the SMS and on any need for improvement.	regarding the responsibility of management representatives and that is similar to what Annex 19 "safety manager"	
1.4 Coordination of Emergency Response Planning	The service provider shall ensure that an emergency response plan is properly coordinated with the emergency response plans of those organizations it must interface with during the provision of its products and services.	**5.27 Coordination of Emergency Response Planning**	Where emergency response procedures are necessary, the accountable executive and management representatives must develop as part of the safety policy of the certificate holder, an emergency response plan that addresses at least the following: (a) Delegation of emergency authority throughout the certificate holder's organization; (b) Assignment of employee responsibilities during the emergency; and (c) Coordination of the certificate holder's emergency response plans with the emergency response plans of other organizations it must interface with during the provision of its services.	Part 5 limits emergency response planning to where necessary. Part 5 has no coordinated emergency response planning requirements [illegible] Annex 19.	**What is Covered in Part 21:** **What is Missing in Part 21:** There are no emergency response requirements defined in Part 21; therefore it does not contain emergency response planning.
		5.21 Safety Policy	(a) The certificate holder must have a safety policy that includes at least the following: (6) An emergency response plan that provides for the safe transition from normal to emergency operations in accordance with the requirements of §5.27.	Part 5 requires an emergency response plan. Annex 19 requires the coordination of emergency response plans.	**What is Covered in Part 21:** **What is Missing in Part 21:** There are no emergency response requirements in Part 21; therefore it does not contain emergency response planning, including requirements associated with the return to normal operations.
1.5 SMS Documentation	1.5.1 The service provider shall develop an SMS implementation plan, formally endorsed by the organization that defines the organization's approach to the management of safety in a manner that meets the organization's safety objectives.	5.1 Applicability	(b) A certificate holder must submit an implementation plan to the FAA Administrator for approval no later than 6 months after the effective date of the final rule. (c) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of this part, including components of an existing SMS.	Part 5 requires implementation plan submittal/approval. Part 5 includes allowance for use of existing programs, policies, or procedures.	**What is Covered in Part 21:** **What is Missing in Part 21:** There is no SMS requirement; therefore, no defined implementation plan requirement is used.

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
	4.1.2 The service provider shall develop and maintain SMS documentation that describes the: a) safety policy and objectives; b) SMS requirements; c) SMS processes and procedures; d) accountabilities, responsibilities and authorities for SMS processes and procedures; and e) SMS outputs.	§ 5.95 SMS Documentation	The certificate holder must develop and maintain SMS documentation that describes the certificate holder's: (a) Safety policy. (b) SMS processes and procedures.	Part 5 documentation has a smaller scope than Annex 19.	**What is Covered in Part 21:** Some documentation is required in §21.137 to describe the PAH. **What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements to document the safety policy, SMS processes and procedures.
		§ 5.97 Records	(a) The certificate holder must maintain records of outputs of safety risk management processes as described in Subpart C of this part. Such records must be retained for as long as the control remains relevant to the operation.	Part 5 adds specific record retention requirements that do not appear in Annex 19.	**What is Covered in Part 21:** Some records are required in §21.137 for the PAH and in other places that are not identified as SMS.
			(b) The certificate holder must maintain records of outputs of safety assurance processes as described in Subpart D of this part. Such records must be retained for a minimum of 5 years.		**What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements exist for SMS records, training records, or communications.
		§ 5.97 Records	(c) The certificate holder must maintain a record of all training provided under § 5.91 for each individual. Such records must be retained for a minimum of 24 consecutive calendar months after completion of the training. (d) The certificate holder must retain records of all communications provided under § 5.93 for a minimum of 24 consecutive calendar months.	Part 5 adds specific record retention requirements that do not appear in Annex 19.	**What is Covered in Part 21:** Some records are required in §21.137 for the PAH and in other places that are not identified as SMS. **What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements exist for SMS records, training records, or communications.
	4.1.3 The service provider shall develop and maintain an SMS manual as part of its SMS documentation.	§ 5.95 SMS Documentation	The certificate holder must develop and maintain SMS documentation that describes the certificate holder's: (a) Safety policy. (b) SMS processes and procedures.	Part 5 allows more documentation flexibility but is more specific regarding content requirements.	**What is Covered in Part 21:** Some documentation is required in §21.137 to describe the PAH. **What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements to document the safety policy, SMS processes and procedures.

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
2. Safety Risk Management		Subpart C — Safety Risk Management			
2.1 Hazard Identification	2.1.1 The service provider shall develop and maintain a process that ensures that hazards associated with its aviation products or services are identified.	5.53 System Analysis and Hazard Identification	(a) When applying safety risk management, the certificate holder must have a process to describe and analyze the systems for use in identifying hazards under paragraph (c) of this section, and develop and implement risk controls related to the system under § [illegible]	Part 5 (5.53) includes only the requirement for hazard identification and risk assessment. Annex 19 has hazard identification defined in 2.1 and risk assessment in 2.2.	**<u>What is Covered in Part 21:</u>** Provides the airworthiness regulations for systems (including airplanes, engines, propellers, articles, and parts) (§ 21.1). **<u>What is Missing in Part 21:</u>** No Part 21 regulations that explicitly require a systems description that encompasses organizational resources or procedures. <u>NOTES</u> 1. Part 21 does not define the term "system". <u>Rulemaking</u> [illegible] <u>Design</u> Part 21 provides the airworthiness regulations for systems (including airplanes, engines, propellers, articles, and parts). § 21.17 [illegible] design requirements (airworthiness standards). Airworthiness regulations have identified hazards (§ 21.[illegible], § 25.1309, etc.). § 21.16 provides special conditions. <u>Continuing</u> § 21.3 defines reporting of [illegible] <u>Production</u> § 21.137 defines the quality system. **<u>What is Missing in Part 21:</u>** <u>Design</u> Does not explicitly require a system description that encompasses a design organization. <u>[illegible]</u> Does not explicitly require a system description that encompasses a [illegible] organization.

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ICAO ANNEX 19 FRAMEWORK COMPONENT / ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT / ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(b) In conducting the system analysis, the following information must be considered: (1) Function and purpose of the system. (2) The system's operating environment. (3) An outline of the system's processes and procedures. (4) The personnel, equipment, and facilities necessary for operation of the system.	[illegible] contains additional specific considerations for determining hazard identification not contained in Annex 19.	**What is Covered in Part 21:** Design - Certification Part 21 provides the airworthiness regulations for systems including airplanes, engines, propellers, articles, and parts. Using design requirements [illegible] description and operational environment in the design and certification process (see §21.[illegible]). Production §21.137 requires a quality system description, with implied requirement in [illegible] and §21.137(a). In-Service Not explicitly covered in Part 21; currently being addressed by [illegible] procedures not required by Part 21. **What is Missing in Part 21:** Does not explicitly require a system analysis that encompasses [illegible] for organizational processes or procedures. Part 21 does not include a requirement for analysis of a system for hazard identification.
	2.1.2 Hazard identification shall be based on a combination of reactive, proactive, and predictive methods of safety data collection.		(c) The certificate holder must develop and maintain processes to identify hazards within the context of the system analysis.	Part 5.5 is more general on hazard identification. Annex 19 specifies a three-tiered hazard identification approach (reactive, proactive, and predictive).	**What is Covered in Part 21:** Provides the airworthiness requirements for systems including airplanes, engines, propellers, appliances, and parts. Airworthiness standards have been developed to address previously identified hazards. Risk mitigation for the product is captured through the airworthiness standards (e.g., 14 CFR Parts 23 and 25). Design §21.16 and §21.17 §21.16 is a means for FAA to apply new mitigations for new and novel technologies. Certification §21.21(b)(2), §21.[illegible] Production §21.137

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
					Indirectly: 1. §21.137(m) and §21.3 [illegible] 2. §21.137(n) [illegible] 3. §21.3 [illegible] reporting of [illegible] failures, malfunctions, and defects 4. [illegible] **What is Missing in Part 21** Hazard identification is not specifically required through Part 21. Requirement to develop and maintain processes for hazard identification is not present in Part 21. Indirectly: [illegible] reporting, [illegible] hazard identification 1. §21.137(m) and §21.3 [illegible] Part 21 does not address organizational processes or procedures.
2.2 Risk Assessment and Mitigation	The service provider shall develop and maintain a process that ensures analysis, assessment and control of the safety risks associated with identified hazards.	5.51 Applicability	A certificate holder must apply safety risk management to a system analysis of the following: (a) Implementation of new systems. (b) Revision of existing systems. (c) Development of operational procedures. (d) Identification of hazards or ineffective risk controls through the safety assurance processes in subpart D of this part.	Part 5 specifies the conditions under which safety risk management must be applied.	**What is Covered in Part 21** **Hazard Identification** [illegible] (a) and (b) would be applied [illegible] design approvals. TC process per §21.17 and §21.[illegible] [illegible] Subpart B STC Subpart E §21.99 TSO Subpart O PMA Subpart K Production [illegible] §21.137 [illegible] (b) Nonconforming product and article control

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
					(i) Corrective and preventive actions; (iii) Investigate feedback, [illegible]. In Service: §21.3 **What is Missing in Part 21:** [illegible] [illegible] [illegible] In Service: [illegible] NOTES: [illegible] required by Part 21.
		5.55 Safety Risk Assessment and Control	(a) The certificate holder must develop and maintain processes to analyze safety risk associated with the hazards identified in §5.53(c). (b) The certificate holder must define a process for conducting risk assessment that allows for the determination of acceptable safety risk. [illegible] in compliance with the applicable regulatory requirements set forth in Chapter I of Title 14 of the Code of Federal Regulations.	[illegible] Part 5 includes an additional requirement [illegible]	**What is Covered in Part 21:** **What is Missing in Part 21:** [illegible] safety risk. **What is Covered in Part 21:** Design: [illegible] requirements in 14 CFR. **What is Missing in Part 21:** [illegible] NOTES: 1. [illegible]

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(c) The certificate holder must develop and maintain processes to develop safety risk controls that are necessary as a result of the safety risk assessment process under paragraph (b) of this section. (1) The certificate holder must evaluate whether the risk will be acceptable with the proposed safety risk control applied, before the safety risk control is implemented. (2) The safety risk controls must be in a [illegible] comply with the applicable regulatory requirements set forth in chapter I of title 14 of the Code of Federal Regulations.	§5.55(c)(1) includes an additional requirement associated with acceptability of the risk control before the control is implemented. §5.55(c)(2) includes an additional requirement or statement associated to acceptable target of safety (i.e., compliance to applicable CFRs).	**What is Covered in Part 21:** **What is Missing in Part 21:** Part 21 does not require definition of processes to develop risk controls to mitigate unacceptable safety risk levels. NOTES: 1. Recommended definition (p.[illegible]) 2. Should differentiate the levels of acceptable safety risk.
3. Safety Assurance		**Subpart D – Safety Assurance**			
3.1 Safety Performance Monitoring and Measurement	3.1.1 The service provider shall develop and maintain the means to verify the safety performance of the organization and to validate the effectiveness of safety risk controls.	**§5.71 Safety Performance Monitoring and Measurement**	(a) The certificate holder must develop and maintain processes and systems to acquire data with respect to its operations, products, and services to monitor the safety performance of the organization. These processes and systems must include, at a minimum, the following:	Part 5 contains specific safety performance aspects that are not in ICAO.	**What is Covered in Part 21:** Production: §21.137(i) requires procedures for implementing corrective and preventive actions. In-Service: §21.3 [illegible], §21.4, §21.3, §21.607, and §21.137(l) require the development of processes and systems to capture data related to products, TSO articles and parts. **What is Missing in Part 21:** Data gathered is not specifically to address the (7) items contained in §5.71, nor is it explicitly identified for monitoring safety performance of the organization.
			(1) Continuous monitoring of operational processes.		**What is Covered in Part 21:** Production: §21.137 requires manufacturing process control. In-Service: §21.137(n) requires procedures for reporting of failures, malfunctions and defects, but not continuous monitoring of operations.

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
					What is Missing in Part 21: [illegible] NOTES: 1. [illegible]
			(2) Periodic monitoring of the operational environment to detect changes.		**What is Covered in Part 21:** [illegible] **What is Missing in Part 21:** [illegible]
			(3) Auditing of operational processes and systems.		**What is Covered in Part 21:** [illegible] **What is Missing in Part 21:** [illegible]
			(4) Evaluations of the SMS and operational processes and systems.		**What is Covered in Part 21:** **What is Missing in Part 21:** [illegible]
			(5) Investigations of incidents and accidents.		**What is Covered in Part 21:** [illegible] **What is Missing in Part 21** NOTES: 1. [illegible]

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
					2. Should focus on information from accident or incident investigation.
			(3) Investigations of hazards including potential noncompliance with regulatory standards or other safety risk controls established by the certificate holder through the safety risk management process established in subpart C of this part.		**What is Covered in Part 21:** Production: §21.137(i) requires procedures for investigation of quality escapes. **What is Missing in Part 21:** Part 21 does not require safety risk controls [illegible] requirements [illegible] Part 21 [illegible] investigation is limited to corrective actions and does not address monitoring of safety performance. NOTES: 1. [illegible]
			(7) A confidential employee reporting system in which employees can report hazards, issues, concerns, occurrences, incidents, as well as propose solutions and safety improvements.	Part 5 reflects the Annex 19 (Section 3.1.1) standard, which is not explicitly part of the Appendix 2 SMS standard.	**What is Covered in Part 21:** **What is Missing in Part 21:** Does not require an employee reporting system.
			(b) The certificate holder must develop and maintain processes that analyze the data acquired through the processes and systems identified under paragraph (a) of this section and any other relevant data with respect to its operations, products, and services.	Part 5 is consistent with Annex 19 3.1.1.	**What is Covered in Part 21:** Production: §21.137(i) requires analysis of the data collected. §21.137(n) requires procedures for [illegible] feedback. **What is Missing in Part 21:** In general, does not require processes to analyze the data collected from paragraph (a).
3.1 Safety Performance Monitoring and Measurement	3.1.2 The service provider's safety performance shall be verified in reference to the safety performance indicators and safety performance targets of the SMS.	§5.73 Safety Performance Assessment.	(a) The certificate holder must conduct assessments of its safety performance against its safety objectives, which include reviews by the accountable executive, to:	Part 5 [illegible] reviews by the accountable executive.	**What is Covered in Part 21:** **What is Missing in Part 21:** Does not require assessments of safety performance [illegible] accountable executive. NOTES: 1. [illegible]

ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(1) Assess the certificate holder's compliance with the applicable regulatory requirements in Chapter I of title 14 of the Code of Federal Regulations and additional safety risk controls established by the certificate holder.	Part 5 introduces a requirement to assess compliance with CFRs.	**What is Covered in Part 21:** Part 21 addresses design approvals and production approvals [illegible] with 14 CFR. Design §21.21 Certification §21.21(b)(1) [illegible] in addition to compliance to CFRs [illegible] characteristics. **What is Missing in Part 21:** Part 21 does not require establishment of additional risk controls or assessing compliance with them. NOTES 1. [illegible] program is an additional safety risk control [illegible]
			(2) Evaluate the performance of the SMS	§5.73(a)(2) is equivalent to Annex 19 Section 3.3 but does not contain the [illegible] requirements.	**What is Covered in Part 21:** **What is Missing in Part 21:** Does not require an SMS or evaluation of its performance. NOTES 1. [illegible] evaluate the safety performance of the organization [illegible] the SMS [illegible]
			(3) Evaluate the effectiveness of the safety risk controls established under §5.55(c) and identify any ineffective controls	§5.73(a)(3) is equivalent to Annex 19 3.3.2 except for the aspects of §5.55(c) that [illegible] Annex 19	**What is Covered in Part 21:** **What is Missing in Part 21:** [illegible] NOTES Typically covered through a [illegible] program.
			(4) Identify changes in the operational environment that may introduce new hazards	Part 5.73(a)(4) is similar to Annex 19, Appendix 2, Section 3.2.	**What is Covered in Part 21:** Production §21.137 addresses changes to the quality system. [illegible] **What is Missing in Part 21:**

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 SMS COMPONENT/ ELEMENT	PART 5 SMS REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
					[illegible] NOTES: 1. [illegible]
			[illegible]	[illegible]	What is Covered in Part 21: [illegible] What is Missing in Part 21: [illegible] NOTES: 1. [illegible] 2. [illegible] 3. [illegible]
			[illegible]	[illegible]	What is Covered in Part 21: What is Missing in Part 21: [illegible] NOTES: 1. [illegible]
3.2 The Management of Change	[illegible]	5.51 Applicability	[illegible]	[illegible]	What is Covered in Part 21: [illegible] What is Missing in Part 21:
		5.53 Safety Performance Assessment	[illegible]	[illegible]	What is Covered in Part 21: What is Missing in Part 21:

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ICAO ANNEX 19 FRAMEWORK COMPONENT/ ELEMENT	SPECIFIC ANNEX 19 FRAMEWORK REQUIREMENTS	14 CFR PART 5 (SMS COMPONENT/ ELEMENT)	PART 5 NPRM REQUIREMENTS	DIFFERENCES BETWEEN ICAO ANNEX 19 AND 14 CFR PART 5	GAPS/ALIGNMENT BETWEEN 14 CFR PART 5 AND PART 21
			(iii) Identify changes in the operational environment that may introduce new hazards.		
3.3 Continuous Improvement of the SMS	The service provider shall monitor and assess the effectiveness of its SMS processes to enable continuous improvement of the overall performance of the SMS.	5.75 Continuous improvement	The certificate holder must establish and implement processes to correct substandard safety performance identified in the assessments conducted under §5.73.	Part 5 requires correction of substandard safety performance. Annex 19 requires continuous improvement.	**What is Covered in Part 21:** Production: §21.137(i) requires corrective and preventive actions for product nonconformity and quality system issues. In-Service: §21.3 addresses product level reported failures. **What is Missing in Part 21:** Does not require assessment of safety performance, hence does not require corrective actions to address substandard performance.
4. Safety Promotion		Subpart E – Safety Promotion			
4.1 Training and Education	4.1.1 The service provider shall develop and maintain a safety training programme that ensures that personnel are trained and competent to perform their SMS duties.	5.91 Competencies and Training	The certificate holder must provide training to each individual identified in §5.23 to ensure the individuals attain and maintain the competencies necessary to perform their duties relevant to the operation and performance of the SMS.	Part 5 is equivalent to Annex 19.	**What is Covered in Part 21:** §21.143 provides the privilege of the FAA to train inspectors and prescribe the [illegible] personnel. In addition, AC 21-43 requires training of [illegible] personnel.
	4.1.2 The scope of the safety training programme shall be appropriate to each individual's involvement in the SMS.				**What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements for training of SMS personnel.
4.2 Safety Communication	The service provider shall develop and maintain a formal means for safety communication that: a) ensures personnel are aware of the SMS to a degree commensurate with their positions; b) conveys safety critical information; c) explains why particular safety actions are taken; and d) explains why safety procedures are introduced or changed.	5.93 Safety Communication	(a) The certificate holder must develop and maintain means for communicating safety information that, at a minimum: (b) Ensures that all personnel are aware of the SMS; (c) Conveys safety critical information; (d) Explains why particular safety actions are taken; (e) Explains why safety procedures are introduced or changed. [illegible]	Part 5 requires all personnel where Annex 19 limits communication to a degree commensurate with their position.	**What is Covered in Part 21:** Limited application in 21.137. (c) Supplier control. Procedures that: (3) Require each supplier to report to the PAH if a product or article has been released from that supplier and found not to conform to the applicable design. **What is Missing in Part 21:** There is no SMS requirement; therefore, no defined requirements for SMS or means of communication of safety information to SMS personnel.

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Appendix D. Safety Risk Management (SRM) and Safety Assurance (SA) in Certification: Description of How Compliance with Airworthiness Standards Meets SRM and SA Requirements During Design

Concept Hypothesis

The certification processes and business practices used to show compliance can meet the intent of Part 5 SRM.

SRM Application (refer to Figure D–1)

SRM is applied by the regulator in developing regulations (above the horizontal dashed line in Figure D–1). SRM is applied by the design organization to comply with the regulations (below the dashed line).

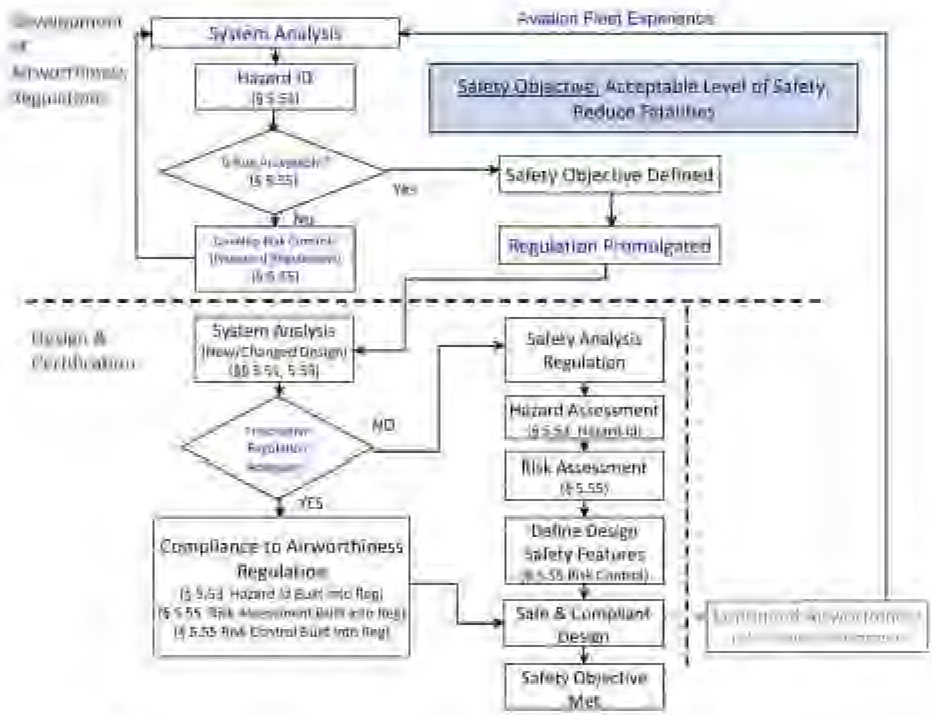

Figure D–1: SRM Process Linkage Between Regulation Development and Design Implementation

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A design transforms safety requirements into risk controls for a product or article. A safety requirement, in the form of an airworthiness regulation is a safety risk control that, when complied with, constitutes an acceptable level of safety risk.

Airworthiness regulations are developed when systemic hazards are discovered and the related outcome(s) have unacceptable risk. Acceptable level of risk is determined as part of the rulemaking process and summarized in the "Costs and Benefits" section of each new regulation. The acceptable level of safety can change over time, e.g., §25.561 per Amendment 25-64 versus §25.562 Amendment 25-64. Each airworthiness regulation provides boundary conditions for a design that, when met, are expected to manage risk to acceptable levels. These boundary conditions range from being prescriptive to being purely performance based. The regulations typically do not specify a detailed design solution. The design organization will design risk controls to comply with the regulations. Validating that the risk controls fulfill the safety requirements is accomplished during the certification process.

The preamble to each regulation contains a discussion of the hazard that has been identified. Many of the hazards that are being controlled via a regulation were discovered following an accident and the subsequent accident investigation. Most hazards, through combinations of other conditions/events of certain probability, can result in multiple outcomes. These outcomes will likely have varying degrees of risk due to different severity and likelihood of occurrence.

The actual regulation itself describes criteria which a design must satisfy. These criteria can be considered boundary conditions for risk controls that a design organization includes in the design of their product or article. The resulting design solution is validated against the regulatory requirements. Often the validation is supported by agreed-upon methodology and performance thresholds as contained in associated ACs.

Holders of production approvals or type certificates are subject to regulatory requirements during the Continued Airworthiness life cycle phase. These include requirements for reporting a variety of events and conditions such as failures, malfunctions, and defects (14 CFR 21.3, 21.137(m)), and for sharing certain data with the FAA and operators (14 CFR 21.99). These activities necessarily include the creation and exercise of processes and systems by the approval holders to monitor both production of a product or article and its operation in service, collect information and data, analyze the information and data, and communicate the information and date to the FAA. The FAA uses the information and data supplied by the approval holders and other sources to develop airworthiness regulations as described above.

Following are examples of how SRM is satisfied through the activities of certification and design approval. Example 1 describes how SRM was used in the development of regulations, in this example a prescriptive regulation, which in turn are used by the design organizations as risk controls without necessity to re-create or repeat SRM. Example 2 explains how specific regulatory design requirements, combined with a requirement that the design organization analyze for unspecified other additional risks, constitutes a "safety analysis regulation" and accomplishes the intent of Part 5 SRM requirements. Examples 3 and 4 illustrate how SRM is accomplished when a design organization devises and incorporates design risk controls to comply with regulations, leading to a certified product. Example 5 shows how compliance with the regulations by a design organization accomplishes SRM for those design aspects that are not specifically covered by the regulations.

Based on these examples, the SMS WG has concluded that the certification processes and airworthiness standards leading to certification of a safe and compliant product or article, accomplish the intent of SRM. With the introduction of Part 5, future rulemaking should be based on SRM transparently applied by the FAA's processes.

Example 1: 14 CFR 23.607, 25.607, 27.607, 29.607 Fasteners

This example describes (above the horizontal dashed line in Figure D–1) how SRM was used in the development of the regulations, in this example a prescriptive regulation, which in turn are used by the design organizations as risk controls without necessity to re-create or repeat SRM.

The development of 14 CFR 23.607, 25.607, 27.607, and 29.607 is a prime example of Safety Risk Management and Safety Assurance that has already been accounted for in the design certification process by way of airworthiness regulations. With regards to fasteners, in the past (prior to Amendments 23-48, 25-23, 27-4 and 29-5) it had been common practice in the manufacture of aircraft to secure fasteners (i.e., bolts, screws, and pins) with a single locking device. While this had proven adequate for most aircraft, there had been a number of instances of loss of fastener integrity involving fasteners installed on rotorcraft and secured with a single locking device. This service experience represents the §5.71 safety performance monitoring, i.e., acquiring data with respect to the safety of the product or article. This adverse service experience was attributed in large part to the fact that fasteners used on rotorcraft are subject to greater than normal vibration. In addition, the FAA was aware that the locking devices can be adversely affected by the environmental conditions existing at the particular installation. The FAA related this service experience to fasteners whose loss could jeopardize the safe operation of the aircraft. This thought process is equivalent to performing the system analysis and hazard identification required by §5.53, i.e., identifying the function and purpose of the system, the system's operating environment, and identifying the hazards within the context of the system analysis.

In view of the adverse service experience with fasteners and the hazards identified, the FAA proposed and subsequently adopted regulations (§§23.607, 25.607, 27.607, and 29.607) requiring two separate locking devices on all removable fasteners in any installation in which the loss of the fastener could jeopardize the safe operation of the aircraft. Additionally, the FAA adopted, in the regulations, requirements that consideration be given to the environmental conditions associated with a particular fastener in determining the appropriate locking device for that fastener. The adoption of airworthiness regulations to address the identified hazard is equivalent to §5.55 safety risk assessment and control, i.e., an unacceptable risk was identified and a risk control put in place to maintain an acceptable safety risk.

The design certification process accounts for §5.51 applicability, i.e., if a new system (product or article) or a change to the system (product or article) is being introduced or a change in the environment conditions, e.g., higher rotor speeds, then a reassessment of the hazards would take place and as appropriate, based on system analysis and hazard identification, additional compliance to §23.607, 25.607, 27.607 or 29.607 would be conducted.

Compliance with §5.73 safety performance assessment would continue to be accomplished as part of the Continued Operational Safety (COS) program.

Example 2: 14 CFR 33.75 Safety Analysis

This example explains how specific regulatory design requirements, combined with a requirement that the design organization analyze for unspecified other additional risks, constitutes a "safety analysis regulation" and accomplishes the intent of Part 5 SRM requirements.

The engine certification process requires that the new design demonstrate compliance to a large number of regulations (14 CFR 33), each one of which represents a hazard or group of hazards identified by the FAA, and an acceptable mitigation strategy which will reduce risk to an acceptable level. In addition to these specific hazards, §33.75 requires that the applicant analyze the proposed design for additional risks, if an engine failure should occur, and demonstrate that these risks are controlled to an acceptable level. In doing so, the intent of SRM is accomplished.

Following is a comparison of Part 5, Subpart C – Safety Risk Management, to existing 14 CFR 33.75 showing the correlation of §33.75 requirements to Part 5. Comments about the correlation appear in blue, italicized font.

CFR PART 5 ELEMENT	CFR PART 5 REQUIREMENTS	14 CFR PART 33.75 REQUIREMENTS
5.53 System analysis and hazard identification	(a) When applying safety risk management, the certificate holder must have a process to describe and analyze the system for use in identifying hazards under paragraph (c) of this section, and developing and implementing risk controls related to the system under §5.55(c).	(a) (1) The applicant must analyze the engine including the control system, to assess the likely consequences of all failures that can reasonably be expected to occur.
	(b) In conducting the system analysis, the following information must be considered: (1) Function and purpose of the system. (2) The system's operating environment. (3) An outline of the system's processes and procedures. (4) The personnel, equipment, and facilities necessary for operation of the system.	(e) If the safety analysis depends on one or more of the following items, those items must be identified in the analysis and appropriately substantiated. (1) Maintenance actions being carried out at stated intervals . . . (2) Verification of the satisfactory functioning of safety or other devices at pre-flight or other stated periods. . . (3) The provisions of specific instrumentation not otherwise required. (4) Flight crew actions to be specified in the operating instructions established under §33.5. *The regulation requires consideration of system processes and procedures, personnel, equipment and facilities necessary to operate the system.* (f) If applicable, the safety analyses must also include, but not be limited to, investigation of the following: (1) Indicating equipment; (2) Manual and automatic controls; (3) Compressor bleed systems; (4) Refrigerant injection systems; (5) Gas temperature control systems;

CFR PART 5 ELEMENT	CFR PART 5 REQUIREMENTS	14 CFR PART 33.75 REQUIREMENTS
		(6) Engine speed, power, or thrust governors and fuel control systems; (7) Engine overspeed, overtemperature or topping limiters; (8) Propeller control systems; and (9) Engine or propeller thrust reversal systems. *The regulation states the system boundaries to be included in the analysis.*
	(c) The certificate holder must develop and maintain processes to identify hazards within the context of the system analysis.	(g) Unless otherwise approved by the FAA and stated in the safety analysis, for compliance with part 33, the following failure definitions apply to the engine: (1) An engine failure in which the only consequence is partial or complete loss of thrust or power (and associated engine services) from the engine will be regarded as a minor engine effect. (2) The following effects will be regarded as hazardous engine effects: (i) Non-containment of high-energy debris; (ii) Concentration of toxic products in the engine bleed air intended for the cabin sufficient to incapacitate crew or passengers; (iii) Significant thrust in the opposite direction to that commanded by the pilot; (iv) Uncontrolled fire; (v) Failure of the engine mount system leading to inadvertent engine separation; (vi) Release of the propeller by the engine, if applicable; and (vii) Complete inability to shut the engine down. (3) An effect whose severity falls between those effects covered in paragraphs (g)(1) and (g)(2) of this section will be regarded as a major engine effect. *The regulation specifies the failure effects to be addressed and their severities.*
5.51 Applicability	A certificate holder must apply safety risk management to a system under any of the following conditions: (a) Implementation of new systems. (b) Revision of existing systems. (c) Development of operational procedures.	*Showing compliance with CFR33.75 is required for each new engine design, and for substantial changes to existing engine designs.* ***Operational procedures:*** (a) (1) The applicant must analyze the engine, including the control system, to assess the likely consequences of all failures that can reasonably be

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CFR PART 5 ELEMENT	CFR PART 5 REQUIREMENTS	14 CFR PART 33.75 REQUIREMENTS
	(d) Identification of hazards or ineffective risk controls through the safety assurance processes in subpart D of this part.	expected to occur. This analysis will take into account, if applicable: (i) Aircraft-level devices and procedures assumed to be associated with a typical installation. Such assumptions must be stated in the analysis." *The rule links the safety analysis to operational procedures and the effectiveness of risk controls such as maintenance actions.* (d) If reliance is placed on a safety system to prevent a failure from progressing to hazardous engine effects, the possibility of a safety system failure in combination with a basic engine failure must be included in the analysis. Such a safety system may include safety devices, instrumentation, early warning devices, maintenance checks, and other similar equipment or procedures." *This paragraph requires consideration of the effectiveness of risk controls.* (e) If the safety analysis depends on one or more of the following items, those items must be identified in the analysis and appropriately substantiated. (1) Maintenance actions being carried out at stated intervals... Additionally, if errors in maintenance of the engine, including the control system, could lead to hazardous engine effects, the appropriate procedures must be included in the relevant engine manuals. (2) Verification of the satisfactory functioning of safety or other devices at pre-flight or other stated periods. (3) The provisions of specific instrumentation not otherwise required. (4) Flight crew actions to be specified in the operating instructions established under §33.5. *Use of lessons learned from service experience in the course of the safety analysis meets the intent of "identification of hazards" through the safety assurance process.*
5.55 Safety risk assessment and control	(a) The certificate holder must develop and maintain processes to analyze safety risk associated with the hazards identified in §5.53(c).	(a) (1) The applicant must analyze the engine, including the control system, to assess the likely consequences of all failures that can reasonably be expected to occur.

CFR PART 5 ELEMENT	CFR PART 5 REQUIREMENTS	14 CFR PART 33.75 REQUIREMENTS
	(b) The certificate holder must define a process for conducting risk assessment that allows for the determination of acceptable safety risk. Acceptable safety risk must, at a minimum, comply with the applicable regulatory requirements set forth in Chapter I of title 14 of the Code of Federal Regulations.	***The rule specifies the acceptable level of risk.*** (a) (3) The applicant must show that hazardous engine effects are predicted to occur at a rate not in excess of that defined as extremely remote (probability range of 10^{-7} to 10^{-9} per engine flight hour). (4) The applicant must show that major engine effects are predicted to occur at a rate not in excess of that defined as remote (probability range of 10^{-5} to 10^{-7} per engine flight hour).
	(c) The certificate holder must develop and maintain processes to develop safety risk controls that are necessary as a result of the safety risk assessment process under paragraph (b) of this section. (1) The certificate holder must evaluate whether the risk will be acceptable with the proposed safety risk control applied, before the safety risk control is implemented. (2) The safety risk controls must, at a minimum, comply with the applicable regulatory requirements set forth in Chapter I of title 14 of the Code of Federal Regulations.	*The engine will not receive a type certificate, if the risks exceed acceptable levels defined in the regulation.* *The applicant introduces risk controls where needed and repeats the safety analysis until the risks can be shown to meet the regulatory requirements* (§33.75). *The risk controls will not violate any part of 14 CFR Part 33, since this would prevent the desired objective of receiving engine design certification.*

Example 3: Ice Detection System

This example illustrates how SRM is accomplished when a design organization devises and incorporates design risk controls to comply with regulations, leading to a certified product.

SRM typically begins with a description of the environment, operating conditions and general product design parameters necessary to identify hazards. When showing compliance to regulations, this description is generally defined within the regulatory material and associated guidance material. The design organization will translate this general description to the actual design for which certification is being sought. With respect to ice detection system this information is contained in 14 CFR 25.1419 (Amendment 25-129) and ACs 25.1419-2 and 20-73A. These actions correspond to "Safety Analysis Regulation" and "Hazard Assessment" in Figure D–1 (below the horizontal dashed line), and are illustrated in the text of the regulation and background information provided in the following associated rulemaking material.

> *14 CFR 25.1419 Ice protection*
>
> If the applicant seeks certification for flight in icing conditions, the airplane must be able to safely operate in the continuous maximum and intermittent maximum icing conditions of Appendix C. To establish this—

(e) One of the following methods of icing detection and activation of the airframe ice protection system must be provided:

(1) A primary ice detection system that automatically activates or alerts the flightcrew to activate the airframe ice protection system;

From the Final Rule

On October 31, 1994, an accident involving an Avions de Transport Regional (ATR) 72 series airplane occurred in icing conditions. This prompted the FAA to initiate a review of aircraft inflight icing safety and determine changes that could be made to increase the level of safety. In May 1996, the FAA sponsored the International Conference on Aircraft Inflight Icing where icing specialists recommended improvements to increase the level of safety of aircraft operating in icing conditions. The FAA reviewed the conference recommendations and developed a comprehensive multi-year icing plan. The FAA Inflight Aircraft Icing Plan (Icing Plan), dated April 1997, described various activities the FAA was contemplating to improve safety when operating in icing conditions. In accordance with the Icing Plan, the FAA tasked the Aviation Rulemaking Advisory Committee (ARAC), through its Ice Protection Harmonization Working Group, to consider the need for ice detectors or other acceptable means to warn flightcrews of ice accretion on critical surfaces requiring crew action. This rule is based on ARAC's recommendations to the FAA.

From the NPRM

The notice of proposed rulemaking (NPRM), Notice No. 07-07, published in the Federal Register on April 26, 2007 (72 FR 20924), is the basis for this amendment. The comment period closed July 25, 2007. In the NPRM, we proposed to revise the airworthiness standards for type certification of transport category airplanes to add requirements to ensure the timely activation of an airframe ice protection system (IPS). We also proposed to add requirements to reduce the flightcrew workload associated with operation of an airframe IPS that is manually cycled, and to ensure the Airplane Flight Manual includes IPS procedures for operation.

Neither the operating regulations nor the certification regulations require a means to warn flightcrews of ice accretion on critical surfaces requiring crew action.

The ARAC Ice Protection Harmonization Working Group reviewed icing events and found accidents and incidents where the flightcrew was either completely unaware of ice accretion on the airframe, or was aware of ice accretion, but judged that it was not significant enough to warrant operation of the airframe ice protection system (IPS). The ARAC Ice Protection Harmonization Working Group concluded and recommended to the FAA that flightcrews must be provided with a clear means to know when to activate the IPS. Flightcrew's observation of ice accretions and such observations can be difficult during times of high workload, operations at night, or when clear ice has accumulated.

Hazard scenarios are used to model the risk analysis ("Risk Assessment" in Figure D–1, below the horizontal dashed line).

<u>*Hazard Scenario*</u>

Model: Hazard coupled with Linking Mechanism = Bad Outcome

Hazard: Flight in icing conditions

Linking Mechanism:

- Failure to recognize ice build-up
- Failure to activate ice protection system
- Failure to activate ice protection system in a timely manner

Bad Outcome: Loss of lift, leading to crash

Risk Control Criteria

Install an ice detection system to automatically alert crew to turn on ice protection system. Required for transport category airplanes by 14 CFR 25.1419.

Acceptable Risk Criteria

Guidance for making a determination of acceptable risk is contained in ACs 25.1419-2, "Compliance with Ice Detection Requirements of 25.1419 (e), (f), (g) and (h)", and AC 20-73A, "Aircraft Ice Protection."

For example, AC 25.1419-2 says in paragraph 4a(7)c:

> "System Safety Considerations. The applicant should consult AC 25.1309-1A for guidance on compliance with §25.1309. In accordance with AC 25.1309-1A, the applicant should accomplish a functional hazard assessment to determine the hazard level associated with failure of the ice detection system. The probability of encountering the icing conditions defined in Appendix C to Part 25 should be considered to be 1. The unannunciated failure of a primary ice detection system is assumed to be a catastrophic failure condition, unless the characteristics of the airplane in icing conditions without activation of the airframe IPS(s) are demonstrated to result in a less severe hazard category. If visual cues are the primary means, the pilots retain responsibility to monitor and detect ice accretions when an advisory ice detection system is installed. However, the natural tendency of flightcrews to become accustomed to using the advisory ice detection system elevates the importance of the detector and increases the need to make flightcrews aware of an advisory ice detection system failure. Therefore, an undetected failure of the advisory ice detector should be considered as at least Major unless substantiated to be a lower failure condition classification."

The hazard(s) and risk control criteria are defined and applied during design and certification. The design processes used to satisfy risk control criteria associated with compliance to 25.1419 and 25.1309 necessitate that the likelihood and severity of the bad outcome(s) are used for a risk based decision on the acceptability of the type design of the ice detection system. (See also section 4.5 of this Working Group Report, Subpart C, Design and Type Certification)

"Risk Assessment" in Figure D–1, below the horizontal dashed line is often satisfied through industry best practices for performing safety assessments in accordance with 14 CFR 25.1309. The AC material provides guidance for a determination of acceptable risk, and design decisions are thusly made ("Define Design Safety Features," Figure D–1). The risk control, as defined through regulation culminates in a "Safe & Compliant Design" Figure D–1) considering the specific design solution presented for compliance.

Testing and further analysis are performed to validate that the as-designed risk controls meet the acceptable risk criteria contained in the rule and guidance material ("Safety Objective Defined", Figure D–1 above the horizontal dashed line). Such validation enables, with regard to design and certification of the product or article, a conclusion of "Safety Objective Met" (Figure D–1).

Example 4: 14 CFR 23.783(b) Doors

This example illustrates how SRM is accomplished when a design organization devises and incorporates design risk controls to comply with regulations, leading to a certified product.

SRM typically begins with a description of the environment, operating conditions and product design necessary to identify hazards. When showing compliance to regulations this description is generally defined within the regulatory material and associated guidance material. The design organization will translate this general description to the actual design for which certification is being sought. With respect to location of passenger doors, this information is contained in 14 CFR 23, Subpart D, Design and Construction, Personnel and Cargo Accommodations, §23.783(b) (Amendment 23-49), and AC 23-17C, Systems and Equipment Guide for Certification of Part 23 Airplanes and Airships. These actions correspond to "Safety Analysis Regulation" and "Hazard Assessment" in Figure D–1 (below the horizontal dashed line), and are illustrated in the text of the regulation and background information provided in the following associated rulemaking material.

14 CFR 23.783 Doors

(b) Passenger doors must not be located with respect to any propeller disk or any other potential hazard so as to endanger persons using the door.

From the Final Rule

This amendment completes part of an effort to harmonize the requirements of Part 23 and JAR 23. The revisions to Part 23 in this amendment pertain to systems and equipment airworthiness standards. Three other final rules are being issued in this Federal Register that pertain to airworthiness standards for flight, powerplant, and airframe. These related rulemakings are also part of the harmonization effort.

In January 1991, the FAA established the Aviation Rulemaking Advisory Committee (ARAC) (56 FR 2190, January 22, 1991). At an FAA/JAA Harmonization Conference in Canada in June 1992, the FAA announced that it would consolidate the harmonization effort within the ARAC structure. The FAA assigned to ARAC the rulemakings related to JAR/Part 23 harmonization, which ARAC assigned to the JAR/FAR 23 Harmonization Working Group. The proposals for systems and equipment airworthiness standards contained in Notice 94-21 were a result of both the working group's efforts and the efforts at harmonization that occurred before the formation of the working group.

Section 23.783 Doors

Proposed paragraph (b) would add a requirement that passenger doors must not be located near any propeller disk or any other potential hazard that could endanger persons using the door. The propeller disk remains the prominent hazard but other items, such as hot deicer surfaces or sharp objects on the airplane structure, are also hazards.

Section 23.783 is amended by revising paragraph (b) ... to read as follows:

Sec. 23.783 Doors.

(b) Passenger doors must not be located with respect to any propeller disk or any other potential hazard so as to endanger persons using the door.

From the NPRM

During the Part 23 harmonization effort, the FAA established an Aviation Rulemaking Advisory Committee (ARAC) (56 FR 2190, January 22, 1991), which held its first meeting on May 23, 1991. The ARAC on General Aviation and Business Airplane

(GABA) Issues was established at that meeting to provide advice and recommendations to the Director, Aircraft Certification Service, FAA, regarding the airworthiness standards in Part 23 as well as related provisions of parts 91 and 135 of the regulations.

The FAA announced, on June 2-5, 1992, at the JAA/FAA Harmonization Conference in Toronto, Ontario, Canada, that it would consolidate within the ARAC structure an ongoing objective to "harmonize" the JAR and the FAR. Coinciding with that announcement , the FAA assigned the ARAC on GABA Issues those rulemaking projects related to JAR/Part 23 harmonization that were in final coordination between the JAA and the FAA. The harmonization process included the intention to present the results of JAA/FAA coordination to the public as NPRM's. Subsequently, the AARC on GABA issues established an ARAC-JAR 23 Study Group.

The JAR 23 Study Group made recommendations to the ARAC on GABA Issues concerning the FAA disposition of the rulemaking issues coordinated between the JAA and the FAA. The draft NPRMs previously prepared by the FAA harmonization team were made available to the harmonization working group to assist them in their effort.

A notice of the formation of the JAR 23 Harmonization Working Group was published on November 30, 1992 (57 FR 56626). The group held its first meeting on February 2, 1993. These efforts resulted in the proposals for systems and equipment airworthiness standards contained in this notice. The ARAC on GABA Issues agreed with these proposals."

Section 23.783 Doors
Current Sec. 23.783(b) requires that passenger doors not be located with respect to any propeller disk so as to endanger persons using the door. Proposed paragraph (b) would add that passenger doors must be located in relation to any other potential hazard that would endanger persons using the door. The propeller disk remains the prominent hazard but other items, such as hot deicer surfaces or sharp objects on the airplane structure, are also hazards.

Section 23.783 is amended by revising paragraph (b) ...to read as follows:

Sec. 23.783 Doors.

(b) Passenger doors must not be located with respect to any propeller disk or any other potential hazard so as to endanger persons using the door.

Hazard scenarios are used to model the risk analysis ("Risk Assessment" in Figure D-1, below the horizontal dashed line).

Hazard Scenario

Model: Hazard coupled with Linking Mechanism = Bad Outcome

Hazard: Proximity of passenger door to propeller disk or other hazards

Linking Mechanism:

- Failure to observe moving propeller
- Failure to observe/recognize other hazards, e.g., hot deicer surfaces or sharp objects on the airplane structure
- Inability to maintain clearance from propeller disk or other hazard while operating door
- Slip/trip/fall while passing through door

Bad Outcome: Injury due to contact with moving propeller, hot surface, or sharp object

Risk Control Criteria
Locate the passenger door(s) away from potential hazards so as not to endanger persons using the door.

Acceptable Risk Criteria
Criteria and guidance for making a determination of acceptable risk are contained in 14 CFR 23.783, 23.811, 23.813, 23.1401, 23.1309, and AC 23-17C

Examples of risk criteria:

- 14 CFR 23.783(b): Location of passenger door with respect to a propeller disk or any other hazard must not endanger persons using the door
- 14 CFR 23.811(a)(2): Each ... external door ... must be externally marked ... by a permanent decal ... which shows the means of opening ... including any special instructions, if applicable
  - "Applicable" might include instructions intended to ensure clearance from hazards
- 14 CFR 23.813(b)(1): The location of the passenger door must still allow for a passageway leading from the aisle to the door that is unobstructed and at least 20 inches wide
- 14 CFR 25.1301(b): Installed equipment must be labeled as to its identification, function, or operating limitations, or any applicable combination of these factors
- 14 CFR 23.1309(a)(2): Any equipment and system does not adversely affect the safety of the airplane or its occupants
- AC 23-17C: 23.783 Doors; the ELOS finding process for Part 23, §23.783(b) should include:
  - (e) A railing or guard that would deploy to guide passengers away from the propeller plane should be provided as an integral part of the door
  - (f) If engagement of the engine starter would be an immediate hazard to a person near the propeller, an interconnection between the door and the engine starting circuit should be included in the design

The hazard(s) and risk control criteria are defined and applied during design and certification. The design processes used to satisfy risk control criteria associated with compliance to 14 CFR 23.783 and 25.1309 necessitate that the likelihood and severity of the bad outcome(s) are used for a risk-based decision on the acceptability of the type design of the ice detection system. (See also section 4.5 of this Working Group Report, Subpart C, Design and Type Certification)

"Risk Assessment" in Figure D–1, below the horizontal dashed line is often satisfied through industry best practices for performing safety assessments in accordance with 14 CFR 25.1309. The AC material provides guidance for a determination of acceptable risk, and design decisions are thusly made ("Define Design Safety Features," Figure D–1). The risk control, as defined through regulation, culminates in a "Safe & Compliant Design" (Figure D–1) considering the specific design solution presented for compliance.

Testing and further analysis are performed to validate that the as-designed risk controls meet the acceptable risk criteria contained in the rule and guidance material ("Safety Objective Defined",

Figure D–1 above the horizontal dashed line). Such validation enables, with regard to design and certification of the product or article, a conclusion of "Safety Objective Met" (Figure D–1).

Example 5: 14 CFR 23.1309 Equipment, systems, and installations (Amendment 23-49); and 14 CFR 23.1431 Electronic equipment (Amendment 23-49)

This example shows how compliance with the regulations by a design organization accomplishes SRM for those design aspects that are not specifically covered by the regulations. The regulations are minimally prescriptive, and thus require the design organization to expansively identify hazards based on the design of the system and the environment in which it will operate. Referring to Figure D–1, compliance with these regulations begins with "System Analysis" (Part 5.51 and 5.53) then to the SRM-equivalent (Part 5.53 and 5.55) path of "Safety Analysis Regulation" leading to a "Safe & Compliant Design."

14 CFR 23.1309 Equipment, systems, and installations

(b) The design of each item of equipment, each system, and each installation must be examined separately and in relationship to other airplane systems and installations to determine if the airplane is dependent upon its function for continued safe flight and landing and, for airplanes not limited to VFR conditions, if failure of a system would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions. Each item of equipment, each system, and each installation identified by this examination as one upon which the airplane is dependent for proper functioning to ensure continued safe flight and landing, or whose failure would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions, must be designed to comply with the following additional requirements:

(1) It must perform its intended function under any foreseeable operating condition.

(2) When systems and associated components are considered separately and in relation to other systems—

(i) The occurrence of any failure condition that would prevent the continued safe flight and landing of the airplane must be extremely improbable; and

(ii) The occurrence of any other failure condition that would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions must be improbable.

14 CFR 23.1431 Electronic Equipment

(a) In showing compliance with §23.1309(b)(1) and (2) with respect to radio and electronic equipment and their installations, critical environmental conditions must be considered.

From the Final Rule:

§23.1309

If the design of the airplane includes equipment, systems, and installations that perform functions whose failure condition would prevent continued safe flight and landing of the airplane, the occurrence of each failure conditions must be extremely improbable. In addition, on airplanes designed for any type of operation not limited to VFR, the systems whose failure conditions would significantly reduce the airplane's capability, or the ability of the crew, to cope with the adverse operating conditions must be improbable. It was recognized that any failure would reduce the airplane's or crew's capability by some degree, but that reduction may not be of the degree that would make operation of the airplane potentially catastrophic. The intent of §23.1309(b) is to require that systems whose failure would be catastrophic or potentially catastrophic be evaluated using the latest available analysis techniques.

Although future airplane designs limited to VFR operations are not likely to include equipment, systems, and installations whose failure condition would prevent continued safe flight and landing of the airplane, the applicability of this requirement, as discussed above, will provide airworthiness standards if the applicant elects to include such systems in the airplane's design. Therefore, the applicability of this requirement has not been revised as suggested by this commenter.

§23.1431
This proposes to amend §23.1431 to revise the current rule that addresses radio equipment only by including other electronic equipment that is installed in a Part 23 airplane. Two comments were received. One commenter asks for a definition of the words "critical environmental conditions" used in proposed §23.1431(a). Critical environmental conditions are those environmental conditions under which a piece of equipment will not perform its intended function. By including this requirement, conditions that may be critical to the operation of a piece of equipment must be considered. Consideration of such conditions would include, but not be limited to, temperature extremes, vibration levels, and humidity.

From the NPRM
§23.1309
A new §23.1309(b) is proposed which will require a detailed examination of each item of equipment, system, and installation. This examination is to determine whether a failure would affect the airplane's continued safe flight and landing. Each item of equipment, each system, and each installation identified by such an examination as being critical to the safe operation of the airplane would be required to meet additional requirements. This will permit the approval of more advanced systems that were not envisioned when §23.1309 was added to Part 23, without the need for special conditions.

§23.1431
This proposal would include electronic equipment that is being installed in Part 23 airplanes as well as radio equipment. When the existing regulation was adopted, radio equipment was the primary electronic equipment installed. For standardization in the application of FAA requirements, this proposal is consistent with §25.1431(a) and (c). §23.1309(b)(1) and (2) that are referenced are the proposed regulations in Notice 5, Small Airplane Airworthiness Review Program.

Hazard Scenario
Model: Hazard coupled with Linking Mechanism = Bad Outcome
Hazard: Failure or malfunction of highly complex safety-critical equipment which could prevent continued safe flight/landing.
Linking Mechanism: The complexity of such items and equipment precludes performance of only a bottoms-up FMEA type analysis; top-down functional decomposition is required as well to properly allocate safety requirements to items and equipment.
Bad Outcome: Loss/malfunction of item/equipment, leading to crash.

Risk Control Criteria: This is defined in §23.1309(b)(1)(2). Additionally, §23.1431(a) requires that critical environmental conditions be considered, i.e., it is not sufficient to consider only failures which could occur within the established environmental limits of the aircraft.

Acceptable Risk Criteria: Acceptable quantitative risk criteria is provided by the regulation and AC 23.1309-1. Additionally, qualitative risk criteria (design rigor requirements expressed as Development Assurance Levels, or DAL) are imposed by AC 23.1309-1, as well as system specific ACs.

Design organizations consider safety aspects of each design through consideration of §23.1309. Draft Advisory Circular AC_AMJ 25.1309 provides a methodical and systematic manner which ensures that this process and its findings are visible and readily assimilated. Figure D–2 illustrates a systematic approach to safety assessments used throughout industry today without the guidance of additional SMS regulation.

Per §23.1309(b), the design of each item of equipment, each system, and each installation is examined separately and in relationship to other airplane systems and installations to determine if the airplane is dependent upon its function for continued safe flight and landing.

For each system reviewed, the failure conditions are identified and classified. All relevant engineering organizations are involved in this process. This identification and classification may be done by conducting a Functional Hazard Assessment. These actions correspond to "Hazard Assessment" and "Risk Assessment" in Figure D–1 (below the horizontal dashed line, right hand column).

The analysis would be conducted to produce the data which is agreed to by the certification authority as being acceptable to show compliance. The analyses and conclusions of multiple safety assessments would be assessed to ensure compliance with the requirements for all aircraft level failure conditions.

The Design organization would then choose the means to be used to determine compliance with §23.1309(b) whether it be through qualitative or quantitative measures or both.

This data is then used to prepare compliance statements, establish certification maintenance requirements, airworthiness limitations and flight manual requirements at the product level, thus defining type design.

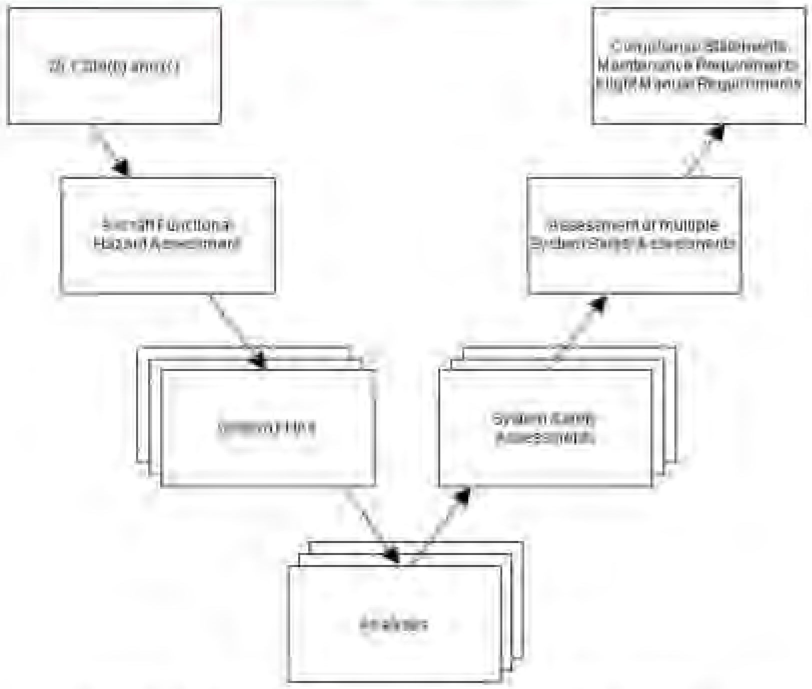

Figure D–2: Airplane-Level System Safety/Certification Process

Simple systems and systems with failure effects classified as no greater than Major do not require quantitative assessment to satisfactorily show compliance to the requirements of §23.1309. A qualitative analysis relying on experienced engineering judgment, service history or operational experience is sufficient. For Major failure conditions, a functional Fault Tree Analysis (FTA) or Failure Modes and Effects Analysis (FMEA) may be required for complex systems. Figure D–3 (taken from AC 23.1309), below, lists the qualitative probability requirements for each failure condition classification.

For failure conditions classified as Hazardous or Catastrophic, quantitative analysis is generally required to supplement qualitative analysis. Failure rate data is assigned to events at the lowest FTA event or FMEA level which can be substantiated. Figure D–3, below, lists the allowable quantitative probabilities for each failure condition classification per class of 14 CFR 23 airplane class.

In addition to qualitative and quantitative requirements Figure D–3 lists the Development Assurance Levels (DALs) for each failure condition classification per class of 14 CFR Part 23 airplane class. These DALs are intended to specify a level of development rigor per FAA AC 20-115 and FAA AC 20-152. "Safety Objective Defined", Figure D–1 above the horizontal dashed line. Compliance to such standards enables, with regard to design and certification of the product or article, a conclusion of "Safety Objective Met" (Figure D–1).

21ARC Working Document – Not for Distribution

Classification of Failure Conditions	**No Safety Effect**	**<—Minor—>**	**<—Major—>**	**<–Hazardous–>**	**< Catastrophic>**
Allowable Qualitative Probability	**No Probability Requirement**	**Probable**	**Remote**	**Extremely Remote**	**Extremely Improbable**
Effect on Airplane	No effect on operational capabilities or safety	Slight reduction in functional capabilities or safety margins	Significant reduction in functional capabilities or safety margins	Large reduction in functional capabilities or safety margins	Normally with hull loss
Effect on Occupants	Inconvenience for passengers	Physical discomfort for passengers	Physical distress to passengers, possibly including injuries	Serious or fatal injury to an occupant	Multiple fatalities
Effect on Flight Crew	No effect on flight crew	Slight increase in workload or use of emergency procedures	Physical discomfort or a significant increase in workload	Physical distress or excessive workload impairs ability to perform tasks	Fatal Injury or incapacitation
Classes of Airplanes:	**Allowable Quantitative Probabilities and Software (SW) and Complex Hardware (HW) Development Assurance Levels (Note 2)**				
Class I (Typically SRE 6,000 pounds or less)	No Probability or SW and HW Development Assurance Levels Requirement	$<10^{-3}$ Note 1 P=D	$<10^{-4}$ Notes 1 and 4 P=C, S=D	$<10^{-5}$ Note 4 P=C, S=D	$<10^{-6}$ Note 3 P=C, S=C
Class II (Typically MRE, STE, or MTE 6,000 pounds or less)	No Probability or SW and HW Development Assurance Levels Requirement	$<10^{-3}$ Note 1 P=D	$<10^{-5}$ Notes 1 and 4 P=C, S=D	$<10^{-6}$ Note 4 P=C, S=C	$<10^{-7}$ Note 3 P=C, S=C
Class III (Typically SRE, STE, MRE, and MTE greater than 6,000 pounds)	No Probability or SW and HW Development Assurance Levels Requirement	$<10^{-3}$ Note 1 P=D	$<10^{-5}$ Notes 1 and 4 P=C, S=D	$<10^{-7}$ Note 4 P=C, S=C	$<10^{-8}$ Note 3 P=B, S=C
Class IV (Typically Commuter Category)	No Probability or SW and HW Development Assurance Levels Requirement	$<10^{-3}$ Note 1 P=D	$<10^{-5}$ Notes 1 and 4 P=C, S=D	$<10^{-7}$ Note 4 P=B, S=C	$<10^{-9}$ Note 3 P=A, S=B

Note 1: Numerical values indicate an order of probability range and are provided here as a reference.
Note 2: The letters of the alphabet denote the typical SW and HW Development Assurance Levels for Primary System (P) and Secondary System (S). For example, HW or SW Development Assurance Level A on Primary System is noted by P=A.
Note 3: At airplane function level, no single failure will result in a Catastrophic Failure Condition.
Note 4. Secondary System (S) may not be required to meet probability goals. If installed, S should meet stated criteria.

Figure D–3: Probability Requirements for Failure Condition Classification

The basic SRM requirements of a Safety Management System are clearly integrated into the abovementioned 14 CFR Part 23 regulations that drive applicants to design safe products as part of the current process required by 14 CFR 21.21. The creation of a new Safety Management regulation in place of applicable airworthiness standards would not contribute materially to the level of safety over that realized by utilizing the existing system for the design and certification of products.

APPENDIX H—OVERSIGHT WORKING GROUP REPORT

Oversight Working Group

Report to Full ARC

February 5, 2014

Approval Signatures

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Table of Contents

1. Executive Summary

This section introduces the Oversight Working Group, its Part 21 / SMS ARC purpose, and a summary of recommendations in this report.

1.a. Introduction

The Oversight Working Group (WG) was created and commissioned to support ARC recommendations and to submit a report addressing the following:

Changes to the FAA oversight methodology based on recommendations for changes to Part 21 that takes into account existing FAA processes and oversight and delegation programs for design and manufacturing related certificates and approvals and authorizations.

1.b Summary of Recommendations

1.b.1 Oversight Model Recommendations are:

- Create a single oversight presence by the FAA. The three key oversight areas are:
  - Organizational: Transition from traditional show / find compliance to organizational performance based oversight model.
  - Product and Articles: Transition from FAA's traditional role of direct project involvement to a Level of Project Involvement (LOPI) approach that is focused on performing governmental functions.
  - Post-Certification (Continued Operational Safety): Transition from today's traditional reactionary approach to a systemic (process based) surveillance model
- Performance Based oversight: Charter a dedicated effort with industry and FAA to develop recognizable performance indicators prior to implementation of the new oversight model.

1.b.2 Assessment Methodology Recommendations:

- The Oversight working group recommends a centralized, systemic (process based) oversight approach for initial and ongoing assessments.
- The assessment methodology will cover a standardized approach to quality, design, and safety
- In support of this recommendation, the team has provided a capability based assessment tool, PROs / CONs analysis of oversight management options, and supporting rationale for the recommendation.
- FAA Oversight Teams report to a centralized FAA organization. Establishing a central FAA oversight organization will achieve standard surveillance practices, create centralized policy, be a single source/repository for the oversight data which will drive the risk based modeling controls, allow for a highly trained staff in system surveillance, skill management, and a single source for corrective actions.

1.b.3 Oversight Implementation Recommendations: The Oversight working group recommends the oversight implementation includes three Major Transition Steps:

1. Proof of Concept – Pre-implementation:
   - Ensure through proof of concept plans that the requirements proposed by the Part21/SMS ARC are practical, effective, and efficient. Determine if the transition from "Mature ODA" to DO has benefits to FAA and Industry.
2. FAA Transition Plan Transition principle:
   - FAA should not release a final rule before FAA has demonstrated the necessary cultural shift to perform system oversight. To achieve a cultural shift, policy and organizational changes may be required.
3. Industry Transition Plan:
   - The organization must establish the systems required of an approved organization while still working as a non-certificated applicant or a delegated organization. Applicants that are working toward becoming a design organization (DO) demonstrate compliance to those requirements on an "as ready" basis.

2. Charter: Requirements / Approach / Taxonomy

This section will describe the foundational elements the Working Group used to build its recommendations.

- Section 2.a. captures the underlying requirements for creating the future oversight. These requirements evolved from "assumptions" created initially by the full ARC and refined by the Working Group as the team studied, compared, and collaborated with the other Working Groups.
- Section 2.b. captures the approach, or the tasks established by the full ARC and refined by the Working Group.
- Section 2.c. captures the taxonomy adopted by the Working Group and shared / collaborated with the other Working Groups. Early development of the taxonomy was critical to baseline discussions, recommendations and interface with other Working Groups / full ARC.

2.a. Requirements

Requirements established by the Oversight Working Group are categorized into three sections:

1. Oversight
2. Assessment
3. Implementation

1. **Oversight Requirements:** Establishment of an FAA systems oversight approach to certification processes and continued airworthiness assumes the part 21 rewrite will require:
   - A single, integrated FAA oversight / surveillance / enforcement approach for organizations that are certificate holders that includes production & design, certification project activities and continued operational safety (COS); and:
   - Will not include Repair Station oversight for those facilities that have multiple approvals.
   - Will be aligned with design organization requirements established by the Organizational Working Group
   - Will consider direct FAA oversight and FAA accepted "other party" oversight
   - Will be based on a risk-based approach
   - For organizational oversight
     - Will address FAA surveillance in terms of frequency and types of audits (design, manufacturing, projects, continued operational safety, etc.)
     - Will include oversight of COS processes - considering the general surveillance process model currently used in Canada
     - Will include performance based oversight methods / measures
   - For product and article oversight:
     - Considering "Level of Project Involvement" (LOPI) process models currently used in Canada and under development in Europe
     - Recognizing the LOPI may be at the "specialist" level
     - Will not require FAA delegation

2. **Assessment Requirements:** Assessment methodologies will be required to:

   - Accommodate / Harmonize processes across FAA organizations (ACO, MIDO, FSDO, AEG, etc.)
   - Establish the initial compliance leading to FAA issuance of an organizational approval (operating certificate) based on qualification criteria (level of acceptance) established by the Organizational Working Group
   - Establish the compliance for FAA acceptance for a design organization progression based on qualification criteria (level of acceptance) established by the Organizational Working Group
   - Establish performance requirements for the on going oversight / surveillance to establish the effectiveness of the systems in place

3. **Implementation Requirements:** Establish the transition plan of today's FAA oversight system to the recommended revised oversight system necessary for part 21 changes. Robust change management will be critical to implementing the revised part 21. Transition plan should include criteria based gates, benefits metrics, etc.

2.b. Working Group Approach

The approach established by the Working Group was to establish task in the charter statement, establish a work plan and execute the work plan with frequent interaction with the Full ARC and other Working Groups. The tasks were broken into Oversight / Assessment Tasks and Implementation Tasks. In addition, relevant questions were brainstormed at the Full ARC and Working Group levels. The relevant questions were applied to the deliverables as a means to ensure completeness.

Oversight / Assessment Tasks / Deliverables:

- A definition of the FAA surveillance / oversight requirements for the organizations that are certificate holders given the predicted outcome of the part 21 rewrite including the who, how, and what using a risk-based approach, including a definition of FAA assessment methods for issuance of new organizational approvals / progressions
- A definition of the FAA surveillance / oversight requirements for project activity including Level of Project Involvement (LOPI) requirements
- A definition of the FAA surveillance / oversight requirements for COS activities

Implementation Tasks / Deliverables:

- A definition of what the transition model would look like, including gaining the needed understanding and support of the changes from key stakeholders in order for the organizational changes to be implemented effectively
- Determine the skills, competencies, and associated training requirements for FAA, Third-Party and/or "Organizational" individuals performing oversight activities
- Maintain FAA technical expertise while transitioning to oversight focus
- Create or revise FAA Orders and advisory material necessary for NPRM, including 8000.367A

Relevant Questions:

Questions were generated by the Full ARC and by the Working Groups as a means to "test" or "exercise" the deliverables to ensure completeness. The relevant questions were categorized by Oversight / Assessment and Implementation. The relevant questions can be found in Appendix F. The oversight working group reviewed each question and made a determination if it was addressed in the report.

2.c. Taxonomy

The following is a list of definitions adopted as part of the Part 21 SMS ARC for use across all Working Groups and the Full ARC:

- **Accountability Framework**: An established set of responsibilities and commitments of the FAA and industry.
- **Applicant DO: tbd**
- **Approved Data**: Data approved by FAA employees, its designees, or a DO acting under the authority of its certificate. *[May need to be re-visited based on approved data discussion]*
- **Assessment**: Process of measuring or judging the value or level of something.
  - Envision this as the means of determining the level certification granted to the design organization.
- **Certificate Surveillance**: FAA actions to monitor the DO certificate holder and to determine the holder's compliance with the provisions of its certificate(s).
  - Note: In the Oversight section we discuss managing these organizations through surveillance.
- **Compliance Assurance System (CAS)**: DO holder's system for ensuring that it complies with the applicable regulations.
- **Determination of Compliance**: A decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. [NOTE: The ARC has referred to "regulatory requirements" rather than just "airworthiness standards" because of its recommendation that DO eventually include determination of compliance with other 14 CFR Parts, such as Parts 26, 34, and 36.]. It may also be a decision made by the certificate holder that data previously approved by the FAA or data determined to comply by another CAA under the provisions of a bilateral airworthiness agreement between the United States and a foreign country or jurisdiction, are valid and applicable to the design of the product, part, or appliance for which it is to be used, including the applicable certification or approval basis.
- **Compliance Finding**: FAA decision (either directly or through a designee) that compliance has been shown with the applicable regulatory requirements.
- **Corrective Action**: An action required to be taken by the Design Organization to address non-compliances and problems with the organization's procedures or performance.
  - The non-compliances may result from:
    - Internal Audits conducted by the DO
    - FAA Surveillance
    - DO Employee Observations
    - Voluntary Disclosures
- **Culture of Compliance**: Knowledge, beliefs, attitudes, and behaviors of an organization that are focused on ensuring regulatory compliance within all its activities.

- **Descriptive Data**
    - **From the Organization WG:** Data that defines the type design that needs to be determined compliant to the applicable airworthiness standards. The descriptive data is what is approved by the FAA when a design approval certificate is issued.

      The drawings and specifications necessary to define the configuration shown to comply.
- **DO Executive**: The company individual directly responsible for ensuring that the DO meets all of its regulatory responsibilities.
- **DO Point(s) Of Contact:** The individual(s) within the DO responsible for all communications with the FAA.
- **Eligible Data:** Data developed under an approved DO system, assuming a specified, but not FAA-established, certification basis, and product type design if appropriate.
- **Enforcement:** An action taken by the FAA most appropriate to promote safety and compliance with the statutory and regulatory requirements.
    - The program provides a wide range of options for addressing noncompliance:
        - Educational and remedial training efforts,
        - Administrative action in the form of either a warning notice or letter of correction,
        - Certificate suspensions for a fixed period of time,
        - Civil penalties,
        - Indefinite certificate suspensions pending compliance or demonstration of qualifications,
        - Certificate revocations,
        - Injunctions, and
        - Referrals for criminal prosecution.
- **Evaluation:** Determining the adequacy and effectiveness of an organization through a review of organizational policies, procedures and systems.
- **FAA Approved Documents:** See Section IV. F. of the CDO ARC Report, titled 'CDO Approval of Data'.
- **FAA Oversight Team**: FAA personnel assigned to provide guidance and oversight of the DO in meeting its regulatory requirements.
- **Finding of Compliance**: See Section IV. F. of the CDO ARC Report, titled 'CDO Approval of Data', and Section IV H. of the CDO ARC Report, titled 'International Considerations'.
- **Governmental Function(s):** Statutory and regulatory functions, actions, processes, and responsibilities of the government which are not eligible to be assigned to private persons, including designees. Particularly because they are so intimately related to the public interest as to mandate performance by Government employees.
    - Examples of Governmental Functions may include:
        - Rulemaking, including issuing an Airworthiness Directives (AD)
        - Establishing the Certification Basis
        - Issue Paper Resolution
        - Establishing Special Conditions
        - Granting Exemptions
        - Defining Equivalent Level(s) Of Safety (ELOS)
        - Determination of unsafe condition(s)
        - Quality System Approvals
- **Holder DO: tbd**

- **Inspection**: A formal systematic and independent review of organizational policies, procedures and systems.
- **Level of Project Involvement (LOPI)**: The interactive process that the Design Organization (DO) shares with their assigned Aircraft Certification Office (ACO) for specific engineering / design elements and with the Manufacturing Inspection District Office (MIDO) for specific production elements during certification projects.

  The criteria/factors influencing the decision of when to be involved will include but is not limited to Governmental Functions, such as:
  - Novel or unusual features which may require issuance of Special Conditions
  - Significant issues which may require Issue Papers
  - Defining Equivalent Level(s) Of Safety (ELOS)
- **Management System**: See the definition for System.
- **Methods (or Means) of Compliance**:
  - ***Need a definition from Organization WG***

  Notes:
  - Method: Process
  - Means: Capability
- **Novel or Unusual**: *"The phrase "novel or unusual" as used in Sec. 21.16 is a very relative term. As used hereafter in applying Sec. 21.16 to justify the issuance of special conditions, "novel or unusual" will be taken with respect to the state of technology envisaged by the applicable airworthiness standards of this subchapter. It must be recognized that in some areas which will vary from time to time the state of the regulations may somewhat lag the state of the art in new design because of the rapidity in which the state of the art is advancing in civil aeronautical design and because of the time required to develop the experience base needed by the FAA to proceed with general rule making. Applicants for type certification of a new design have the opportunity to mitigate the impact of not knowing the precise airworthiness standards to be applied for "novel or unusual design features" by consulting with the FAA early in their certification planning when such features are suspected or known by the applicant to exist. It should also be recognized that: because of the intentional objective nature of the airworthiness standards of this subchapter, many new design features which might be thought of as "novel or unusual design features" may already be adequately covered by existing regulations, thus obviating the need to issue special conditions."* – Preamble material to 14CFR 21.16
- **Oversight**:
  - A systems approach to review an organization's performance; validate the development of their defined system and verify compliance to the requirements of a certified design organization to determine sufficiency.

  Oversight activities, include:
  - Reviewing the work performed,
  - Evaluating performance for quality assurance
  - Ensuring that required training has been completed, and
  - Providing constructive feedback
  - Taking corrective action, including enforcement as necessary
- **Procedure**: A fixed, step-by-step sequence of activities or course of action (with definite start and end points) that must be followed in the same order to correctly perform a task.

- **Quality Management System**:

- From the Organization WG - A set of interrelated or interacting quality processes accomplished by the organization through the establishment of policy and objectives, and achieving those objectives.
- Notes:
  - The baseline Part 21.137 for PAH how are we defining this for DO?

- **Safety Assurance**:
  - *Need a definition from SMS WG*
- **Safety Critical**:
  - *Need a definition from SMS WG*
- **Safety Culture:** The product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to an organization's safety programs
- **Safety Management:** The act of understanding and making decisions and taking actions to lower risk, inherent in all human activity, to acceptable levels
- **Safety Management System**:
  - *Need a definition from SMS WG*
  - **From the Organization WG:**
    - **Safety Management System**: An integrated collection of processes, procedures, and programs that ensures a formalized and proactive approach to system safety through risk management. Risk analysis and assessment are required for all changes to identify safety impacts. The SMS is a closed-loop system, ensuring all changes are documented and all problems or issues are tracked to conclusion. When properly implemented, an SMS establishes a safety philosophy or culture that permeates the entire organization in the monitoring and continuous improvement of safety
  - Notes:
    - Is the baseline definition in 14 CFR Part 5 or are we expanding/redefining this for DO?
- **Senior Company Management**: Those in the company management chain above the DO Executive who are accountable for the actions of the DO
- **Showing**:
  - **From Organization WG**
    - **Showing of Compliance**: **tbd**
  - Notes:
    - The DO is responsible for 100% showings
- **Statement of Compliance**: A statement from the DO to the Administrator certifying that compliance with the applicable regulatory requirements has been determined and the procedures listed in its FAA-approved DO Procedures Manual have been followed.
- **Substantiating Data:**
  - **From the Organization WG:** Documentation related to a design approval applicant's showing of compliance to the applicable airworthiness standards
- **Supplier DO**: A separate DO entity in its own right provides an article to an applicant/holder DO.
- **Surveillance**: The combination of Evaluation and Inspection to accomplish a review of organizational system to determine the adequacy and effectiveness of an organization.

- **System:** An integrated set of constituent elements that are combined in an operational or support environment to accomplish a defined objective. These elements include people, hardware, software, firmware, information, procedures, facilities, services and other support facets.
- **Validation:** Validation is the process of proving that the functions, procedures, controls, and safety standards are correct and the right system is being built. i.e. the requirements are unambiguous, correct, complete, and verifiable
- **Verification:** The process that ensures that the system requirements have been met by the design solution and the system is ready to be used in the operational environment for which it is intended.

3. Existing FAA Oversight Model

The Oversight Working Group established as one of its deliverables an existing definition of today's FAA oversight. Today's FAA oversight is captured with:

- Existing FAA oversight delineated by FAA lines of business (ACO, MIDO, and Flight Standards)
- Existing uniquely designed Oversight Management Teams created for larger, complex industry Organization Designation Authorizations (ODAs)
- Existing FAA Oversight Opportunities

3.a Existing FAA Oversight Activities / Descriptions

Table 3-1 outlines existing FAA certification policy, oversight functions and activities for the FAA organizations at the time of this report. The heading in each row shows various certification and oversight activities that cross FAA organizations. The columns show all the functions of each FAA organization to support each of the certification and oversight activities.

Table 3-1. Current FAA Certification and Oversight Functions

ACO Functions	MIDO Functions	FSDO / AEG Functions

Design Certification Activity
• TC/STC/TSO/PMA applications – 8110.4, 8110.42, 8150.1
• RBRT system - 8110.4
• Issue papers - 8110.4
• Undue Burden – 8100.11
• Certification basis - 8110.4, 8110.48
• Operational suitability - 8110.4
• ELOS - 8110.4
• ICA – 8110.54
• Commercial Parts – 8110.118
• Certification and conformity plans PSCP & CIP– 8110.4
• Disposition of deviations- 8110.4
• Finding compliance - 8110.4, 8110.51
  ○ Review substantiation data - 8110.4
  ○ Witness test - 8110.4
  ○ Flight tests – 8110.41
  ○ Compliance Inspection – 8110.4
  ○ TIA/TIR - 8110.4 , 4040.1
  ○ PMA Life limited Articles – 8110.42, 8120.22
• Issue TC/STC/TSOA – IGF except STC - 8110.4, 8110.42, 8150.1
	Design Certification Activity
	• RBRT system - 8110.4
	• Certification and conformity plans PSCP & CIP – 8110.4
	• Finding compliance - 8110.4
	  ▫ Conformity Inspections – 8110.4
	  ▫ Review process specifications - 8110.4
	  ▫ Witness test - 8110.4
	  ▫ TIA/TIR - 8110.4
	  ▫ NDT evaluation – 8110.4
	  ▫ Teardown inspections– 8110.4
	  ▫ Configuration control of design changes – 8110.4
	• Airworthiness certification for flight testing (R&D, Show Compliance, SFA) – 8110.4, 8130.29
	• Periodic Safety checks for flight test aircraft– 8110.4
		Design Certification Activity by AEG
		• ICA – 8110.4
		• Operational and Maintenance Evaluations – 8110.4
		• TIA flight tests– 8110.4
		• Flight Standardization Board – 8110.4
		• Maintenance Review Board – 8110.4
		• Flight Operations Evaluation Board – 8110.4
		• Type Ratings for airmen -8110.4

Design Certification Oversight
• Investigations - IGF – 8020.11 2150.3
  ○ Voluntary disclosures - 2150.3
• Special Technical Audits - IGF - 8110.4
• COS
  ○ Service Difficulty Reports 21.3 – 8110.107
  ○ NTSB recommendations – 1220.2
  ○ Issue ADs – 8040.4, 8040.5, IR-M8040.1
  ○ AMOC – 8110.103
  ○ MSAD - Failures, malfunctions, defects – 8110.107
	Design Certification Oversight
	• Special Technical Audits - IGF - 8110.4
	• COS:
	  ▫ Service Difficulty Reports 21.3 – 8110.107
	  ○ MSAD - Failures, malfunctions, defects – 8110.107
		Design Certification Oversight
		N/A

ACO Functions	MIDO Functions	FSDO / AEG Functions

Foreign TC/STC Validations
• International agreements
  o Finding compliance - 8110.52, 8110.51
  o Witness test - 8110.52, 8110.51
  o Issue VTC and VSTC - 8110.52, 8110.51
	Foreign TC/STC Validations
	• International agreements
	  o Finding compliance - 8110.52
		Foreign TC/STC Validations
		N/A

Delegation Oversight • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15, 8110.37 • Review and approve ODA procedures manuals - 8100.15 • Delegated Organization Inspection Program (DOIP) – 8100.15 • Supervisory visits - 8100.15 • Review internal audits – 8100.15	**Delegation oversight** • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15 • Airworthiness application package and limitations review - 8100.8 • Review and approve ODA procedures manuals - 8100.15 • Conformity report review individual designees 8100.8 • Delegated Organization Inspection Program (DOIP) - 8100.15 • Supervisory visits - 8100.15 • Over the shoulder reviews individual designees 8100.8 • Review internal audits - 8100.15	**Delegation oversight** • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15 • Airworthiness application package & limitations review - 8100.8 • Review and approve ODA procedures manuals - 8100.15 • Delegated Organization Inspection Program (DOIP) - 8100.15 • Supervisory visits - 8100.15 • Review internal audits - 8100.15 • AFS Designees and Designations Volume 13 Chapters 1 thru 10

Production Certification
• Review new quality system – 8120.22
  o Production Flight Testing Procedure (PFTP) - 8120.22
  o Design change procedures – 8120.22
  o MRB procedures – 8120.22
  o Service difficulty reporting – 8120.22
	Production Certification
	• PC/PMA applications – 8120.22
	• Review and approve new quality system – IGF - 8120.22, 8120.23
	• PC/PMA/TSOA pre-production approval audits –IGF – 8120.22,
	• Conformity plans (CIP) – 8110.4
	• Production Conformity inspection - 8120.22, 8110.4
	• Witness test production - 8120.22, 8110.4
	• Undue Burden – 8100.11
	• Commercial Parts – 8110.118, 8120.22
	• Issue PC/PMA –IGF - 8120.22
	• Issue Production Limitation Revision (PLR) –IGF – 8120.22
	• International agreements - IGF - BAA/IPA, AC21-21, 21-1
		Production Certification
		N/A

ACO Functions	MIDO Functions	FSDO / AEG Functions

Production Certification Oversight
• Review changes to quality system – 8120.22
  o Production Flight Testing Procedure (PFTP) – 8120.22
  o Design change procedures – 8120.22
  o MRB procedures – 8120.22
  o Service difficulty reporting – 8120.22
• Audits:
  o QSA – IGF – 8120.23
  o Periodic checks of production flight test – 8120.22
	Production Certification Oversight
	• Review and approve changes to quality system – 8120.23, 8100.15
	• Audits:
	  o RBRT system – 8120.23
	  o Principal Inspector (PI) – 8120.23
	  o Product – 8120.23
	  o Special Technical Audits – 8120.23
	  o QSA – IGF – 8120.23
	  o SCA (Supplier Control Audits) – 8120.23
	  o Corrective action verification – 8120.23
	  o International agreements – IGF – 8120.23, 8120.13
	• Investigations – IGF – 2150.3
	  o Voluntary disclosures – 2150.3
	  o Corrective action verification – 2150.3
	• COS:
	  o Service Difficulty Reports 21.3 – 8120.23
	  o Quality failures, malfunctions, defects – 8120.23, 8110.107
	  o NTSB recommendations – 1220.2
	  o MSAD – 8110.107
		Production Certification Oversight
		N/A

Aircraft Certification
• Review operational / emergency procedures used for experimental certificates 8130.2
• Review and resolution of nonconformities for aircraft manufactured under a TC only 8130.2
	Aircraft Certification (Original)
	• Issue airworthiness certificates/approvals:
	  o Export – 8130.2, AC21-23, 21-2
	  o Standard A/W – 8130.2
	    ▪ Import – 8130.2, AC21-23, 21-2
	  o Special A/W – 8130.2,
		Aircraft Certification (Recurrent)
		• Issue airworthiness certificates/approvals
		  o Export – 8130.2
		  o Standard A/W – 8130.2
		    ▪ Import – 8130.2
		  o Special A/W – 8130.2, 8110.56, 8130.29
		  o Special Flight Authorizations

ACO Functions	MIDO Functions	FSDO / AEG Functions
• Evaluation of structure for excess aircraft weight 8130.2 • Evaluation of used Dual use engines 8130.2 • Special purpose operations for restricted Category 8130.2	8110.56, 8130.29 ○ Special Flight Authorizations (SFA) - IGF-8130.2 ○ Special flight permits – 8130.2 ○ 8130-3 tags new product 8130.21	(SFA) - 8130.2 ○ Special flight permits - 8130.2 ○ 8130-3 tags used parts – 8130.21
Repair Station Certification **N/A**	**Repair Station Certification** **N/A**	**Repair Station Certification** Repair Station (RS) Certification: Volume 2 Chapter 11 Part 145 Repair Stations • Certification of RS and Satellites RS w/i USA and its Territories V2 C11 S2 • Certification of RS Located outside the USA not under a MIP V2 C11 S3 • Evaluating RS Manual and Quality Manual or Revision V2 C11 S4 • Facilities and Equipment V2 C11 S5 • Certification of RS located in the US applying for EASA 145 V2 C11 S6 • Maintenance Implementation Procedures (MIP) FAA Order 8000.85A
		Oversight Activity – Certificate Management and Surveillance Activities per Flight Standards Information Management System (FSIMS) 8900.1 Surveillance Volume 6 Chapter 13 Part 145 • ***Risk Management*** V6 C13 S2 **Inspection Activity** Surveillance Volume 6 Chapter 9 Part 145 • Applications V6 C9 S 2, S3 & S7 • Certificate Requirements V6 C9 S1 • In-Depth Inspection of Part 145 RS V6 C9 S2 • Record System V6 C9 S3 • Manual System V6 C9 S4 • Housing and Facilities V6 C9 S5 • Tools and Equipment V6 C9 S6 • Technical Data V6 C9 S7 • Quality Control System V6 C9 S8 • Parts and Material Program V6 C9 S9 • Personnel V6 C9 S10 • Training Program V6 C9 S11 • Maintenance Process V6 C9 S12 • Work Away from Fix location V6 C9 S13 • Maintenance and Alteration V6 C9 S15 • Contract Maintenance (i.e. Suppliers)

ACO Functions	MIDO Functions	FSDO / AEG Functions
		V9 C9 S20 **COS** • Service Difficulty Reports 21.3 - 8120.23 • Quality failures, malfunctions, defects– 8120.23, 8110.107 NTSB recommendations – 1220.2 **Investigations** – 2150.3 • Voluntary disclosures - 2150.3 • Corrective action verification - 2150.3
		Air Operator Certification Activity • Certification Process: 8900.1 Volume 2 C 3, 4, 5 & 7 **Air Agency Certification Activity** • Certification 8900.1 Volume 2 C 8, 9, 10, 11& 12 **Aircraft Equipment Authorization** • 8900.1 Volume 4 C 1 thru 16

3.b. Existing FAA Oversight Models for Complex ODAs

With the introduction of ODA, the FAA instituted Oversight Management Teams (OMT) for every ODA. The OMT operations and requirements are captured in FAA Order 8100.15. The fundamental purpose of an OMT is to oversee the ODA holder which includes the ODA unit. In certain ODA applications, the FAA created "customized" OMTs for companies with large and / or complex ODAs. In general, these OMTs utilize dedicated resources to oversee the volume, complexity and integration of ODA operations. Two examples will be provided:

- Boeing Aviation Safety Oversight Office (BASOO)
- Gulfstream Aviation Safety Oversight Office (GASOO).

The OMT structure for BASOO and GASOO could serve as a preliminary step toward future oversight. The structure is designed to combine current FAA offices (ACO, MIDO, FSDO). The centralized nature of these OMT structures enables increased commonality for ODA oversight. The dedicated resources reduce priority ODA support from competing with other FAA priorities.

3.b.1 FAA Oversight of the Boeing ODA

The Boeing Aviation Safety Oversight Office (BASOO) is the Boeing Commercial Airplanes ODA Organization Management Team.

- The BASOO Structure consists of the BASOO Oversight and Certification Services branches, a COS representative, a FSDO representative, an AEG representative, a Manufacturing representative, and ACO specialists when performing ODA oversight activities.
  - Program related items are reviewed with the BASOO Program Managers.
  - Technical Cross Model related items are reviewed with the BASOO Technical Project Managers.
  - Program related retained items are worked within the Airplane Program Compliance Team (APCT)
  - The structure also has dashed line support for manufacturing, continued operational safety, AEG, and Flight Standards activities.
- Oversight
  - The BASOO Oversight branch manages all oversight: enforcement, supervision, inspection, voluntary disclosure and notification.
  - The Boeing Company has seen a growing volume of BASOO oversight since becoming an ODA.

Organizational Charts can be found in Appendix B.

3.b.2 FAA Oversight of the Gulfstream ODA

The Gulfstream Aviation Safety Oversight Office (GASOO) is Gulfstream ODA's Organization Management Team.

- The GASOO Structure was driven by a cross regional, enterprise implementation of Gulfstream ODA:
  - Single ODA unit /procedures manual covering multiple sites (FAA regions) with TC, STC, MRA, PC, PMA ODA authorities.
  - Traditional regional FAA ACO, MIDO, FSDO oversight processes needed adjustment to accommodate complex ODA.
- Program, and functional, and compliance roles are defined
- Oversight role is growing
  - The GASOO organizational structure enables a single FAA Program Manager to oversee the company's STC activity originating from multiple company sites and business units. Dedicated FAA TC Program Managers enable priority support for Gulfstream's new and amended TC projects. A dedicated Delegation Program Manager enables single oversight of ODA designee management, ODA procedures and audit / corrective action management activities. The structure also has dashed line support for manufacturing, continued operational safety and Flight Standards activities. All of these FAA support activities report up to the GASOO manager.
  - The GASOO depends on dedicated part time support from FAA technical specialists, pilots, inspectors, etc. Having the formal dedication documented helps with priority ODA support, there remains competing priorities at this working level. In addition, sometimes the competing priorities come from different Gulfstream ODA areas and / or Gulfstream company support requirements.

Organizational Charts can be found in Appendix B.

3.c. Opportunities with Today's Oversight

Before describing the desired oversight model for a certificated design organization, it is important to consider opportunities for improvement in the current ODA oversight model, and ensure that those are addressed in the future state. Based on information shared within the ARC, opportunities exist in the following areas:

- **Risk based volume / frequency of oversight** - there is a high degree of inconsistency in the volume or frequency of oversight performed on an ODA holder. One ODA holder received over 200 supervision inquiries in the past year, while others only received an annual visit. Furthermore, there is no apparent correlation to risk or performance in today's ODA oversight model.
- **Transition to Process focused oversight approach** - ODA oversight today is often based on a product based review. For example, *"please provide the project folder to the OMT when available for supervision review"*, or *"please make available the following project folders for the upcoming DOIP inspection"*. This approach can undermine the integrity of the process system, and lacks the benefits of a more systemic approach.
- **Consideration for self surveillance** - Another opportunity in today's oversight system is the approach to using an ODA holder's self-surveillance data. A healthy organization continually monitors itself through internal audit, as well as self disclosure, and non-compliance notification. An effective corrective action system within the organization will ensure continuous improvement of the organization and its processes. The FAA should work with an organization to recognize, help develop, and promote this system of self-surveillance as a measure of the

organization's performance. *"The FAA believes that the open sharing of apparent violations and a cooperative as well as an advisory approach to solving problems will enhance and promote aviation safety."* – FAA AC 00-58

- **Findings are often subjective or inconsistent** – A healthy compliance organization requires stability to allow expertise and skills in a given area or process to develop over time. In today's ODA oversight environment, previously accepted processes are often overturned based on involvement of new individuals or changes in interpretation. In order to maintain an effective compliance system, an applicant needs to be assured that established / accepted procedures will remain valid, unless compelling safety reasons necessitate changes.
- **Fully integrated oversight organization** – Under ODA today, most OMTs are made up of a loose association (not directly reporting to the OMT leader) of ACO, AEG, MIDO and FSDO resources. This often results in inefficient resolution of cross organizational issues, poor communication, and lack of accountability. The future oversight organization should integrate around a common systemic (process based) approach to organizational oversight for design, manufacture and operational activities.
- **More concise definition of oversight** - OMTs have developed oversight processes & procedures without robust national guidelines / standards or training. Many ODA manual procedures, project management, audit / corrective action management processes, and designee appointment processes were created with a level of OMT member best judgments.
- **More concise criteria for ODA autonomy** – ODA autonomy for delegated findings, delegated projects, designee appointments / expansions, root cause / corrective action have somewhat loose criteria for "acceptability". In other words, an acceptable root cause analysis, an acceptable corrective action plan, an acceptable designee appointment process / package, etc. may be determined by OMT member best judgment versus a national standard. Without a national standard for "acceptability" criteria, there is and will be different standards and potential "unlevel playing fields" for many ODAs. Recognizing the balance between prescriptive national requirements and flexibility of general guidelines, there is an opportunity to establish a level of criteria for industry.
- **Infrastructure enhancement to better assuring oversight success** – It is not apparent there are measures, metrics, or incentives for today's ODA oversight to produce the desired outcome of reducing FAA resources on routine certification functions to enable resource reassignment to aviation safety enhancements. The cultural adjustments required to improve the success should address infrastructure issues like incentives, training, skill management and metrics designed for the desired behavior.

4. Future Oversight Model

This section will provide the Working Group's recommended elements for the future oversight model.

Figure 1

Capability Maturity with Oversight Linkage

The recommended future oversight model is fundamentally comprised of assessment and surveillance. Figure 1 depicts the general oversight concept. The concept is presented graphically by a company capability over time, with certain capability "thresholds". It is envisioned that in the future the FAA will require minimum organization capabilities to justify application. Those capabilities and expanded capabilities will be determined by an FAA oversight assessment methodology. Similarly, capability requirements to become a Design Organization will be defined. The same FAA assessment approach will be used to determine whether a company meets the Design Organization qualifications. As that Design Organization company develops additional capabilities that are further assessed by the FAA, they may gain additional privileges. In between the application, Design Organization certification, and expanded privileges, the future FAA oversight will be surveillance of the company's performance.

As a point of reference, in the figures depicting the actual oversight models, any time there is an assessment or surveillance in the figure, it represents an FAA oversight touch point.

The future oversight model concept Figure 2 introduces oversight for design / manufacturing organizations, product / article, and Post Certification (Continued Operational Safety). Each of these areas will be reviewed in detail. The three areas introduce level of capability (organization), level of project involvement (product/article), and level of surveillance (post certification).

4.a. Oversight Key Areas

This section will present the recommended oversight models. The oversight basis will be risk based / performance based. The future oversight model addresses three key areas while striving to maintain a single oversight presence by the FAA. The three key areas are:

- Organizational: Transition from traditional show / find compliance to organizational performance based oversight model (see section 4b).
- Product and Articles: Transition from FAA's traditional role of direct project involvement to a performance based project oversight model (see section 4d).
  - FAA participation will be limited to Level of Project Involvement (LOPI).
- Post Certification (Continued Operational Safety): Transition from today's traditional Reactionary to a systemic (process based) surveillance model (see section 4c).

Figure 2

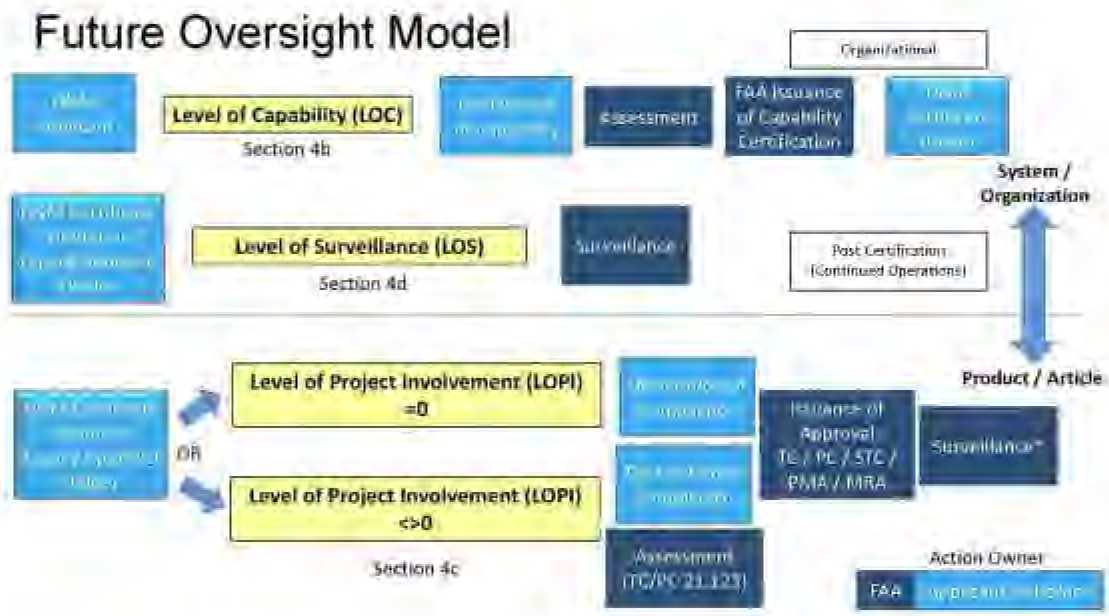


Figure 2 depicts the three areas (1-Organizational; 2-Post Certification (continued operations); 3-Product and Article) in a "swim-lane" chart. The top half of the chart shows the organizational and post-certification (continued operations), while the bottom half presents the product and articles "swim-lane". Each of these oversight areas will be described in more detail in this chapter.

The future FAA oversight system will be based on two principles: Performance Based Oversight (PBO) and Compliance Based Oversight (CBO). Each oversight principle has advantages and disadvantages and collectively they balance the safety performance goals. PBO has greater advantages than CBO. PBO focuses FAA resources to areas of higher risk in the aviation system and moves the FAA from a total dependence on compliance findings, auditing and inspections to a more effective approach of monitoring safety and compliance performance data from the aviation industry. CBO is at point of manufacture / integration vs storefront, while PBO can be virtual. Increases in compliance, conformity and safety performance will adjust the traditional Compliance Based Oversight activity and frequency.

A fully functioning PBO system provides risk based prioritization of FAA resources to areas of high safety and compliance risk. It would ensure that acceptable levels of safety and compliance risk are not exceeded in the system. Companies with high levels of safety and compliance performance would see reductions of FAA LOPI and oversight. The FAA can then focus its LOPI and oversight on companies with lower safety and compliance performance. In addition, the performance based oversight system would be more proactive vs reactive by emphasizing the use of data-driven decisions before an accident occurs.

PBO establishes performance objectives, measures and expectations, and focuses on results rather than prescriptive requirements. PBO assesses and monitors safety and compliance performance using various indicators. PBO relies on a certain amount of trust and accountability of data being assessed; it fosters improved and timely communications between the company and the FAA; it encourages a company to maintain and continuously improve its safety and compliance performance. Capability of a company is another determining factor in PBO (experience, training and systems in place).

Performance assessments include ongoing monitoring and analysis of performance data. Section 5 will introduce the assessment methodology approach for initial and expansion assessments. In addition, a prototype assessment tool has been developed (reference Appendix C). This tool could also be used for: Periodic audits, evaluations and inspections to validate the performance when necessary. Good and reliable performance data from the company will influence the frequency and level of FAA oversight. The FAA will scale the kinds of performance data collected from each company.

Performance data has target goals that are mutually agreed to by the company and the FAA (vitals show health of company's compliance, conformity and safety). A company maintains its system to move in the direction of acceptable / better performance. The FAA and industry need to develop recognizable performance indicators to be used (see recommendation). This would enable selection of performance indicators best suited in establishing the safety and compliance health of a company. The types of indicators used would be added, deleted or adjusted based on acceptable performance trends. The FAA would also identify minimum types of performance data the FAA should monitor that is risk based.

Recommendation: The oversight working group recommends a dedicated effort with industry and FAA to develop recognizable performance indicators prior to implementation of the new oversight model. Consideration for the effort would include review of an existing documentation such as the '*Strategy and Framework to Manage* Safety Performance *in AVS*', reference Appendix D. In addition, the development of the performance level indicators needs to consider the EASA approach which intends to assign a performance level to a company based on performance parameters from its surveillance of the company's organization and as well as its involvement in projects activities . This is captured in EASA '*Embodiment of LOI and SMS Requirements into Part 21*', reference Appendix E.

4.b Design / Manufacturing Organizations

The design / manufacturing oversight model for system / organization is identified in Figure 3. Any time there is an assessment or surveillance in the figure, it represents an FAA oversight touch point. The D&M applicant has a level of capability or is looking to expand that capability makes a declaration of capability to the FAA. The FAA makes an assessment of that capability (see section 5) and ultimately acknowledges the organization's capability through certification. The result is a D&M certificate holder with specified capabilities. Capability is shown and determined based on the product (e.g. aircraft, engine, propeller) and approval types (e.g. STC, TC, PMA). There may be instances where an existing DO would like to expand their capabilities to support their existing approvals. An example of this could be an Engine TC DO (part 33) wanting to expand an authority into 14 CFR 25.903.

Figure 3

Note: *The DO concept does not address manufacturing privileges yet the single FAA oversight model will address both design and manufacturing, and MRA aspects of the business organization. The DO defines requirements only for design aspects of SMS, CAS, and QMS. Additional rule changes will be required to minimize FAA manufacturing involvement in DO activities. For example, most ODAs today have delegated authority to issue routine Standard Airworthiness Certificates. Without specific regulatory provisions, a DO would not have the ability to perform this government function. The solution could be to include specific regulatory provisions for the retention of select delegated functions under a certificated DO company. See section 4.e for the expected manufacturing level of project involvement with the current definition of design organization privileges.*

Capability is shown / determined by the experience of the organization, or the demonstration of capability by existence of adequate processes and their use to conduct projects with FAA involvement prior to DO. Additional third party suppliers can be used to achieve capability not resident within the DO.

FAA oversight consists of the organization processes that include DO required processes (SMS, CAS, QMS) as well as manufacturing and MRA processes. As discussed, the FAA will focus on the process evaluation vs individual product / article compliance.

4.c. Product / Article

The design / manufacturing oversight model for product / article certification is identified in Figure 4. The key item is the Level of Project Involvement (LOPI). The two extremes of LOPI are "0" or no involvement from the FAA to "1" where the FAA has to perform a governmental function.

Figure 4

In the case where a certificated DO has previously demonstrated their engineering / design capabilities and they are not seeking to expand that capability, the LOPI should be "0" outside of any required governmental functions and the expectation is that the design organization has the autonomy to complete all certification efforts. Once these efforts are complete, the design organization makes a declaration of compliance which does not require an assessment by the FAA before it issues the certification / approval to the DO for that product / article.

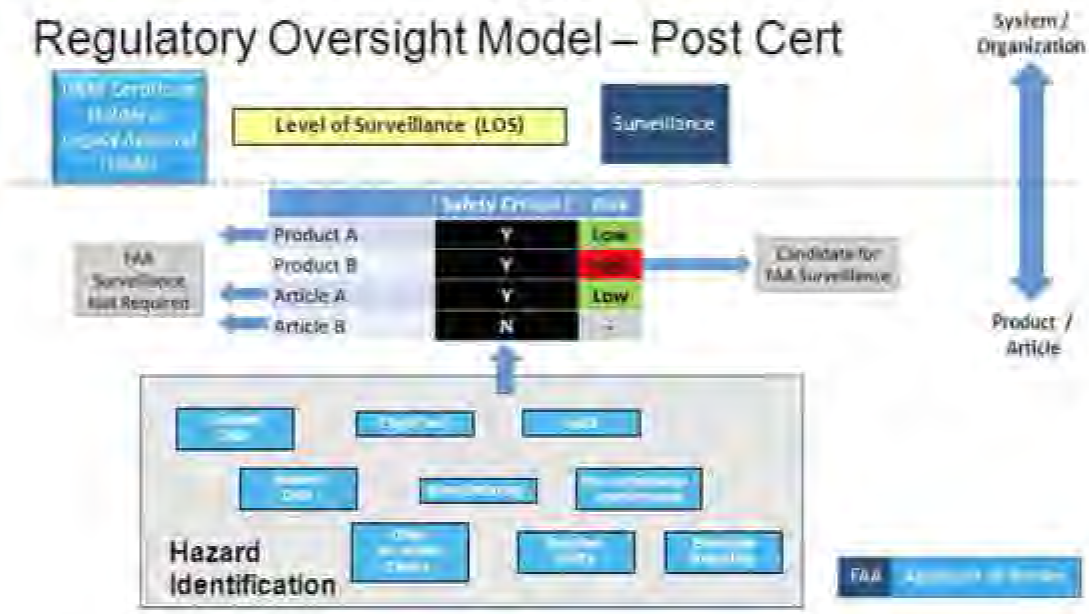
In cases where special conditions, equivalent level of safety, issue papers, alternate methods of compliance, or any other governmental functions are required, there will be a LOPI by the FAA. The intent here is that a LOPI is required but should minimize impact to the DO's critical path activities.

In terms of oversight, the expectation is that regardless of the LOPI, surveillance of the DO is the primary function performed by the FAA. Note that DO activities that required LOPI for a specific product / article can be used as demonstration of capability for future product / articles efforts.

4.d Post-Certification (Continued Operational Safety)

FAA and certificate holders will transition from today's traditional reactionary to a systemic (process based) surveillance model. The Level of Surveillance (LOS) will be dependent on processes for hazard identification, criticality of products, and a risk based safety criteria determinations. The process shall include outputs for corrective actions to the FAA (SB's, AD, SAIB, etc) [*One has to have parameters in place to be careful on the imposing of corrective actions such that they do not impose added costs to the operators, i.e. improved part.*].

Figure 5



Hazard Identification will include monitoring and trending safety analysis data with multilevel inputs by incorporating a data driven risk based approach for safety assurance and safety risk management. Current governmental and holder processes should be evaluated for effectiveness and readiness. (MSAD, BOEING Process, Bombardier, etc.)

Hazard Identification Inputs

- Service Alert Notifications (Declared Emergencies)
- Service Difficulty Reports, Incidents, and Accidents
- Flight Test
- Manufacturing
- Audits
- Non Compliance
- Anonymous reporting

The expectation is that a DO with a functional SMS has the responsibility to propose the corrective actions required to address safety issues to the FAA. For example, a DO could make a request to the FAA to release an AD based on their risk assessment.

4.e LOPI for Manufacturing

LOPI has been defined for the engineering activity in section 2.c. The following identifies and defines the potential areas for level of project (manufacturing) involvement depending on the performance of the organization as discussed in section 4.a.

Type Certification - Areas where agency manufacturing inspection may be involved during a TC program:

- Conformity inspections - critical articles, parts and installations on flight test aircraft (airworthiness and production certification risk areas).
- Conformity inspections - developmental (proto-type) layouts / drawings that turn into final production drawings.
- Undue Burden decisions for prototype articles manufactured at new production locations. Mitigation of burden may require conformity inspections and FAA audits. Sec 21.43, Sec 21.122, 21.139
- Flight test aircraft:
    - Establishing experimental certification requirements.
    - Issue experimental certificates, R&D and Show Compliance.
    - Issue Special Flight Authorizations (SFA) for foreign registered test aircraft.
    - Coordinating and approval of flight test locations and operating limitations.
- Review and approval of design change procedures (configuration control) that are part of the 21.137 quality system.
- Progressive conformity inspections of flight test aircraft that will be presented for Standard Airworthiness Certificate after type certification.

Production certification - Areas where agency manufacturing inspection may be involved during a PC/PLR project:

- Inspections for product manufactured under a Type Certificate Only. Inspection or test at a supplier facility, necessary to determine compliance. Sec 21.123.
- Conformity inspections of developmental layouts or drawings into final production drawings.
- Production locations approvals (Undue Burden decisions may require conformity inspections and FAA audits) Sec 21.139.
- Concurrent production conformity inspections on prototype products during TC projects.
- Production inspections of design changes during manufacturing.
- Review and approval of quality system changes during TC projects.
- Review and approval of MRB procedures, design change procedures, and production flight test procedures.
- Inspection of quality system, articles, witness test to determine compliance. Sec 21.140 and 21.147.

Airworthiness Certification - Areas where agency manufacturing inspection may be involved during a TC/PC project:

- Progressive conformity inspection of flight test aircraft presented for Standard Airworthiness Certificate.
- Establishing experimental certification requirements.
- Issuing Experimental certificates, R&D, Show compliance, crew training.
- Issuing Special Flight Authorizations (SFA) for foreign registered test aircraft.
- Coordinating and approval of flight test locations and operating limitations.

5. Oversight Assessment Methodologies

5.a. Initial Assessment

The initial assessment (referred to as appraisal in the 2008 CDO ARC Report, see section IV. J.) of a Design Organization (DO) should be an evaluation of the organization's ability to satisfy the requirements for a DO. The initial assessment establishes that the organization meets the basic requirements for the authority, and has process capabilities in place in accordance with the requirements for a DO. The effectiveness of that organization in ensuring compliance, safety of its products, and managing safety risk will be assessed by performance measures as discussed in section 4. These performance measures will determine the frequency and depth of ongoing surveillance activities (see section 5.b).

The initial assessment is intended to establish whether an organization has the required process coverage and the required level of process maturity. There are several models in use across industry to assess process maturity. In April 2012, the Safety Management International Collaboration Group (SM ICG) published the 'Safety Management System Evaluation Tool' as an objective method *"to indicate the expected standard of an organisation's SMS in terms of compliance with the SMS regulation and its performance to effectively manage safety risk"*. This tool provides an internationally harmonized standard for assessing process maturity, and can be expanded to include additional regulatory requirements for a DO. The report can be found on the SM ICG 'SKYbrary' page, at http://www.skybrary.aero/index.php.

The Oversight Working Group has expanded the SM ICG SMS Assessment Tool to include requirements for a Compliance Assurance System and Quality Management System. These components, SMS, CAS, and QMS form the basic components of a Certificated Design Organization. In advance of final requirements for CAS and QMS, the working group has used the draft proposed regulations from the 2008 CDO ARC Report. The working group presents this 'prototype' tool in Appendix C, as an example of what an assessment tool could look like. Before endorsing this as a tool for broader use, FAA and industry should revise the model to incorporate lessons learned from recent applications of the ICG SMS Assessment tool.

In the 2008 CDO ARC Report, the ARC recommends that *"an organization applying for a CDO certificate or an expansion of its existing certificate undertake a self-assessment. This self-assessment should be a formal undertaking with records generated of the findings and observations of the evaluators."* The self-assessment should apply the same evaluation tool as the FAA assessment; however, the FAA may consider the extent and thoroughness of the self-assessment in developing their plan for assessment. Upon satisfactory completion of the self-assessment, the candidate organization may submit application for Design Organization to the central FAA DO office (see recommendation below).

The application process (preferably electronic / on-line), will be defined by FAA policy and should consist of:

- Completed application form
- Written request for assessment
- Identification of requested capabilities
- Enclosure of self-assessment

It is the recommendation of this ARC that the FAA Assessment Team report to a centralized FAA DO office rather than placing that responsibility on an ACO. The ARC evaluated various options as shown in Table 5-1, below.

Table 5-1. Oversight Management Option Evaluation

Oversight Management	PROs	CONs
Local Surveillance and Assessment	• Team familiar with the products, the company, and the organization's performance to determine level of capability • Some familiarity with DO's processes	• Difficult to change the existing culture to systemic oversight model • Lack of standardization of the oversight across DO's • Variations in DO Manual Content • Additional workload levied on strained resources.
Local Surveillance / Central Assessment	• Team familiar with the products, the company, and the performance of the organization to determine appropriate surveillance (LS) • Some familiarity with DO's processes (LS) • Consistency in the assessments of organizations seeking DO privileges. (CA) • Unbiased Assessment from an uninvolved team of specialized DO system auditors. (CA) • Ability to gauge relative performance across multiple DO applicants (CA)	• Difficult to change the existing culture to systemic oversight model (LS) • Lack of standardization of the oversight across DO's (LS) • Lack of familiarity of DO products, the company, and the performance of the organization prior to assessment (CA) • Additional workload levied on strained resources (LS)
Local Assessment / Central Surveillance	• Team familiar with the products, the company, and the organization's performance to determine level of capability (LA) • Some familiarity with DO's processes (LA) • Consistency in the surveillance of organizations. (CS) • Unbiased surveillance from a team of specialized DO system auditors. (CS) • Ability to gauge relative performance across multiple DO (CS)	• Lack of standardization of the assessment for applicant/expanding DO's (LA) • Variation in DO Manual Content (LA) • Additional workload levied on strained resources (LA) • Lack of familiarity of DO products, the company, and the performance of the organization prior to beginning surveillance (CS) • Does not address oversight when there are targets of opportunity during project work (CS)
Central Surveillance and Assessment	• Unbiased surveillance from a team of specialized DO system auditors. • Allows ACOs to focus in on Safety Priorities • Oversight completed by DO Policy Owners (no interpretations) • Gatekeepers of DO Manual Content • Data Analysis Group for Continuous System Improvement both internal (FAA) and external (DO)	• Does not address oversight when there are targets of opportunity during project work • Lack of familiarity of DO products, the company, and the performance of the organization prior to beginning surveillance

Once the "Applicant DO" has applied and requested capabilities as defined in the DO regulations, the FAA will conduct an Initial Assessment. This will include:

- Inspection of the "Applicant DO" for compliance to the regulatory requirements
- Evaluation of the "Applicant DO's" processes abilities to meet the regulatory requirements with the respect to the capabilities requested.

An effective assessment will both ***validate*** that the organization has procedures and supporting processes in place to satisfy the DO requirements, and ***verify*** that the processes are followed by personnel who meet the qualifications defined in those processes. The validation step can be described as *"did you build the **right product**?"*, and the verification step can be thought of as *"did you build the **product right**?"*

It is important to ensure that both steps are effective. For example, an applicant needs to rely on the expectation that if people in the organization follow approved processes, then the result will be compliant products. This requires effective validation of the process during their development and their initial assessment. Effective validation ensures that all applicable requirements are allocated to the procedures (no requirements are missed), that requirements captured are valid (based in regulatory requirements), and that supporting processes define clear, unambiguous steps to be performed (see definitions of verify and validate in section 2.c.).

Furthermore, the industry needs to rely on the expectation that a certificated design organization will meet their obligations, and ensure that qualified personnel follow their approved processes. This includes the individual performing a self-assessment of their own work, the organization performing self assessments of their own activities, and the FAA performing ongoing surveillance activity of the design organization.

Figure 6
DO Validation and Verification

The result of the initial assessment is a determination that an organization either does or does not have adequate procedures and the necessary level of process maturity to ensure compliance and manage safety risk. This requires validation of the organization's procedures and supporting processes, as well as verification that those processes are followed. This assessment can be accomplished using a process maturity approach, combined with a risk / performance based surveillance program.

5.b. Certificated Design Organization (DO) Surveillance

As part of their fundamental oversight responsibilities, the FAA will conduct surveillance on the organizations to evaluate performance through inspection. The surveillance conducted by the FAA will utilize a systematic approach that will focus on the validation of the processes/procedures by means of inspection, and a verification of the organizations capability of following their procedures through an evaluation of the products and/or approvals that are the result of the system. Surveillance could include (but is not limited to):

- Review of the DO Process / Procedures within the Operating Manual,
- Review of the DO self-assessment / self-surveillance data and corrective actions,
- Inspecting the DOs for compliance with their Process / Procedures within the Operating Manual,
- Reviewing the work performed and Evaluating performance for quality assurance,
- Ensuring that required training has been completed,
- Providing constructive feedback, and
- Taking corrective action, as necessary.

Surveillance does not include program specific involvement; it is based at the system and process levels. The FAA will still have the responsibilities that are contained in governmental functions. However, the ARC has termed these actions as Level of Program Involvement (LOPI) and will be the tasks required of the FAA office in charge of the respective program and not within the job duties the Oversight Office (See Figure 4).

Oversight Team

The DO Oversight Team will be a team of individuals that have a corresponding role with the organization. For example, if a company holds design, manufacturing, and/or repair certificates, the Oversight Team will consist of Engineers (ASE), Manufacturing and Flight Standards Inspectors (ASI), and Aircraft Evaluation Group (AEG) members in order to parallel the DO's capabilities.

It is the recommendation of this ARC that these FAA Oversight Teams report to a centralized organization. As shown previously in Table 5-1, the ARC found that establishing a central oversight organization will:

- Achieve standard surveillance practices,
- Centralize policy responsibility ensuring consistency in interpretations,
- Allow the ACO to focus on safety critical functions,
- Provide "3rd-party objectivity" as the office does not work programs with the DO,
- Provide a single source/repository for the oversight data which will drive the risk based modelling controls,
- Manage skill development practices for surveillance staff,
- Allow for a highly trained staff in system surveillance, and
- Provide a single source for oversight of corrective actions.

Surveillance by 3rd party independent organization within a DO is acceptable as a means of validating or performing a DO's own self-audit / surveillance.

Figure 7 depicts the different offices and their roles, responsibilities, and actions with respect to standard applicants and design organizations.

Figure 7
Roles, Responsibilities and Actions

Surveillance Scope

As mentioned previously, the surveillance activities are not program specific, but at a process, system level. Therefore, there will be no specific criteria contained in policy by which the FAA will inspect and evaluate the organization. The oversight team will base their surveillance on the procedures contained within the organization's operating manual, the adherence to the procedures/processes, and evaluating the outcomes from the process for quality.

Risk Based Decision Making

The interval and depth of surveillance activities should be based on the safety risk of the product or article, capability of the organization, past performance of the organization, complexity of the programs, and the authority/privileges granted to the organization. First, an organization's self-surveillance activity, including their performance in addressing voluntary disclosures and notifications of non-compliance, is an indication of a closed loop system that will ensure continual improvement of the organization and address lessons learned. In addition, as discussed in section 4, an organization's performance, as indicated by the factors below, will determine the level and frequency of surveillance.

- Capability
- Past Performance
  - ADs / Safety Findings on approved products
  - Quality Escapes
  - Non-compliances
  - Self-Surveillance Findings
- Complexity
  - New and Novel Technology with respect to current processes
  - LOPI from ACO: If the program has a high level of involvement from the ACO, is it a good candidate for oversight?
  - The ability to manage and maintain control over large programs
  - Process Robustness
- Multiple Authorizations/Privileges/Certificates

5.c. Expansion Assessment

When a DO requests an expansion to the scope of its authority that involves substantially new processes that have not been previously demonstrated, the DO must demonstrate that it is capable of operating under its proposed processes prior to receiving an amended certificate with the expanded capabilities. As a tool in the performance of the self-assessment and the subsequent FAA evaluation, the DO applicant should have traceability between its processes and the regulatory requirements they are intended to address (see Figure 6).

Self-assessment: The application for expanded scope would include a self-assessment to show its readiness to function with the new processes, and exercise its capabilities to make determinations under the changed scope. The self-assessment should be a formal undertaking with records generated of the findings and observations of the evaluators utilizing the same process/performance measures used for the initial assessment (reference 5.a.). This assessment may be abbreviated based on the delta between regulatory requirements with respect to the additional capabilities requested. The FAA may use this assessment in focusing its assessment activities.

FAA Assessment: Following DO application for expanded scope, the FAA will perform an assessment based on the criteria used for the initial assessment (reference 5.a.) to determine the DO has shown that it is fully capable of operating within the changed scope.

- In the case of an expansion in scope for a DO in good standing, the FAA may rely on the self-assessment in issuing the expansion of the DO certificate.
- If the expansion in scope is minor, applicant DO self-assessment may be sufficient to allow the FAA to expand the certificate scope with no further demonstration.
- The use of the applicant's self-assessment to adjust the scope of FAA activities is solely at the discretion of the FAA and should follow the safety management principles of targeting safety critical efforts.
- The FAA is under no obligation to complete its assessment within a minimum time limit or number of projects.

6. Future Oversight - Assessment Model Implementation

6.a. Implementation Boundaries

The implementation approach covers the portion of the industry located above the DO threshold. This approach addresses the implementation of the Organizational and SMS elements as applicable to a Design Organization. The current underlying assumption is that there is no change for the portion of the industry below the threshold.

6. b. Implementation Assumptions

- Implementation covers global aspects of DO implementation:
  - Implementation plan split into industry specific actions and FAA specific actions.
  - Implementation plan for industry and FAA will be limited to above the DO threshold.
  - Implementation plan will address the transition from a "Mature ODA" to a DO.
  - Implementation plan will not address the production and maintenance, including the applicable ODA function codes.
  - Implementation plan for FAA apply to the different FAA lines of business having oversight responsibilities, under the DO oversight model, for design organizations, design projects and fleet activity.
  - For design approval holders and applicants below the DO threshold, confirmation of the requirements from the other WGs needs to be provided before determining need for extending the scope of the implementation plan. The current assumption is that this oversight system of this portion of the industry does not change.
- DO / SMS
  - Not all design approval holders will be required to be DOs.
  - DOs require an SMS. SMS will be evaluated at initial DO assessment and during DO surveillance.
  - Some non-DOs may require SMS. Non-DOs may elect to develop a SMS without a certificate or privileges and it will reduce risk indicators and influence the level of direct oversight by the FAA.
  - DO will only be in effect after new application above the DO threshold.
- Delegation
  - DOs will not have a delegation for design approval activities (DMIR, ODA, DAR may be used for production / maintenance – see section 4.b.).
  - Non DOs may have a delegation of delegated persons.
- The FAA Oversight approach covers 3 major areas:
  - System / organization
  - Products, articles certification activities
  - Post-certification (COS)
- FAA will perform direct Oversight of all DOs. FAA will not delegate direct oversight of a DO to a third party.

- DO and SMS WG defines the need for independent auditing / monitoring that may be carried out in-house or by a third party. The extent of independent auditing may influence the level of direct oversight by the FAA.
- FAA issues DO certificate. DO perform product / articles certification process with minimal FAA involvement.
- Central FAA Oversight organization performs organizational assessment & surveillance in integration / coordination with local FAA field offices.
- Engineering LOPI only at local ACO level. Manufacturing LOPI will be performed by agency manufacturing inspectors (e.g. MIDO, ODA, etc.).
- The minimum qualifications for DAH will be defined. The PAH minimum requirements remain the same.

6.c. Implementation Approach

Three Major Transition Steps:

1. Proof of concept projects – Pre-implementation
2. FAA Transition Plan
3. Industry Transition Plan

Note: A phased-in approach to implementation may be effective where regulator/industry defines organizational requirements and applicants show compliance to those requirements on an "as ready" basis.

6.c.1. Proof of concept projects

- Objectives:
  - Ensure through proof of concept plans, that the requirements proposed by the Part21 / SMS ARC are practical to implement and achieve their effectiveness.
  - Determine if the transition from "Mature ODA" to DO has benefits to FAA and Industry and therefore should be executed or not.
  - Validate the DO elements and get operational experience on LOPI and fleet monitoring.
- Who will be involved?
  - Organizational (including SMS)
    - One large and experienced company and one medium-size company above DO threshold
  - Products and Articles certification (LOPI)
    - Central Office of Oversight and FAA field offices of selected companies involved in both organizations assessment /surveillance and Products and Articles certification
  - Post-certification (COS) / fleet activities
- How to run the simulation?
  - Organizational (including SMS / Fleet activities) requirements
    - 1st phase:
      - DO test-companies use requirements applicable to this simulation.

- DO test-companies perform gap-analysis, implement missing elements, conducts self-assessment and contact the FAA (central office + field offices) when they are ready for assessment by the FAA.
- 2nd phase:
  - FAA conducts assessment and when satisfied, grants letter of authorization to the DO test-companies to work on projects as a "DO".
- 3rd phase:
  - FAA / DO test-companies perform routine organization external/internal oversight. See figure 8 "applicant types diagram".

Products and Articles certification (LOPI)

- 1st phase: FAA consults Project test-companies to develop guidance material on LOPI (DO test-companies should be part of this group)
- 2nd phase: Simulation on selected projects
- 3rd phase: FAA review and uses feedback to develop fine-tuned guidance materials

- Benefits, Metrics

  To be defined for pass/fail. Mature ODA needs to be defined in order to set the baseline (see below). Capture any cost, resource, timing or autonomy benefits.

  Use metrics lessons learned to develop implementation metrics.

6.c.2. FAA transition plan

1. Objectives: identifying how the FAA can transition from its traditional role of project involvement to a role of coach and mentor with system oversight responsibilities.
2. Transition principle:
   - FAA needs to be ahead of the industry to be ready to support industry transition to DO (on an "as ready basis) and project work (LOPI).
   - Develop performance measures prior to implementation.
   - FAA should not release a final rule before FAA has implemented the infrastructure (training, policy change, incentives, organizational changes, metrics, etc.) to better ensure the necessary cultural shift to perform system oversight.
   - "Mature ODA FAA Oversight" is defined as the baseline for determining the DO benefit metrics for the industry and the FAA. Level of FAA oversight appropriate for a Mature ODA is considered as the minimum criteria before moving to DO oversight. "Mature ODA oversight" may be understood as FAA engagement being limited only to inherent governmental functions, with ODA holding responsibilities intended by the ODA regulation.
3. Transition methodology:
   - FAA Office of Rulemaking
     - Review existing regulatory and guidance material for consistency and revision as required.

- Publish necessary policies for pushing the cultural changes.
- Apply lessons learned from proof of concept and incorporate into future rulemaking.
- Release or issue new rule(s).

FAA Central Oversight organization

- Formalize roles & responsibilities including coordination with local offices (Orders)
- Complete training and qualification of staff (Organization and Projects oversight)
- Ensure effectiveness of FAA's surveillance processes, procedures and tools.
- Develop metrics that measure the desired outcome / results / behaviors for both regulators and industry. For FAA, measuring effective auditing, LOPI disruption. For the DO, measuring effectiveness of corrective actions.

Local Field Offices

- Roles & responsibilities well-established including coordination with Central Oversight organization.
- Complete training and qualification of staff.
- Ensure effectiveness of LOPI and COS Surveillance Processes, Procedures and Tools.

FAA International Branch

- Bilateral agreements and associated Technical Implementations Procedures should be updated based on new DO system.

6.c.3. Industry transition plan

- Objectives: identifying how an organization could establish the systems required of an approved organization while still working as a non-certificated applicant or a delegated organization.
- Transition principle:
  - FAA publishes final requirements with a cut off date for industry to implement them. FAA published guidance materials using lessons learned from proof of concept projects.
  - Applicants above threshold (e.g. TCH) demonstrate compliance to those requirements on an "as ready" basis
  - Other DAH below threshold may apply for a DO on a voluntary basis.
- Transition methodology:
  - Organization processes:
    - Identify and implement needed organizational changes: Structure, Roles and responsibilities, Procedures & processes, Documentation. List of changes depends on current system (e.g. ODA vs. Delegates) and DO Objectives (Privileges / Functions).
    - Identify and develop necessary skills and competencies (e.g. Training, 3rd party utilization, etc.)
    - Run the preliminary steps before application for a DO (Implementation of requirements, self-assessment).

- Product / Articles (LOPI) and Fleet activities:
    - Run projects under LOPI principles, as soon as DO certificate issued by the FAA, IAW Limitations and Privileges defined in the DO certificate.

6.d. Implementation Issues Requiring Full ARC Coordination

- PBO / CBO Metrics at the DO system Level

- Metrics remain to be developed jointly by FAA and Industry
- What metrics should be established and how would they be applied consistently?

- DO needs to have the ability to issue certain certificates

- Recommend the ARC put together a team to evaluate the production aspects of a DO and the ability to issue certain certificates (ie Airworthiness Certificates)
- This team also will evaluate SMS benefits to production

6.e Applicant Types in "Design Organization World"

Figure 8 is presented as a concept to identify the various applicant types in the future state including Design Organizations. The checklist represents the QMS, SMS, DAS / CAS requirements to be met to qualify for the desired level of certification.

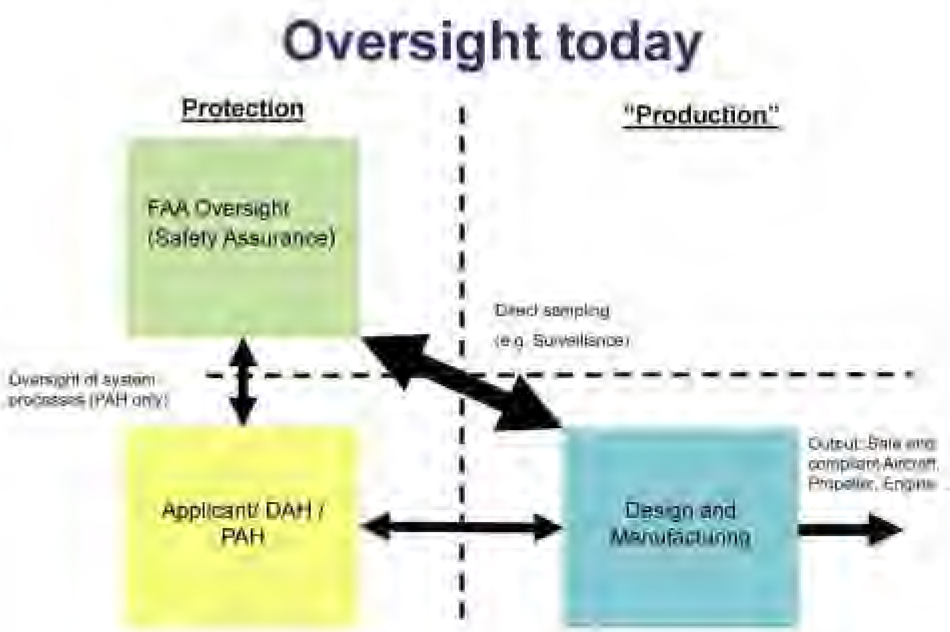
Figure 8

6.f Implementation Evolution

Figures 9 -11 and Table 6-1 capture the concepts and details of future oversight.

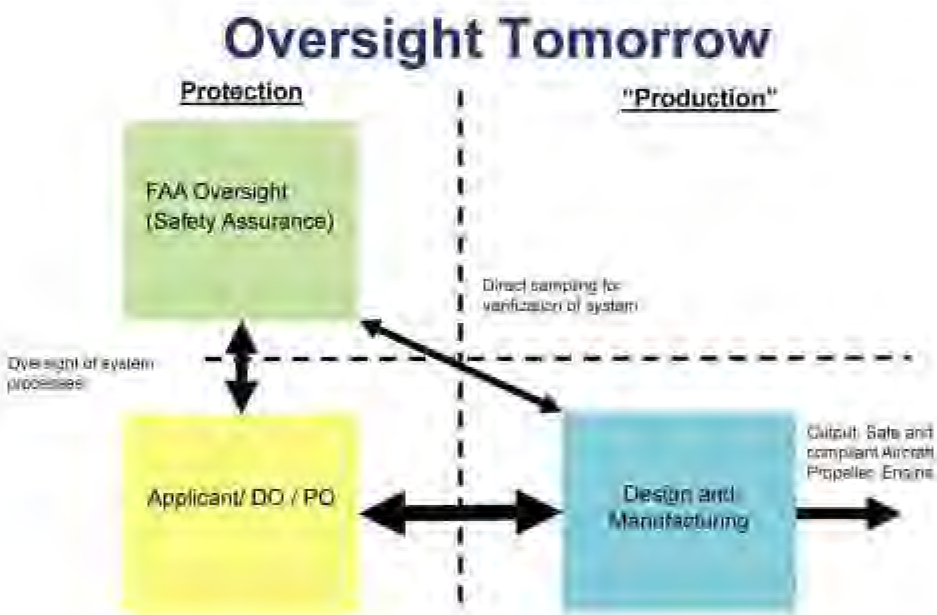
Oversight Today:

Figure 9



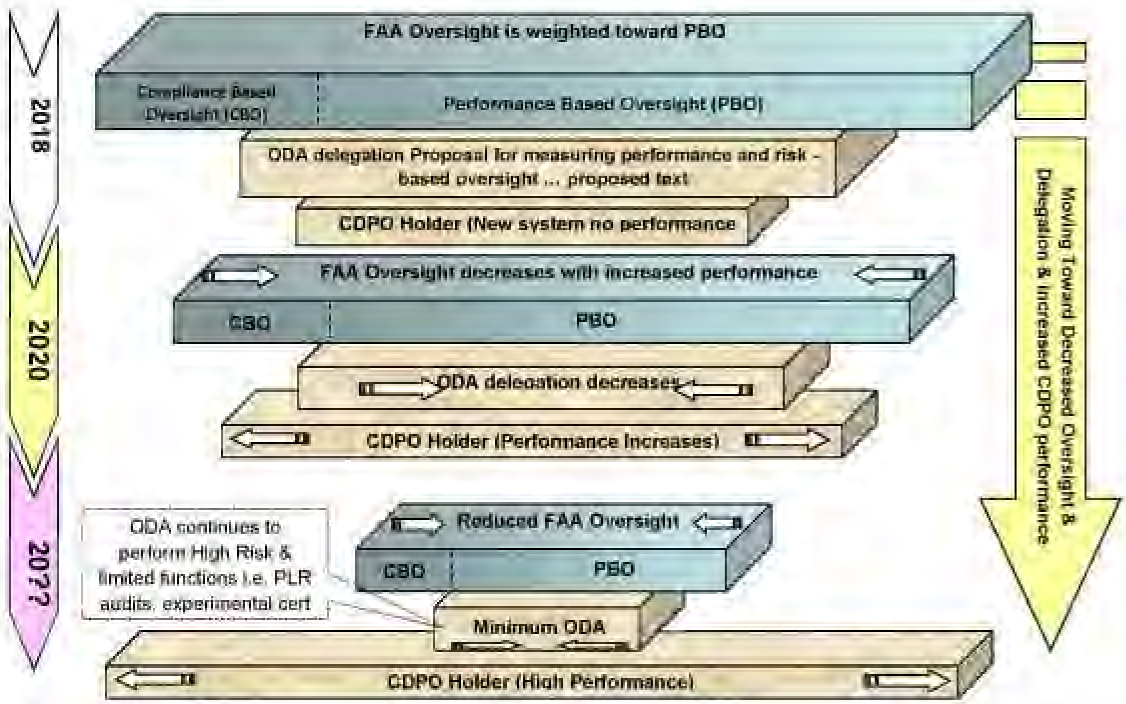
- **Oversight tomorrow**

Figure 10



- **CBO/PBO Chart**

Figure 11



FAA oversight of a CDPO and ODA includes SMS, Quality system and Design System. It shows FAA oversight is predominately performance based and full delegation. As the CDPO system matures the FAA oversight and ODA functions will decrease. When the CDPO reaches full maturity and with acceptable safety risk the FAA oversight is significantly lowered and delegation is reduced to only those functions that can only be performed by FAA or designees, i.e. issuing experimental certificates or airworthiness certificates. The FAA can concentrate more on high risk companies.

– **Future oversight table ("4th Column")**

Table 6-1. Proposed FAA Certification and Oversight Functions

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*

Design Certification Activity
• TC/STC/TSO/PMA applications - 8110.4, 8110.42, 8150.1
• RBRT system - 8110.4
• Issue papers - 8110.4
• Undue Burden – 8100.11
• Certification basis - 8110.4, 8110.48
• Operational suitability - 8110.4
• ELOS - 8110.4
• ICA – 8110.54
• Commercial Parts - 8110.118
• Certification and conformity plans PSCP & CIP- 8110.4
• Disposition of deviations- 8110.4
• Finding compliance - 8110.4, 8110.81
  ○ Review substantiation data - 8110.4
  ○ Witness test - 8110.4
  ○ Flight tests - 8110.41
  ○ Compliance Inspection - 8110.4
  ○ TIA/TIR - 8110.4, 4040.1
  ○ PMA Life limited Articles – 8110.42, 8120.22
• Issue TC/STC/TSOA - IGF except STC - 8110.4, 8110.42, 8150.1
	Design Certification Activity
	• RBRT system - 8110.4
	• Certification and conformity plans PSCP & CIP – 8110.4
	• Finding compliance - 8110.4
	  ○ Conformity Inspections - 8110.4
	  ○ Review process specifications - 8110.4
	  ○ Witness test – 8110.4
	  ○ TIA/TIR - 8110.4
	  ○ NDT evaluation - 8110.4
	  ○ Teardown inspections – 8110.4
	  ○ Configuration control of design changes - 8110.4
	• Airworthiness certification for flight testing (R&D, Show Compliance, SFA) – 8110.4, 8130.2?
	• Periodic Safety checks for flight test aircraft- 8110.4
		Design Certification Activity by AEG
		• ICA – 8110.4
		• Operational and Maintenance Evaluations – 8110.4
		• TIA flight tests- 8110.4
		• Flight Standardization Board – 8110.4
		• Maintenance Review Board – 8110.4
		• Flight Operations Evaluation Board – 8110.4
		• Type Ratings for airmen -8110.4
			Design Certification Activity
			• *Undue Burden ACO, MIDO*
			• *Certification basis ACO*
			• *ELOS ACO*
			• *LOPT ACO*
			• *Commercial parts ACO, MIDO*
			• *Issue TC/STC/TSOA*
			• *A/W certification (SFA, R&D, Show Compliance)*
			• *Flight Standardization Board 8110.4*
			• *Maintenance Review Board 8110.4*
			• *Flight Operations Evaluation Board 8110.4*
			•

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*

Design Certification Oversight
• Investigations - IGF - 8020.11, 2150.3
  ○ Voluntary disclosures - 2150.3
• Special Technical Audits - IGF - 8110.4
• COS:
  ○ Service Difficulty Reports 21.3 – 8110.107
  ○ NTSB recommendations - 1220.2
  ○ Issue ADs – 8040.4, 8040.5, IR-M8040.1
  ○ AMOC – 8110.103
  ○ MSAD - Failures, malfunctions, defects – 8110.107
	Design Certification Oversight
	• Special Technical Audits - IGF - 8110.4
	• COS:
	  ○ Service Difficulty Reports 21.3 – 8110.107
	  ○ MSAD - Failures, malfunctions, defects – 8110.107
		Design Certification Oversight
		N/A
			Design Certification Oversight
			• *Investigations - IGF - 8020.11, 2150.3*
			  ○ *Voluntary disclosures - 2150.3*
			• *Special Technical Audits - IGF - 8110.4*
			• *COS:*
			  ○ *Service Difficulty Reports 21.3 8110.107*
			  ○ *NTSB recommendations 1220.2*
			  ○ *Issue ADs – 8040.4, 8040.5, IR-M8040.1*
			  ○ *AMOC – 8110.103*
			  ○ *MSAD – Failures, malfunctions, defects – 8110.107*

Foreign TC/STC Validations
• International agreements
  ○ Finding compliance - 8110.52, 8110.51
  ○ Witness test - 8110.52, 8110.51
  ○ Issue VTC and VSTC - 8110.52, 8110.51
	Foreign TC/STC Validations
	• International agreements
	  ○ Finding compliance - 8110.52
		Foreign TC/STC Validations
		N/A
			Foreign TC/STC Validations
			• *International agreements*
			  ○ *Finding compliance - 8110.52, 8110.51*
			  ○ *Witness test - 8110.52, 8110.51*
			  ○ *Issue VTC and VSTC – 8110.52 8110.51*

Delegation Oversight • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15, 8110.37 • Review and approve ODA procedures manuals - 8100.15 • Delegated Organization Inspection Program (DOIP) - 8100.15 • Supervisory visits –	**Delegation oversight** • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15 • Airworthiness application package and limitations review - 8100.8 • Review and approve ODA procedures manuals - 8100.15 • Conformity report review individual	**Delegation oversight** • Delegation to individual designees and designations – 1100.2, 8100.8, 8100.15 • Airworthiness application package & limitations review - 8100.8 • Review and approve ODA procedures manuals - 8100.15 • Delegated Organization Inspection Program	***Delegation oversight*** • *Delegation to individual designees - 1100.2, 8100.8* • *Over the shoulder reviews - 8100.8* • *Airworthiness application review 8100.8* • *Conformity report review individual designees - 8100.8* • *Over the shoulder reviews individual designees - 8100.8* •

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*
8100.15 • Review internal audits - 8100.15	designees 8100.8 • Delegated Organization Inspection Program (DOIP) - 8100.15 • Supervisory visits - 8100.15 • Over the shoulder reviews individual designees 8100.8 • Review internal audits - 8100.15	(DOIP) - 8100.15 • Supervisory visits - 8100.15 • Review internal audits - 8100.15 • AFS Designees and Designations – Volume 13 Chapters 1 thru 10	

Production Certification
• Review new quality system – 8120.22
  ○ Production Flight Testing Procedure (PFTP) – 8120.22
  ○ Design change procedures - 8120.22
  ○ MRB procedures – 8120.22
  ○ Service difficulty reporting – 8120.22
	Production Certification
	• PC/PMA applications - 8120.22
	• Review and approve new quality system - IGF - 8120.22, 8120.23
	• PC/PMA/TSOA pre-production approval audits - IGF - 8120.22,
	• Conformity plans (CIP) – 8110.4
	• Production Conformity inspection - 8120.22, 8110.4
	• Witness test production - 8120.22, 8110.4
	• Undue Burden – 8100.11
	• Commercial Parts - 8110.118, 8120.22
	• Issue PC/PMA –IGF - 8120.22
	• Issue Production Limitation Revision (PLR) - IGF - 8120.22
	• International agreements - IGF - BAA/IPA AC21-23, 21-2
		Production Certification
		N/A
			Production Certification
			• *PC/PMA applications – 8120.22*
			• *Review and approve new quality system – IGF - 8120.22, 8120.23*
			• *PC/PMA/TSOA pre-production approval audits - IGF - 8120.22,*
			• *Conformity plans (CIP) – 8110.4*
			• *Production Conformity inspection – 8120.22, 8110.4*
			• *Witness test production - 8120.22 8110.4*
			• *Undue Burden – 8100.11*
			• *Commercial Parts – 8110.118, 8120.22*
			• *Issue PC/PMA – IGF – 8120.22*
			• *Issue Production Limitation Revision (PLR) – IGF - 8120.22*
			• *International agreements - IGF - BAA/IPA, AC21-23, 21-2*

Production Certification Oversight
• Review changes to quality system – 8120.22
  ○ Production Flight Testing Procedure (PFTP) – 8120.22
  ○ Design change procedures – 8120.22
	Production Certification Oversight
	• Review and approve changes to quality system – 8120.23, 8100.15
		Production Certification Oversight
		N/A
			Production Certification Oversight
			• *Review and approve changes to quality system – 8120.23*

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*
○ MRB procedures – 8120.22 ○ Service difficulty reporting – 8120.22 • Audits ○ OSA – IGF – 8120.23 ○ Periodic checks of production flight test – 8120.22	• Audits: ○ RBRT system – 8120.23 ○ Principal Inspector (PI) – 8120.23 ○ Product – 8120.23 ○ Special Technical Audits – 8120.23 ○ OSA – IGF – 8120.23 ○ SCA (Supplier Control Audits) – 8120.23 ○ Corrective action verification – 8120.23 ○ International agreements – IGF – 8120.23, 8120.13 • Investigations – IGF – 2150.3 ○ Voluntary disclosures – 2150.3 ○ Corrective action verification – 2150.3 • COS ○ Service Difficulty Reports 21.3 – 8120.23 ○ Quality failures, malfunctions, defects – 8120.23, 8110.107 ○ NTSB recommendations – 1220.2 ○ MSAD – 8110.107		• *Audits* ○ *RBRT system* ○ *Audits based on performance* ○ *Corrective action verification 8120.23* ○ *International agreements – IGF – 8120.23, 8120.13* • *Investigations – IGF – 2150.3* ○ *Voluntary disclosures – 2150.3* ○ *Corrective action verification – 2150.3* • *COS* ○ *Service Difficulty Reports 21.3 – 8120.23* ○ *Quality failures, malfunctions, defects – 8120.23, 8110.107* ○ *NTSB recommendations – 1220.2* ○ *MSAD – 8110.107*
Aircraft Certification • Review operational / emergency procedures used for experimental certificates 8130.2 • Review and resolution	**Aircraft Certification (Original)** • Issue airworthiness certificates/approvals: ○ Export – 8130.2, AC21-23, 21-2 ○ Standard A/W-	**Aircraft Certification (Recurrent)** • Issue airworthiness certificates/approvals: ○ Export – 8130.2 ○ Standard A/W- 8130.2	*Aircraft Certification* • *Issue airworthiness certificates/approvals* ○ *Export – 8130.2, AC21-23, 21-2* ○ *Standard A/W – 8130.2* ▪ *Import – 8130.2, AC21-23*

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*
of nonconformities for aircraft manufactured under a TC only 8130.2 • Evaluation of structure for excess aircraft weight 8130.2 • Evaluation of used Dual use engines 8130.2 • Special purpose operations for restricted Category 8130.2	8130.2 • Import - 8130.2 AC21-23, 21-2 ○ Special A/W - 8130.2, 8110.56, 8130.29 ○ Special Flight Authorizations (SFA) – IGF- 8130.2 ○ Special flight permits - 8130.2 ○ 8130-3 tags new product 8130.21	• Import - 8130.2 ○ Special A/W - 8130.2, 8110.56, 8130.29 ○ Special Flight Authorizations (SFA) - 8130.2 ○ Special flight permits – 8130.2 ○ 8130-3 tags used parts – 8130.21	*21-2* ○ *Special A/W - 8130.2, 8110.56, 8130.29* ○ *Special Flight Authorizations (SFA) – IGF– 8130.2* ○ *Special flight permits - 8130.2* – *8130-3 tags new product 8130.21*
Repair Station Certification **N/A**	**Repair Station Certification** **N/A**	**Repair Station Certification** Repair Station (RS) Certification: Volume 2 Chapter 11 Part 145 Repair Stations • Certification of RS and Satellites RS w/i USA and its Territories V2 C11 S2 • Certification of RS Located outside the USA not under a MIP V2 C11 S3 • Evaluating RS Manual and Quality Manual or Revision V2 C11 S4 • Facilities and Equipment V2 C11 S5 • Certification of RS located in the US applying for EASA 145 V2 C11 S6 • Maintenance Implementation Procedures (MIP) FAA Order 8000.85A	***Repair Station Certification*** *Repair Station (RS) Certification: Volume 2* *Chapter 11 Part 145 Repair Stations* • *Certification of RS and Satellites RS w/i USA and its Territories V2 C11 S2* • *Certification of RS Located outside the USA not under a MIP V2 C11 S3* • *Evaluating RS Manual and Quality Manual or Revision V2 C11 S4* • *Facilities and Equipment V2 C11 S5* • *Certification of RS located in the US applying for EASA 145 V2 C11 S6* • *Maintenance Implementation Procedures (MIP) FAA Order 8000.85A*
		Oversight Activity - Certificate Management and Surveillance Activities per Flight Standards Information Management System (FSIMS) 8900.1 Surveillance Volume 6	***Oversight Activity - Certificate Management and Surveillance Activities per Flight Standards Information Management System (FSIMS) 8900.1*** *Surveillance Volume 6, Chapter 11 Part*

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*
		Chapter 13 Part 145 • **Risk Management** V6-C13 S2 **Inspection Activity** Surveillance Volume 6 Chapter 9 Part 145 • Applications –V6 C9 S 2, S3 & S7 • Certificate Requirements V6 C9 S1 • In-Depth Inspection of Part 145 RS V6 C9 S2 • Record System V6 C9 S3 • Manual System V6 C9 S4 • Housing and Facilities V6 C9 S5 • Tools and Equipment V6 C9 S6 • Technical Data V6 C9 S7 • Quality Control System V6 C9 S8 • Parts and Material Program V6 C9 S9 • Personnel V6 C9 S10 • Training Program V6 C9 S11 • Maintenance Process V6 C9 S12 • Work Away from Fix location V6 C9 S13 • Maintenance and Alteration V6 C9 S15 Contract Maintenance (i.e. Suppliers) V9 C9 S20 **COS** • Service Difficulty Reports 21.3 - 8120.23 • Quality failures, malfunctions, defects - 8120.23, 8110.107 NTSB recommendations - 1220.2 **Investigations** - 2150.3 • Voluntary disclosures -	*145* • ***Risk Management*** *V6 C13 S2* ***Inspection Activity*** *Surveillance Volume 6 Chapter 9 Part 145* • *Applications V6 C9 S 2, S3 & S7* • *Certificate Requirements V6 C9 S1* • *In-Depth Inspection of Part 145 RS V6 C9 S2* • *Record System V6 C9 S3* • *Manual System V6 C9 S4* • *Housing and Facilities V6 C9 S5* • *Tools and Equipment V6 C9 S6* • *Technical Data V6 C9 S7* • *Quality Control System V6 C9 S8* • *Parts and Material Program V6 C9 S9* • *Personnel V6 C9 S10* • *Training Program V6 C9 S11* • *Maintenance Process V6 C9 S12* • *Work Away from Fix location V6 C9 S13* • *Maintenance and Alteration V6 C9 S15* *Contract Maintenance (i.e. Suppliers) V9 C9 S20* ***COS*** • *Service Difficulty Reports 21.3 - 8120.23* • *Quality failures, malfunctions, defects - 8120.23, 8110.107* *NTSB recommendations - 1220.2* ***Investigations*** *- 2150.3* • *Voluntary disclosures - 2150.3*

ACO Functions	MIDO Functions	FSDO / AEG Functions	*Future State ACO/MIDO/FSDO/AEG*
		2150.3 • Corrective action verification - 2150.3	• *Corrective action verification - 2150.3*
		Air Operator Certification Activity • Certification Process: 8900.1 Volume 2 C 3, 4, 5 & 7 **Air Agency Certification Activity** • Certification 8900.1 Volume 2 C 8, 9, 10, 11& 12 **Aircraft Equipment Authorization** • 8900.1 Volume 4 C 1 thru 16	***Air Operator Certification Activity*** • *Certification Process: 8900.1 Volume 2 C 3, 4, 5 & 7* ***Air Agency Certification Activity*** • *Certification 8900.1 Volume 2 C 8, 9, 10, 11& 12* ***Aircraft Equipment Authorization*** *8900.1 Volume 4 C 1 thru 16*

7. Membership

Segment	Organization	Name
Assoc - ASD	Airbus	Eric Lesage
Assoc - AIAC	Bombardier	Chris Watkins
Assoc - AIAB	Embraer	Jose Luiz Beldemain
Assoc – MARPA	Heico	John Hunter
Assoc – MARPA	Jet Parts Engineering	Rod Sands
Assoc – MARPA	KSS Enterprises	Simon Gonzales
Assoc – MARPA	Measure Tech	Todd Haroutunian
Transport	Boeing	Rick Baggette
Transport GA	**Gulfstream**	**Bill Whitton***
Full ARC Co-chair	**FAA**	**Mike Reinert**
GA Part 23	Beechcraft	Randy Shields
GA Part 23	Beechcraft	Larry Moore
GA Part 23	Beechcraft	Wes Klinkerman
GA Part 23	Cessna	Joan Bouma
Engines	GE	Dave Chapel
Avionics	Rockwell Collins	Marisa Stephenson
Avionics	Garmin	Van Ruggles
Rotorcraft	Sikorsky Global	Dan Shapiro
FAA	AIR-110	Sarah Thatcher
FAA	ANE-170	Cesar Gomez
FAA	ANM-108L	Kurt Krumlauf
Observer	EASA	Jan Novak
Observer	EASA	Eric Sivel
Observer	EASA	Peter Corbeel
Observer	TCCA	Marcus Tittiger
FAA	AES-340	Carlos Quiles
FAA	AES-340	Paul Cloutier
FAA		Tony Janco
Observer	ANAC	Fabio Piovesan
Observer	ANAC	Guilherme Macedo
Observer	SAE	Bruce Mahone

* Chairman

Appendix A

Oversight Working Group Charter

Dated April 18, 2013

Scope and Boundaries

This Working Group (WG) will support ARC recommendations and submittal of a report addressing the following: *Changes to the FAA oversight methodology based on recommendations for changes to part 21 that takes into account existing FAA processes and oversight and delegation programs for design and manufacturing related certificates and approvals and authorizations.*

Assumptions

a. Oversight Requirements: Establishment of an FAA systems oversight approach in certification processes and continued airworthiness assumes the part 21 rewrite will require:

   i. A single, integrated FAA oversight/surveillance/enforcement approach for organizations that are certificate holders that includes production & design, certification project activities and continued operational safety (COS); and:

      (a) Will not include Repair Station oversight for those facilities that have multiple approvals.

      Will be aligned with design organization requirements established by the Organizational Working Group

      Will consider direct FAA oversight and FAA accepted "other party" oversight

      Will be based on a risk-based approach

      For organizational oversight

         (1) Will address FAA surveillance in terms of frequency and types of audits (design, manufacturing, projects, continued operational safety, etc.)

         (2) Will include oversight of COS processes - considering the general surveillance process model currently used in Canada

         (3) Will include performance based oversight methods / measures

      For project activity oversight:

         (1) Considering "Level of Involvement" (LOI) process models currently used in Europe and Canada

         Recognizing the LOI may be at the "specialist" level

         Will not require FAA delegation

   Assessment methodologies that:

      (a) Accommodate / Harmonize processes across FAA organizations (ACO, MIDO, FSDO - AEG, etc.)

      (b) Establish the initial compliance leading to FAA issuance of an organizational approval (operating certificate) based on qualification criteria (level of acceptance) established by the Organizational Working Group

      (c) Establish the compliance for FAA acceptance for a design organization progression based on qualification criteria (level of acceptance) established by the Organizational Working Group

      (d) Establish performance requirements for the on-going oversight / surveillance to establish the effectiveness of the systems in place

Oversight Implementation: Establish the transition plan of today's FAA oversight system to the recommended revised oversight system necessary for part 21 changes. Robust change management will be critical to implementing the revised part 21. Transition plan should include criteria based gates, benefits metrics, etc.

Tasking

WG Tasking

a. Oversight Requirements

1. A definition of the FAA surveillance / oversight requirements for the organizations that are certificate holders given the predicted outcome of the part 21 rewrite including the who, how, and what using a risk-based approach, including a definition of FAA assessment methods for issuance of new organizational approvals / progressions

A definition of the FAA surveillance / oversight requirements for project activity including Level of Involvement (LOI) requirements

A definition of the FAA surveillance / oversight requirements for COS activities

Oversight Implementation

1. A definition of what the transition model would look like, including gaining the needed understanding and support of the changes from key stakeholders in order for the organizational changes to be implemented effectively

Determine the skills, competencies, and associated training requirements for FAA, Third-Party and/or "Organizational" individuals performing oversight activities

Maintain FAA technical expertise while transitioning to oversight focus

Create or revise FAA Orders and advisory material necessary for SPRM, including 8000.367A

Relevant Questions

a. Oversight Requirements

1. What FAA organizational changes have to be implemented to support robust oversight? Will the FAA need to have Centers of Excellence?

What is the appropriate intent level of the oversight function?

How will "one" oversight process be designed for AVS? Single surveillance model between engineering and production? Should the oversight be implemented for AIR initially with AFS to follow?

Is it necessary to differentiate the oversight approach based on organization size, certification authority, etc.? If so what are the oversight criteria?

How will oversight be aligned to appropriately match the privilege and responsibility level of the organization?

How is systems approach organizational oversight differentiated from level of involvement (LOI) at a project level?

If ongoing oversight is based on performance and not compliance how can it be normalized by company and scalable?

How important is it that the US model is harmonized, or at least recognized as fully equivalent, with other authorities' DOA/DO systems – today and in the future as they evolve?

How does oversight change from overseeing a delegated organization (ODA holder) to an applicant showing organization?

Should there be routine FAA oversight and audit of the design organization's processes or should this be accomplished via self-audit and reported to the FAA? Should it be a combination of both?

What safety risk-based structure will be imposed for assessed deviations to procedure?

How does AS9100, or equivalent, outside auditing equate to the FAA oversight system? (Compare actual FAA Approved Production QMS audit versus AS9100 findings.)

Should internal FAA QMS audits be used as a model? If not, what best practices can be benchmarked to develop framework? (Consider other industries.)

Should a system be generated to allow FAA resources to perform maintenance of organizations instead of a formal audit process (i.e., review of internal audits with a focus on verification and validation)? (Audit the management system elements not the findings.)

Oversight Implementation:

1. What metrics / measures need to be established to ensure a successful implementation of organizational showing oversight?

What is the impact on oversight model / approach if any part of today's delegation system (individual or organization) authorization is retained?

Can FAA accept Third-Party certification in lieu of FAA audit?

What critical criteria will be used to identify frequency and scope of oversight activity?

What are the other "triggers" that would cause additional FAA oversight?

Deliverables

Deliver a report that defines an oversight model that addresses oversight requirements (the "what") and oversight implementation (the "who and how") as identified by [illegible]

Milestones and Dates

Date	Action	Expected Deliverable
April 2013	Define current FAA oversight in terms of activities and descriptions	Documented baseline of current FAA oversight
May 2013	Face-to-Face meeting in Washington DC to review / refine future oversight model and establish preliminary template for final report	1. Interim "future" oversight model 2. Preliminary template for final report
July 2013	Face-to-Face meeting in Washington DC to baseline oversight model against current development of design organization requirements as developed by the Organizational and SMS Working Groups	Agreement with Organizational and SMS WGs on aligned oversight model with design organization / SMS requirements
August 2013	Establish assessment methodologies for level of acceptance for initial and enhanced design organization. Establish assessment methodologies for performance based effectiveness of ongoing operations.	Assessment methodologies.
September 2013	Face-to-Face in Seattle or Washington DC to establish preliminary transition model. Baseline transition model with current development of cost benefit analysis methodologies and data agreements. Update alignment with SMS WG deliverables.	Transition model. Agreement with Cost Benefit Analysis WG on benefit methodologies and data agreements. Agreement with SMS WG on ongoing alignment.
October 2013	Establish skills, competencies, and training requirements for individuals performing	Skills, competencies, and training requirements for future oversight model

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Date	Action	Expected Deliverable
	oversight	
November 2013	Review impacts to existing FAA orders, advisory material, etc.	Definition of necessary FAA document changes
December 2013	Complete Oversight WG final report and submit to ARC	Final Report

WG Integration

a. Oversight WG will need clear understanding of the Organizational and SMS WG recommendations to develop specific oversight requirements and implementation strategies.

Cost Benefit Analysis (CBA) WG will identify data needs for CBA from other working groups: costs and benefits are dependent in part on what WG's recommend.

References

Working Group Lead(s) and Members

Airbus	Eric Lesage
Bombardier	Chris Watkiss
Embraer	Jose Luiz Bekierman
Heico	John Hunter
Jet Parts Engineering	Rod Sands
K&S Enterprises	Simon Gonzales
Measure Tech	Todd Harutunian
Boeing	Rick Baggette
Gulfstream	**Bill Whitton (Working Group Lead)**
Beechcraft	Randy Shields
Cessna	Jacque Holloway
GE	Dave Chapel
Rockwell Collins	Monica Stephenson
Garmin	Van Ruggles
Sikorsky Global	Don Shapiro
FAA AIR-110	Sarah Thatcher
FAA ANE-170	Cesar Gomez
FAA ANM-108L	Kurt Kruntiel
FAA AFS-340	Carlos Quiles
FAA AFS-340	Paul Cloutier
EASA	Jan Novak
TCCA	Marcus Finger
ANAC	Fabio Rivesana
ANAC	Guilherme Macedo

SAB	Ernest Mahone

Appendix B

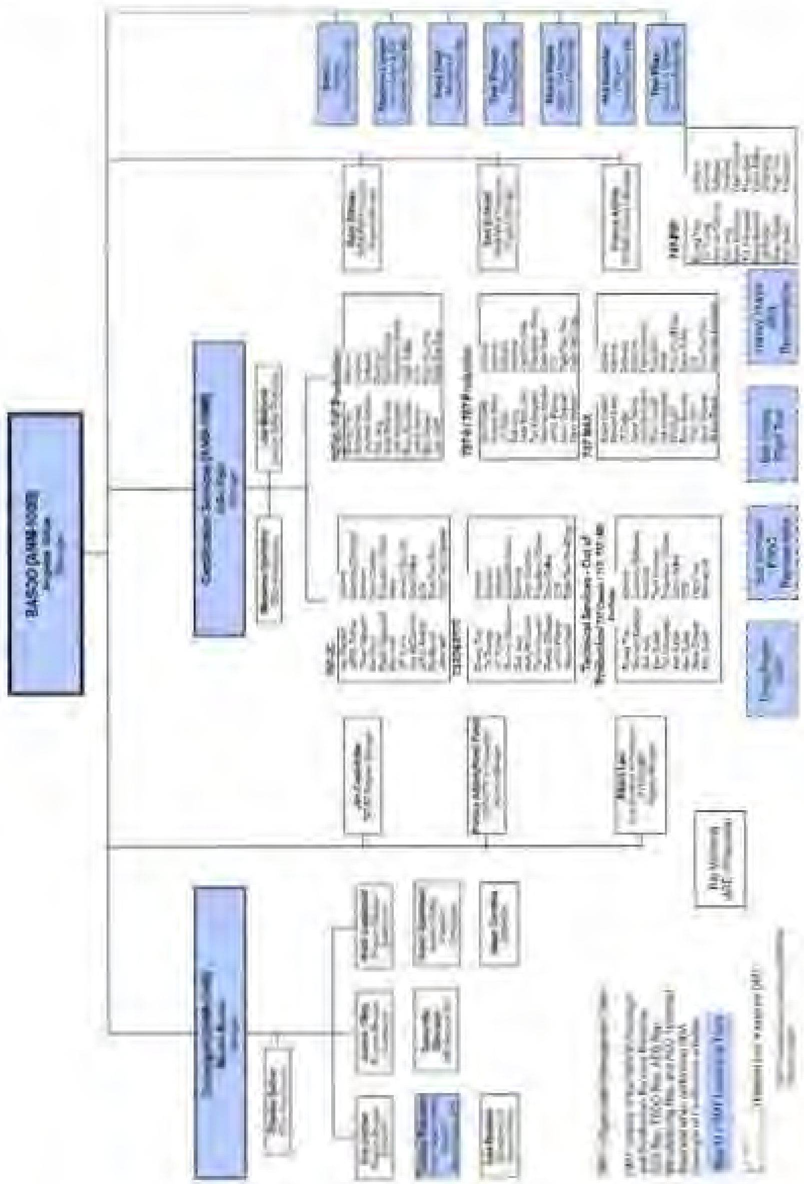
Boeing Aviation Safety Oversight Office (BASOO)

and

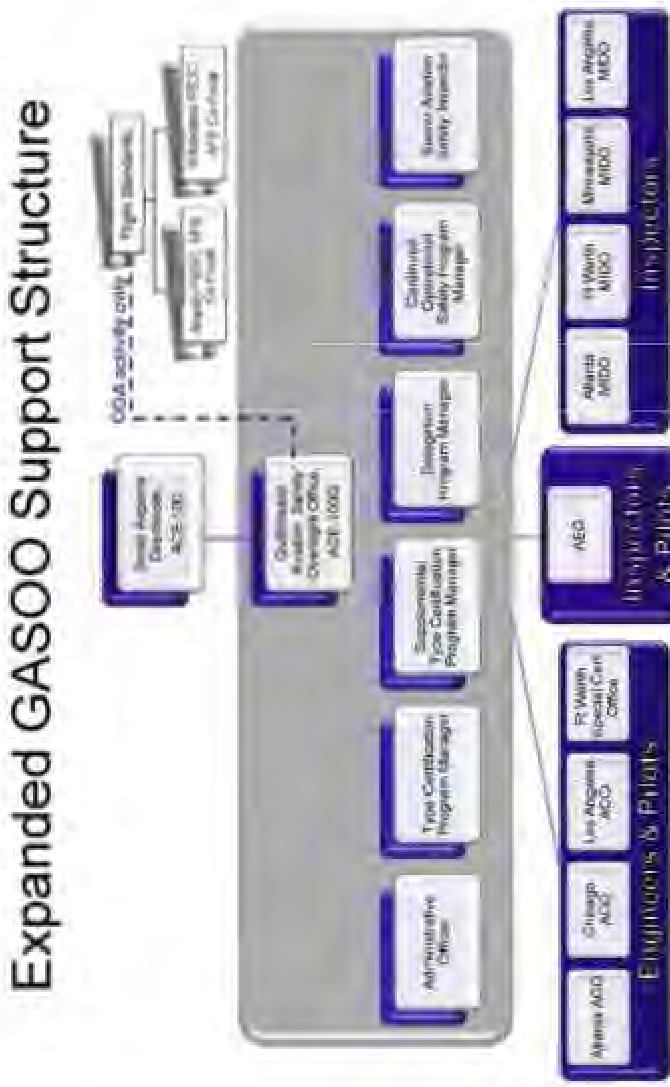
Gulfstream Aviation Safety Oversight Office (GASOO)

Charts

1. FAA Oversight of the Boeing ODA



2. FAA Oversight of the Gulfstream ODA



Appendix C

DO Assessment Tool

CDO Assessment Tool

Adapted from the SM ICG SMS Assessment Tool

By the Part 21 ARC Oversight Working Group

CDO Assessment Tool Guidance

Background and Purpose
This tool was originally developed by the Safety Management International Collaboration Group (SM ICG) to be used for assessing an organisation's SMS, and has been expanded for use in evaluating a Certified Design Organization (CDO) by the Part 21 Aviation Rulemaking Committee (ARC). It can be used for initial assessment or ongoing surveillance and oversight. The Tool is based on a series of indicators that help a regulator assess the effectiveness of an organisation's CDO. It requires an interaction with the organization including face to face discussions and interviews with a cross section of people as part of the assessment. It recognizes the difference in oversight methodologies from traditional compliance-based oversight to performance-based oversight that assesses not only compliance but also the effectiveness of the CDO.

It has been designed to indicate the expected standard of an organisation's CDO in terms of compliance with the CDO regulations[1] and its performance to those requirements.

Initial assessment
The Regulator may use the tool as part of an initial assessment and should define the expectations on the individual indicators before a certificate is issued.

For example an initial assessment could be based a desk top review of the documentation that focuses on assessing whether the 'indicators for compliance and performance' are present and suitable. Once the desk top review has been satisfied an on-site visit should be carried out to assess whether the indicators are operating and overall effectiveness is achieved.

The on-site visit should normally be carried out by a team including a team leader with an appropriate level of competence in CDO and technical specialists to support the assessment. It is important to structure the assessment in a way that allows interaction with a number of people at different levels of the organisation to determine how effective aspects are throughout the organisation. For example, to determine the extent that the safety policy has been promulgated and understood by staff throughout the organisation will require interaction with a cross-section of staff.

For small organizations it may be more practical to have a single assessor appropriately trained in CDO and with the technical competencies to assess the organization.

Another approach is for the regulated organization to partially complete the tool as a self-assessment, including the 'how it is achieved' box, and submit this to the Regulator who would decide whether it was sufficiently progressed to warrant an on-site visit and then verify and validate the organizations self-assessment.

Ongoing surveillance

For ongoing surveillance regulators may also define expectations for individual indicators. However the SM ICG has recommended, and the Part 21 ARC agrees, that all individual 'indicators of compliance and performance' should be at least operating and that effectiveness is achieved in all of the elements.

[1] This tool uses the proposed draft CDO regulations that are contained in 2008 CDO ARC Report, Appendix [illegible]. The tool should be updated upon publication of final CDO regulations.

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Competencies

The Tool should be used by regulatory staff with training and competency in:

- Safety Management Systems based on the ICAO SMS Framework
- Understanding of Quality Management Systems, compliance and auditing
- Understanding of Compliance Assurance Systems, and regulatory compliance
- Interview techniques
- Understanding of risk management
- Appreciation of the difference between compliance and performance
- Report writing techniques to allow narrative to be used to summarise the assessment

It is recommended that as well as being trained to use the tool in the classroom environment staff are provided additional training during a live assessment to familiarize themselves with the tool and its practical use.

Using the tool (instructions)

This Tool evaluates the compliance and effectiveness of the CDO through a series of indicators. It is set out using the 12 elements of the ICAO SMS Framework with the Framework definition followed by an effectiveness statement for that element, plus the 18 elements of a Compliance Assurance System (CAS), and the 7 elements of a Quality Management System (QMS)[1]. For each element, a series of 'indicators for compliance and performance' is listed followed by a series of 'indicators of best practice'. Each indicator should be reviewed to determine whether the indicator is present, suitable and operating and effective, using the definitions and guidance set out below, so that the overall effectiveness of the element can be justified and supported.

The tool would normally be used by the regulator to record and document the assessment. Alternatively it can be partially completed by the organisation to assess itself ("How it is achieved" column) and by the regulator to verify and validate the organisation's assessment ("Verification" column and "Summary comments" box).

Applicability

The evaluation tool can be used to assess any regulated organisation. However, due consideration should be given to the size, nature and complexity of an organisation in carrying out the assessment and that for smaller organisations a reduced number of indicators may be used as defined by the regulator.

Definitions used in the tool

Present

There is evidence that the 'indicator' is clearly visible and is documented within the organisation's CDO Documentation.

Suitable

The indicator is suitable based on the size, nature, complexity of the organisation and the inherent risk in the activity, including consideration of the industry sector.

Operating

There is evidence that the indicator is in use and an output is being produced.

Effective

There is evidence that the indicator is effective and achieving the desired outcome.

[1] See CDO ARC Report Appendix J. Proposed NPRM
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Evidence
Evidence includes documentation, reports, records of interviews and discussions and is likely to vary for different levels of indicator assessment. For example, for an indicator to be present the evidence is likely to be documented only, whereas for assessing whether it is operating it may involve assessing records as well as face to face discussions with personnel within an organisation.
'How it is achieved' should include summary statements and any references to documentation and manuals.

Verification
The Verification Column should be for the regulator to record any observations, conversations, records and documents sampled.

Summary comments
Once all indicators have been assessed by the regulator, a judgement can be made on whether the overall effectiveness of the CDO element has been achieved; this should be noted in the summary comments box.

Modifying the Tool
A regulator may adapt the terminology and tool to meet its own national requirements but aligning to this version may enable mutual recognition across States.

Developing Procedures
Each regulator will need to define procedures around the use of the tool, customised to its own organisational structure and approach to CDO oversight activity.

Complementary SM ICG products
The tool may be used in conjunction with other SM ICG products.

I. COMPLIANCE ASSURANCE

A certificate holder must maintain a regulatory compliance assurance system (CAS) for the control and management of design and production regulatory compliance within the scope of its certificate.

I.a. COMPLIANCE ASSURANCE SYSTEM

The compliance assurance system must provide assurance that its design and production processes, and any changes to them, are in compliance with the applicable requirements. The assurance should be consistent with what would result from a skilled independent review of compliance. The CAS must monitor processes and procedures used by the CDO throughout its system to:

INDICATORS OF COMPLIANCE + PERFORMANCE		P	E	O	E	How it is achieved	Verification
I.a.1	Make available all applicable regulations and regulatory guidance material associated with the scope of its certificate						
I.a.2	Perform compliance planning;						
I.a.3	Execute compliance plans;						
I.a.4	Verify compliance;						
I.a.5	Identify and define criteria for the transitions between compliance planning, the compliance determination, and the compliance verification activities defined in (a)(2), (a)(3), and (a)(4)						
I.a.6	Document processes and procedures for the configuration management of products, components, parts, appliances, and compliance data;						
I.a.7	Coordinate with the cognizant FAA office to establish certification requirements and acceptable methods of compliance; and						
I.a.8	Ensure the statement certifying compliance is properly executed.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification

I.a. SUMMARY COMMENTS

I.b. QUALIFIED INDIVIDUALS

When the system is dependent on the [illegible]

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	D	E	How it is achieved	Verification
I.b.1	The initial qualifications of the individual are appropriate to the tasks being performed						
I.b.2	The continuing qualification of the individual						
I.b.3	A periodic review of the work is performed to verify it is consistent with the compliance assurance system objectives, and						
I.b.4	A record at least of the individual's accomplishment of the compliance activity						

BEST PRACTICE INDICATORS		P	S	D	E	How it is achieved	Verification

I.b. SUMMARY COMMENTS

I.c. QUALIFIED TOOLS

When the CAS is dependent on the use of a mechanized, electronic or other tool, [illegible]

INDICATORS OF COMPLIANCE – PERFORMANCE		P	S	D	E	How it is achieved	Verification
I.c.1	The tool conforms to required function.						
I.c.2	Tool and its output are being controlled under a configuration management program.						
I.c.3	The tool is periodically verified for its applicability to the processes and methods for which it is used, and						
I.c.4	A record is kept that indicates when the tool was used to accomplish the compliance activity, and the outcome of its use.						

BEST PRACTICE INDICATORS		P	S	D	E	How it is achieved	Verification

I.c. SUMMARY COMMENTS

II. QUALITY MANAGEMENT SYSTEM

A certificate holder must maintain a quality management system (QMS).

INDICATORS OF COMPLIANCE – PERFORMANCE		P	S	D	E	How it is achieved	Verification
II.a	Enables the CDO to ensure it meets the qualification requirements of the subpart for the scope of its certificate and continues to follow the processes and procedures it has defined in its procedures manual.						
II.b	Conducts surveillance and audits of processes and procedures identified in the procedures manual to ensure they are followed and continue to meet their intended purpose.						
II.c	Uses proactive and reactive corrective action processes, and updates those processes when there is an identified need.						
II.d	Incorporates a configuration management process which includes a documented change control process.						
II.e	Verifies its personnel are trained and qualified to understand and operate in accordance with its processes and procedures.						
II.f	Includes high-level management oversight of surveillance and audit findings, and						
II.g	Ensures its processes and procedures provide for approval and oversight of its supply chain.						

BEST PRACTICE INDICATORS		P	S	D	E	How it is achieved	Verification

II. SUMMARY COMMENTS

III. SAFETY MANAGEMENT SYSTEM

A certificate holder must maintain a safety management system (SMS) that incorporates the following:

III.1 SAFETY POLICY AND OBJECTIVES

III.1.1 MANAGEMENT COMMITMENT AND RESPONSIBILITY

The organisation shall define its safety policy which should be in accordance with international and national requirements, and which shall be signed by the Accountable Executive of the organisation. The safety policy shall reflect organisational commitments regarding safety, including a clear statement about the provision of the necessary human and financial resources for its implementation and its communication, with visible endorsement, throughout the organisation. The safety policy shall include the safety reporting procedures and clearly indicate which types of behaviour are unacceptable and shall include the conditions under which disciplinary action would not apply. The safety policy shall be periodically reviewed to ensure it remains relevant and appropriate to the organisation.

EFFECTIVENESS is achieved when the organisation has defined its safety policy that clearly states its intentions, safety objectives and philosophies and there is visible evidence of safety leadership and management 'walking the talk' and demonstrating by example.

INDICATORS OF COMPLIANCE – PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.1.1.1	There is a safety policy that includes a commitment towards achieving the highest safety standards signed by the Accountable Executive.						
III.1.1.2	The organisation has based its safety management system on the safety policy.						
III.1.1.3	The Accountable Executive and the senior management team promote and demonstrate their commitment to the Safety Policy through active and visible participation in the safety management system.						
III.1.1.4	The safety policy is communicated to all personnel with the intent that they are made aware of their individual contributions and obligations with regard to Safety.						
III.1.1.5	The safety policy includes a commitment to observe all applicable legal requirements, standards and best practices, providing appropriate resources and defining safety as a primary responsibility of all Managers.						
III.1.1.6	The safety policy actively encourages safety reporting.						
III.1.1.7	The safety policy states the organisation's intentions, management principles and commitment to continuous improvement in the safety level.						
III.1.1.8	The safety policy is reviewed periodically to ensure it remains current.						

III.1.1.9	There is commitment of the organization's senior management to the development and ongoing improvement of the safety management system.						
III.1.1.10	A disciplinary policy has been defined that clearly identifies the conditions under which punitive action would be considered (e.g. illegal activity, negligence or wilful misconduct).						
III.1.1.11	There is evidence of decision making, actions and behaviours that reflect a positive safety culture.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.1.1.12	Personnel at all levels are involved in the establishment and maintenance of the safety management system.						
III.1.1.13	There is one common safety policy used throughout the organization, and it is implemented at all levels of the organization.						
III.1.1.14	The safety policy is clearly visible, or available, to all personnel and is reflected in key documentation and communication media.						
III.1.1.15	Safety policy objectives drive the organization's goals and mission statements.						
III.1.1.16	The organization regularly verifies that personnel throughout the organization are familiar with and have understood the policy and its message.						
III.1.1.17	The Accountable Executive demonstrates their commitment by attending training and /or safety conferences.						
III.1.1.18	Senior Management have adopted an integrated safety planning process with published and measurable safety targets and objectives.						

III.1.1 SUMMARY COMMENTS

III.1.2 SAFETY ACCOUNTABILITIES
The organization shall identify the Accountable Executive who, irrespective of other functions, shall have ultimate responsibility and accountability, on behalf of the organization, for the implementation and maintenance of the SMS. The organization shall also identify the safety accountabilities of all members of senior management, irrespective of other functions, as well as personnel, with respect to the safety performance of the SMS. Safety responsibilities, accountabilities and authorities shall be documented and communicated throughout the organization, and shall include a definition of the levels of management with authority to make decisions regarding safety risk tolerability.

EFFECTIVENESS is achieved when there are clear lines of safety accountabilities throughout the organization including an accountable person who has ultimate accountability for the SMS and the Accountable Executive and management team fully understand the risks faced by the organization.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.1.2.1	An Accountable Executive has been appointed with full responsibility and ultimate accountability for the SMS to ensure it is properly implemented and performing effectively.						
III.1.2.2	The Accountable Executive has control of the financial and human resources required for the proper implementation of an effective SMS.						
III.1.2.3	The Accountable Executive is fully aware of their SMS roles and responsibilities in respect of the safety policy, safety standards, and safety culture of the organization.						
III.1.2.4	Safety accountabilities, authorities and responsibilities are defined and documented throughout the organization.						
III.1.2.5	Personnel at all levels are aware of and understand their safety accountabilities, authorities and responsibilities regarding all safety management processes, decisions and actions.						
III.1.2.6	Safety management is shared across the organization (and is not just the responsibility of the Safety Manager and their team).						
III.1.2.7	There are documented management organizational diagrams and job descriptions for all personnel.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.1.2.8	There is evidence of personnel involvement and consultation in the establishment and operation of the SMS.						
III.1.2.9	There is evidence that safety management system principles have penetrated all levels of the organization and safety is part of the everyday language.						
III.1.2.10	Safety accountabilities throughout the organization are clearly documented and individuals sign for their accountabilities.						
III.1.2.11	Key safety activities are clearly described in senior management duties and responsibilities and incorporated into personnel performance targets.						
III.1.2.12	There is evidence that senior management recognises the significance of contributions from all levels of the organization and has a mechanism for acknowledging those contributions.						

III.1.2 SUMMARY COMMENTS

III.1.3 APPOINTMENT OF KEY PERSONNEL
The organisation shall identify a Safety Manager to be the responsible individual and focal point for the implementation and maintenance of an effective SMS.

EFFECTIVENESS is achieved when the SMS is facilitated by the responsible individual and there is a safety structure of key personnel from the various operational areas of the organisation. Business area heads are actively engaged in the safety management system.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.1.3.1	A competent person with the appropriate knowledge, skills and experience has been nominated to manage the operation of the SMS.						
III.1.3.2	The person managing the operation of the SMS fulfils the required job functions and responsibilities.						
III.1.3.3	There is a direct reporting line between the Safety Manager and the Accountable Executive.						
III.1.3.4	The organisation has allocated sufficient resources to manage the SMS including manpower for safety investigation, analysis, auditing and promotion.						
III.1.3.5	Personnel in key safety roles are kept current through additional training and attendance at conferences and seminars.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.1.3.6	The organisation has established a structured safety committee or equivalent, appropriate for the size and complexity of the organisation, consisting of a full range of senior management representatives.						
III.1.3.7	The Safety Committee or its equivalent monitors the safety performance of the operations and the effectiveness of the SMS and is normally chaired by the Accountable Executive.						
III.1.3.8	The person (s) responsible for managing and maintaining the SMS is/are given appropriate status in the organisation reflecting the importance of the safety role within the organisation.						
III.1.3.9	Safety committees include stakeholders and significant contracted organisations.						

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[illegible]	[illegible]							

III 1.3 SUMMARY COMMENTS:

III.1.4 CO-ORDINATION OF EMERGENCY RESPONSE PLANNING

The organisation shall ensure that an emergency response plan that provides for the orderly and efficient transition from normal to emergency operations and the return to normal operations is properly coordinated with the emergency response plans of those organisations it must interface with during the provision of its services.

EFFECTIVENESS is achieved when the organisation has an emergency response plan that is appropriate to the organisation and is properly tested and updated including coordination with other organisations as applicable.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.1.4.1	An emergency response plan (ERP) that reflects the size, nature and complexity of the operation has been developed and defines the procedures, roles, responsibilities and actions of the various organisations and key personnel.						
III.1.4.2	Key personnel in an emergency have easy access to the ERP at all times.						
III.1.4.3	The organisation has a process to distribute the ERP procedures and to communicate the content to all personnel.						
III.1.4.4	The ERP is periodically tested for the adequacy of the plan and the results reviewed to improve its effectiveness.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.1.4.5	The organisation has Memorandums of Understanding (MOU) or agreements with other organisations for mutual aid and the provision of emergency services.						
III.1.4.6	The organisation has implemented Critical Incident Stress Management for its Personnel.						

III.1.4 SUMMARY COMMENTS

III.1.5 SMS DOCUMENTATION

The organisation shall develop and maintain SMS documentation describing the safety policy and objectives, the SMS requirements, the SMS processes and procedures, the accountabilities, responsibilities and authorities for processes and procedures, and the SMS outputs. The organisation may incorporate the SMS documentation into its existing organisation documentation, or may develop and maintain a safety management system manual (SMSM) to communicate its approach to the management of safety throughout the organisation.

EFFECTIVENESS is achieved when the organisation has SMS documentation that describes their approach to the management of safety that is [illegible] throughout the organization and is regularly reviewed and updated. The documentation meets the safety objectives of the organization.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.1.5.1	There is documentation that describes the safety management system and the interrelationships between all of its elements.						
III.1.5.2	SMS documentation is regularly reviewed and updated with appropriate version control in place.						
III.1.5.3	SMS documentation is readily available to all personnel.						
III.1.5.4	The SMS documentation details and references the means for the storage of other SMS related records.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.1.5.5	Safety management procedures are integrated into existing organizational manuals.						
III.1.5.6	The organization has analyzed and uses the most appropriate medium for the delivery of documentation at both the corporate and operational levels.						

III.1.5 SUMMARY COMMENTS

III.2 SAFETY RISK MANAGEMENT
III.2.1 HAZARD IDENTIFICATION
The organisation shall develop and maintain a formal process that ensures that aviation safety hazards are identified. This should include the investigation of incidents and accidents to identify potential hazards. Hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection.

EFFECTIVENESS is achieved when aviation safety hazards are being identified and reported throughout the organisation. Hazards are captured in a [illegible] register and assessed in a systematic and timely manner.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.2.1.1	The organisation has a reporting system to capture errors, hazards and near misses that is simple to use and accessible to all Personnel.						
III.2.1.2	The organisation has proactively identified all the major hazards and assessed the risks related to its current activities.						
III.2.1.3	The safety reporting system provides feedback to the reporter of any actions taken (or not taken) and, where appropriate, to the rest of the organisation.						
III.2.1.4	Safety investigations are carried out to identify underlying causes and potential hazards for existing and future operations.						
III.2.1.5	Safety reports are acted on in a timely manner.						
III.2.1.6	Hazard identification is an ongoing process and involves all key personnel and appropriate stakeholders.						
III.2.1.7	Personnel responsible for investigating reports are trained in investigation techniques.						
III.2.1.8	Investigations establish causal/contributing factors (why it happened, not just what happened).						
III.2.1.9	Personnel express confidence and trust in the organisations reporting policy and process.						

		P	S	O	E	How it is achieved	Verification
III.2.1.10	The records identified are documented and kept accessible for future reference.						
III.2.1.11	The organisation uses the results of investigation of incidents and accidents as a source for hazard identification in the system.						
BEST PRACTICE INDICATORS		**P**	**S**	**O**	**E**	**How it is achieved**	**Verification**
III.2.1.12	There is an active reporting system indicated by reporting levels of more than, on average, 1 report per person per year.						
III.2.1.13	Safety Reports include the reporter's own errors and events that the reporter would not normally report (events where no-one was watching).						
III.2.1.14	The reporting system empowers personnel to propose preventative and corrective actions.						
III.2.1.15	There is evidence that the reporting system is actively used throughout the entire organisation (in each department and in each location).						
III.2.1.16	The reporting system is available to contracted organisations and customers to make reports.						
III.2.1.17	There is a process in place to analyse reports and hazard logs to look for trends and gain useable management information.						

III.2.1 SUMMARY COMMENTS

III.2.2 RISK ASSESSMENT AND MITIGATION

The organisation shall develop and maintain formal process that ensures analysis, assessment and control of safety risks in operations to an acceptable level.

EFFECTIVENESS is achieved when there is a formal process that ensures analysis, assessment and control of the safety risks in operations to an acceptable level

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	D	E	How it is achieved	Verification
III.2.2.1	There is a structured process for the management of risk that includes the assessment of risk associated with identified hazards, expressed in terms of severity and probability.						
III.2.2.2	There are criteria for evaluating the level of risk the organisation is willing to accept.						
III.2.2.3	The organisation has risk control strategies that include hazard elimination, risk control, risk avoidance, risk acceptance, risk mitigation, and where applicable an action plan						
III.2.2.4	Mitigating actions resulting from the risk assessment, including timelines and allocation of responsibilities are documented						
III.2.2.5	Risk management is routinely applied in decision making processes						
III.2.2.6	Effective and robust mitigations and controls are implemented						
III.2.2.7	Risk assessments and risk ratings are appropriately justified						
III.2.2.8	Senior management have visibility of medium and high risk hazards and their mitigation and controls						

BEST PRACTICE INDICATORS		P	S	D	E	How it is achieved	Verification
III.2.2.9	There is evidence that risks are being managed to as low as reasonably practical						
III.2.2.10	The organisation uses its risk management results to develop best practice guidelines that it shares with the industry						
III.2.2.11	The risk management processes are reviewed and improved on a periodic basis						

III.3 SAFETY ASSURANCE

III.3.1 SAFETY PERFORMANCE MONITORING AND MEASUREMENT

The organisation shall develop and maintain the means to verify the safety performance of the organisation and to validate the effectiveness of safety risk controls. The safety performance of the organisation shall be verified in reference to the safety performance indicators and safety performance targets of the SMS.

EFFECTIVENESS is achieved when the organisation has developed a range of safety performance measures that are appropriate to the type of operation. There is a means to measure and monitor trends and take appropriate action when necessary.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.3.1.1	Safety objectives have been established.						
III.3.1.2	Safety performance indicators have been defined, promulgated and are being monitored and analysed for trends.						
III.3.1.3	Risk mitigations and controls are being verified/audited to confirm they are working and effective.						
III.3.1.4	Safety audits are carried out that focus on the safety performance of the organisation and its services and assess normal operations.						
III.3.1.5	Safety objectives and performance indicators are reviewed and updated periodically.						
III.3.1.6	Safety objectives and targets are specific, measurable, agreed to, relevant and time-based.						
III.3.1.7	Information obtained from Safety Assurance and Compliance Monitoring activities feeds back into the safety risk management process.						
III.3.1.8	Safety assurance will monitor the effectiveness of risk controls including those applied by contracted organisations.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.3.1.9	The organisation is monitoring its current, future and third party safety risks and is taking action to address unacceptable safety risks.						
III.3.1.10	When establishing and reviewing objectives and performance indicators, the organisation considers: hazards and risks; financial, operational and business requirements; views of interested parties.						
III.3.1.11	Safety objectives and performance indicators encompass all areas of the organisation.						
III.3.1.12	Performance measurements have been defined for serious safety risks identified on the safety risk profile.						
III.3.1.13	Personnel at all levels are aware of the safety performance measurements in their areas of responsibility and the results of performance measurements are transmitted to them.						
III.3.1.14	Safety performance indicators are linked to the organisation's safety objectives, and State SPIs are considered where appropriate.						
III.3.1.15	The analysis and allocation of resources are based on outputs from the performance measurement.						

III.3.1 SUMMARY COMMENTS

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III.3.2 THE MANAGEMENT OF CHANGE
The organisation shall develop and maintain a formal process to identify changes within the organisation and its operation, which may affect established processes and services, to describe the arrangements to ensure safety performance before implementing changes, and to eliminate or modify safety risk controls that are no longer needed or effective due to changes in the operational environment.

EFFECTIVENESS is achieved when the organisation uses the safety risk management system to proactively assess all major changes in the organisation and its operations.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.3.2.1	The organisation has established a process and conducts formal hazard analyses/risk assessment for major operational changes, major organisational changes and changes in key personnel.						
III.3.2.2	Safety Case/Risk assessments are aviation safety focused.						
III.3.2.3	Key stakeholders are involved in the change management process.						
III.3.2.4	During the change management process previous risk assessments and existing hazards are reviewed for possible effect.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.3.2.5	Validation of the safety performance after organisational and operational changes have taken place to ensure assumptions remain valid and the change was effective.						
III.3.2.6	All organisational and operational changes are subject to the change management process.						
III.3.2.7	Safety accountabilities, authorities and responsibilities are reviewed as part of the change.						

III.3.2 SUMMARY COMMENTS

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III.3.3 CONTINUOUS IMPROVEMENT OF THE SMS
The organisation shall develop and maintain a formal process to identify the causes of substandard performance of the SMS, determine the implications of substandard performance of the SMS, determine substandard performance in operations, and eliminate or mitigate such causes.

EFFECTIVENESS is achieved when the organisation routinely monitors the SMS performance to identify potential areas of improvement and the outcomes of this process lead to improvements in the safety management system.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	D	E	How it is achieved	Verification
III.3.3.1	The Safety Committee has the necessary authority to make decisions related to the improvement and effectiveness of the SMS.						
III.3.3.2	The SMS is periodically reviewed for improvements in safety performance.						

BEST PRACTICE INDICATORS		P	S	D	E	How it is achieved	Verification
III.3.3.3	There is evidence of lessons learnt being incorporated into the policy and procedures.						
III.2.3.4	The organisation benchmarks its SMS against other organisations and is an active promoter of SMS within the aviation industry.						
III.3.3.5	Best practice is sought and embraced.						
III.3.3.6	Surveys and assessments of organisational culture are carried out regularly and acted upon.						
III.3.3.7	For safety related services the organisation requires contracted organisations not required by regulations to have an SMS.						
III.3.3.8	Contracted organisations have the ability to participate and share information in the SMS.						

III.3.3 SUMMARY COMMENTS

III.4 SAFETY PROMOTION

III.4.1 TRAINING AND EDUCATION

The organisation shall develop and maintain a safety training programme that ensures that personnel are trained and competent to perform the SMS duties. The scope of the safety training shall be appropriate to each individual's involvement in the SMS.

EFFECTIVENESS is achieved when all personnel are trained and competent to perform their SMS related duties and the training programme is monitored for its effectiveness and updated.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.4.1.1	There is a documented process to identify Safety Management training requirements so that personnel are competent to perform their duties.						
III.4.1.2	There is a process in place to measure the effectiveness of training and to take appropriate action to improve subsequent training.						
III.4.1.3	There is a process that evaluates the individual's competence and takes appropriate remedial action when necessary.						
III.4.1.4	Training includes initial and recurrent training.						
III.4.1.5	A training record is maintained for each all personnel trained.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.4.1.6	Training includes human and organisational factors including non technical skills with the intent of reducing human error.						
III.4.1.7	Training requirements are documented for each area of activity within the organisation, including areas where training requirements are not defined by regulations.						
III.4.1.8	A training needs analysis is carried out for all personnel and is regularly reviewed.						
III.4.1.9	Training is provided for personnel working for contracted organisations related to the operation.						
III.4.1.10	Personnel have a mechanism to request additional SMS training in relation to their role in SMS.						
III.4.1.11	Management recognise and uses informal opportunities to instruct all personnel on safety management.						

III.4.1.12	Training includes [illegible]							
III.4.1.13	[illegible]							

III.4.1 SUMMARY COMMENTS

III.4.2 SAFETY COMMUNICATION

The organisation shall develop and maintain formal means for safety communication that ensures that all personnel are fully aware of the SMS, conveys safety critical information, and explains why particular safety actions are taken and why safety procedures are introduced or changed.

EFFECTIVENESS is achieved when all personnel are aware of the SMS, safety critical information and their role in respect of aviation safety.

INDICATORS OF COMPLIANCE + PERFORMANCE		P	S	O	E	How it is achieved	Verification
III.4.2.1	Safety plans and strategies are communicated throughout the organisation to all personnel.						
III.4.2.2	Significant events and investigation outcomes associated with the organisation are communicated to all personnel, including contracted organisations where appropriate.						

BEST PRACTICE INDICATORS		P	S	O	E	How it is achieved	Verification
III.4.2.3	There is a safety communication strategy that includes electronic communication, frequent meetings, SMS award schemes, employee recognition system, SMS bulletins etc.						
III.4.2.4	Significant events and investigation outcomes from external organisations communicated to all personnel including contracted organisations where appropriate.						
III.4.2.5	The effectiveness of safety communication is routinely assessed and the strategy revised as required.						
III.4.2.6	Safety related information is proactively shared with other parties.						

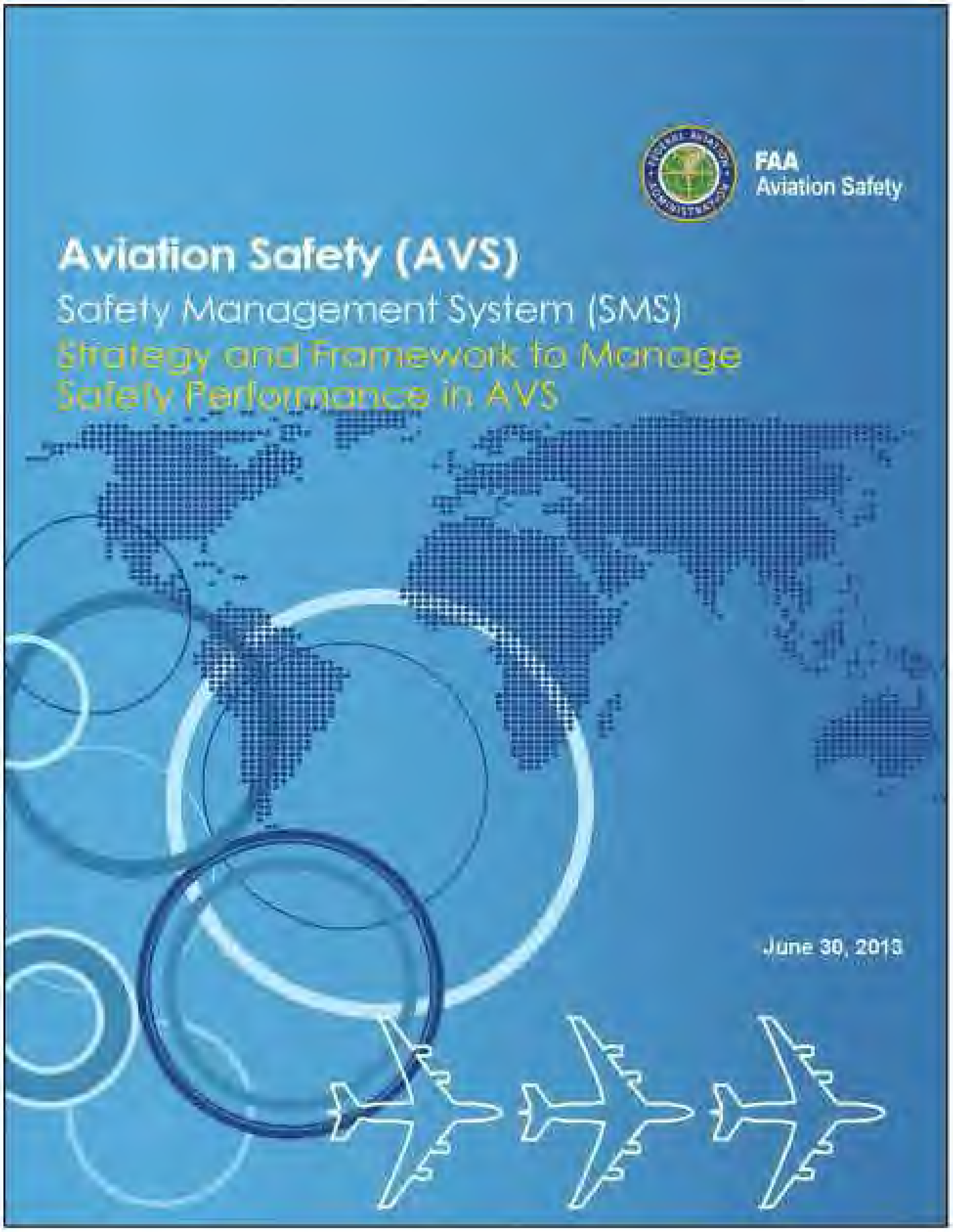
III.4.2 SUMMARY COMMENTS

Appendix D

Aviation Safety (AVS) Safety Management System (SMS)

Strategy and Framework to Manage

Safety Performance in AVS


FAA
Aviation Safety
Aviation Safety (AVS)
Safety Management System (SMS)
Strategy and Framework to Manage Safety Performance in AVS
June 30, 2013

Document Overview

The purpose of this document is to establish a strategy and framework to measure and manage safety performance in AVS. The intended audience of the document is the individuals involved in the design, development, implementation, and operation of the Aviation Safety Safety Management System (AVSSMS). Specifically, this document will facilitate the AVSSMS Coordination Group in setting expectations regarding the Safety Performance Design Team's activities and the methodology the team is seeking to employee in AVS for safety performance management.

The *Strategy* section starts with background information followed by a description of the concept. The objective of these subsections is to provide the reader the overarching context for safety performance management in the aerospace system with a focus on the regulator's activities. The background and concept is based on work done by the Safety Management International Collaboration Group. Next, the scope of safety performance management in AVS is described to focus on the expected results in AVS. Then, the requirements and assumptions used by the Safety Performance Design Team are listed to further specify the expected results in AVS, as well as highlight some of the related, but likely necessary activities/actions that are outside of the Safety Performance Design Team's control.

In the *Framework* section, the high-level model of safety performance management in AVS is described. This model is placed in the context of the Aviation Safety Safety Management System (AVSSMS). Safety performance management is part of Safety Assurance and has important interfaces with Safety Risk Management (SRM). The model describes the high-level steps of safety performance measurement at the corporate AVS-level and within AVS Services and Offices. The Safety Performance Design Team will develop more details regarding these high-level steps through the course of development of the safety performance management process in AVS.

The *Development and Implementation* section describes the high-level plan for establishment of safety performance management in AVS. The section includes the Safety Performance Design Team's high-level activities, schedule, and milestones.

This document will serve as a touchstone for the design of safety performance management in AVS. Throughout the development process the strategy and framework may be adapted as a result of testing, interface needs and the critical thinking in any design activity. As such, any changes will be documented and shared accordingly.

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1 Strategy to Measure Safety Performance in AVS

1.1 Background

Measures of safety performance should focus on how well the system is able to manage safety risks. An emphasis on system behaviors that can reduce the risk of adverse outcomes allows for meaningful safety performance metrics. Effective safety measures must reflect system behaviors related to safety risk control and contribute to decisions related to risk reduction.

Measurements of safety performance at both the Federal Aviation Administration (FAA) Aviation Safety (AVS) and individual product/service provider levels are essential for effective safety management. A measurement strategy should provide a set of measures, rather than a single "magic number." These measures should also be interactive, cover all aspects for which AVS is responsible, and reflect both outcomes (e.g. accidents, incidents, regulatory violations) and indicators of the proper functioning of critical system processes.

The complex and highly coupled nature of the global air transportation system give rise to unusual dependencies and latent conditions that, from experience, have been known to cause accidents. There will always be variability in this type of system and, therefore, the best option is to monitor the system's performance to discover early on any potentially uncontrolled variability.

The basic management axiom is that one cannot manage what one cannot measure. In any system, it is necessary to define a set of measurable performance outcomes in order to determine whether the system is truly operating in accordance with design expectations, as opposed to simply meeting regulatory requirements. The definition of a set of measurable performance outcomes also allows the identification of where action may be required to bring operational performance of the system to the level of design expectations. Thus, measurable performance outcomes permit the actual performance of activities critical to safety to be assessed against existing organizational controls; this allows safety risk to be maintained to acceptable levels and necessary corrective action taken.

Figure 1 depicts accident rates over time, dividing the trends into phases. Common cause occurrences or hazards are those to which all or a large segment of the population of interest are exposed and for which there are equivalent or highly similar (and thus "common") causes. In Phase 1, prescriptive rules or regulations manage common cause hazards.

In Phase 2, a large degree of the risk that can be effectively controlled through prescriptive regulations has been addressed. Remaining hazards occur more randomly, typically associated with problems unique to individual service providers. Service providers' SMS processes are essential to identify and treat those hazards. Safety measurements must, therefore, address the design and performance of product/service providers' SMS processes and their ability to address unique hazards.

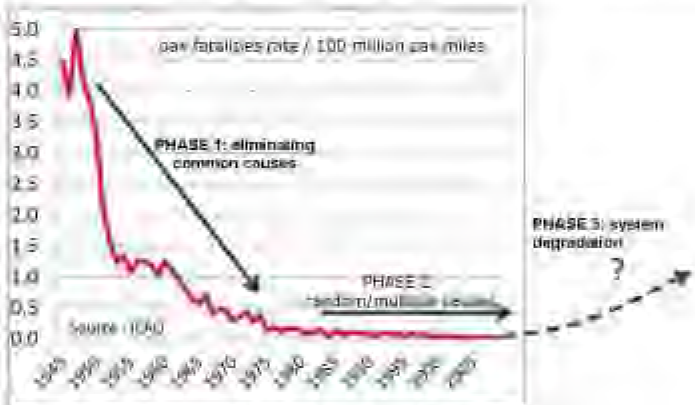


Figure 1 - Accident Trends and Causes

At the same time, management of risk addressed through compliance with existing rules must be maintained. Phase 3 represents a situation where the relaxation of prescriptive regulations erodes the gains made in Phase 1. Thus implementation and compliance with basic safety standards must be part of the safety management strategy and be included in the safety performance measurement strategy.

Phase 3 may also indicate that the aviation system is changing, thus reducing the effect of existing regulations/risk controls. Safety performance measurement must seek to recognize these changes and adapt existing risk controls to effectively manage risk.

Figure 2 illustrates the relationship between "things that are unsafe" (risk – circle on the right) and "things that are illegal" (contrary to prescriptive regulations – circle on the left). Managing risk would entail identification and management of all possible "unsafe" situations. Measurement of the effectiveness of risk management involves assessing how completely this is done. There is typically an intersection between the two, meaning the overlap is not total and not zero. The intersection between the two circles represents the set of situations where hazards and threats are covered by regulations, typically focusing on technology, training, or procedures. These are the "common cause" hazards that were discussed earlier. Note that this is a subset of compliance and, if all rules appropriately addressed legitimate hazards, would represent the totality of compliance.

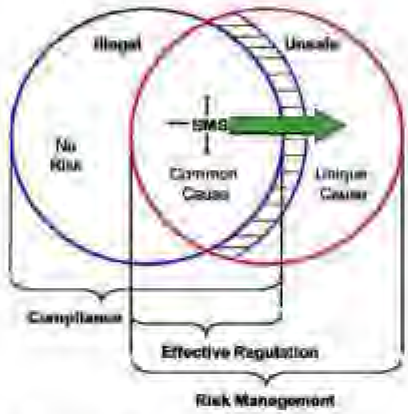


Figure 2 - Relationship Between Regulatory Requirements and Risk

TSMS requirements are placed in this overlap area between the circles. This takes the position that the need for an SMS is common to all service providers. It further recognizes that effective compliance entails use of an operator's SRM processes to tailor the method of compliance to their situation. Unique hazards are best controlled by the processes incorporated in an SMS. The SMS also requires product and service providers to identify hazards in their systems and operational environment, assess these hazards for their degree of risk, and take action to control those that pose an unacceptable degree of potential harm, whether those risks are the subject of regulations or not.

The overlap area is noted with the bracket "effective regulation." This is not to say that all rules and compliance efforts are assumed a priori to be effective, but that assessment of regulatory effectiveness should be based on how well this is done. Regulatory effectiveness should be considered within safety performance management.

The area of "things that are unsafe" but not illegal, represents unique cause risks where the regulator has not implemented regulations. The area bounded by the hatched area outside of the area of overlap represents a situation where effective risk controls are either outside of current technology or where the costs of implementing controls outweigh their benefits to society.

The area of "things that are illegal" but not harmful (the part of the left hand circle outside of the "unsafe" circle) represents ineffective regulations where compliance is not correlated with safety. This could be because the rules were inadequately developed to begin with, are obsolete, or were applied too broadly to service provider groups that are not exposed to the hazard that the regulation addresses.

1.2 Concept

1.2.1 Safety Performance Management System Summary

The measurement system structure depicted in Figure 3 is based on three tiers of analysis that represent the activities and performance of both the regulator (AVS) and product/service providers (industry) in the aerospace system. This concept was developed by the Safety Management International Collaboration Group (SM ICG). The three tiers of the system include: measures of the integrated aerospace system, measures of product/service provider system behaviors, and measures of activities of regulatory authorities. The four columns describe the way safety is measured and managed.

Figure 3 - Safety Performance Measurement Matrix

Indicators of performance (column B) consist of both process and outcome measures. Process measures are measures of the functioning of key safety management processes such as Safety Risk Management (SRM) and Safety Assurance on the part of both AVS and service providers. Outcome measures are designed to measure the effectiveness safety management processes. For example, consider an outcome measure as the reduction of the accident rate due to "loss of control" events. The regulator (AVS) will use SRM to determine activities to mitigate common cause hazards associated with loss of control. These activities may involve rulemaking, enhanced oversight or promotional activities to influence product/service provider behavior to reduce loss of control events. The product/service provider will in turn deploy its SRM to address unique hazards associated with loss of control particular to their product or service. Measuring performance of the SRM functions in conjunction with a reduction of loss of control events provides rationale that the safety management processes are indeed resulting in a reduction of the accident rate.

1.2.2 Safety Performance Indicator Framework

The Safety Performance Measurement Matrix in Figure 3 provides a top-level concept for safety performance measurement. Figure 4 represents an expansion of the second column of the Safety Performance Measurement Matrix (Figure 3) to guide actual indicator development.

	A: Indicator usage	B: Outcome Indicators	C: Process Indicators	D: Inter-tier correlation
Tier 1 INTEGRATED CIVIL AVIATION SYSTEM	Public information/ long-term trending, identification of significant safety issues	• Accident rates, incident rates, Fatalities, etc. • Breakdown of Event rates for significant safety issues	Σ Safety Management capability • Identifying common cause hazards • Establishment of regulatory risk controls	N/A
Tier 2 PRODUCT SERVICE PROVIDER PERFORMANCE	Risk mitigation by product/ service provider and regulator "most wanted issues"	Per category of product/service provider • Outcomes related to significant safety issues	SMS performance • SRM compliance with regulatory specifications • Ability to identify unique cause threats • Risk control actions	Influence of product/service provider activities on safety outcomes
Tier 3 REGULATOR PERFORMANCE (ACTIVITIES)	Safety Risk Management (SRM) by regulator	• Activities and initiatives to address specific risk areas • Effectiveness of risk controls (correlation with Service Provider behaviors and aggregate outcomes) • Effectiveness of risk control application (oversight of system performance) ◦ Design Assurance ◦ Performance Assurance	Safety risk management capability • Ability to identify common cause threats • Ability to develop risk controls • Resource allocation	• Influence of regulatory activities on product/service provider behaviors • Influence of regulator activities on safety outcomes

Figure 4 - Safety Performance Indicator Framework

The Indicator Framework is organized into the same three tiers used in the measurement matrix depicted in Figure 3. Each level of the proposed framework is divided into two related dimensions—outcomes and processes (columns B and C). Column D represents correlations between tiers of the model. Validity of the measures at tiers two and three is based upon the correlation with the next tier above it. For example, the validity of measures of oversight activities is based upon the relationship between the measured oversight activities and their influence on service provider behaviors and outcomes.

Tier 1 outcome measures come in two varieties—overall event rates (e.g. accident rates, hull loss rates) and event rates related to significant safety issues. The main distinction between these event rates is level of detail. Overall event rates are the highest level metrics used in the system. Event rates related to significant safety issues are typically lower level metrics specifically focused on measuring the effectiveness of mitigations/controls established to address identified significant safety issues. In any case, event types in Tier 1 are those associated with common cause hazards – those hazards to which all or large segments of the product/service provider community are exposed.

Tier 2 safety performance indicators address the behavior of aviation service systems whose performance relates to safety outcomes. At Tier 2, a set of safety outcomes should be identified for tracking. These should start with the significant safety issues identified for Tier 1 representing an association with common cause hazards. This set of outcomes should also include measures related to hazards that are unique to the product/service provider.

Compliance with regulations (AVS's specifications for control of hazards common to the product/service provider's population) is part of the process of risk management. Therefore, measurement of compliance should also include measures of how well the service provider has used its SRM process to incorporate relevant regulations into their processes and product design. Product/service providers should also develop measures for hazards that are unique to their operational environments.

Tier 3 indicators are process and outcome measures to gauge the safety interventions and initiatives of the regulator. Effective regulator activities should motivate and facilitate product/service provider behaviors that, in the aggregate, result in overall improvements in safety outcomes. Tier 3 indicators will in many cases be linked directly to Tier 2 indicators as the latter are required to measure how effectively regulator activities and behaviors have addressed key safety issues identified. The ability to influence future performance is an important characteristic of both Tier 2 and Tier 3 indicators.

At Tier 1, regulator activities must be based upon influencing the behaviors of product and service providers. Regulator action at Tier 1 considers the entire aerospace system or major system components or domains. Thus, this responsibility entails management of common cause hazards. Accountability for identifying and designing risk controls for these common cause hazards rests primarily with the regulator. Effectiveness of the regulator's accomplishment of this responsibility is, therefore, a matter of evaluating these functions and are critical to AVS safety performance.

1.3 Scope

The concept described above provides the context through which safety performance management will be developed and applied by AVS. The safety performance management process will be used at the corporate AVS-level to develop an aggregate view of safety in the components of the aerospace system for which AVS has oversight responsibility (Tier 1 in the model). Further, AVS Services and Offices with oversight responsibility, i.e., Flight Standards (AFS), Aircraft Certification (AIR), Aerospace Medicine (AAM), and Air Traffic Safety Oversight (AOV), apply safety performance management to measure safety within the components of the aerospace system for which they have oversight responsibility (in Tier 3 with the objective of influencing Tier 2) and contribute to the aggregate AVS-level (at Tier 1). Accident Investigation and Prevention (AVP) will have the primary responsibility for aggregation of safety performance measures and developing the system-view. The safety performance management process is applicable to any AVS organization that directly influences (or regulates) industry behaviors to manage risk.

The Safety Performance Design Team was established to develop processes and an implementation plan to incorporate safety performance management into AVS. Throughout the development, processes for measuring and monitoring safety performance at the AVS-level and within the domains of AVS Services/Offices will be prototyped and tested. Just as the Safety Management System (SMS) has a focus on continuous improvement, so too will safety performance measurement processes. In addition, as we learn more about safety performance measurement through testing, we may re-scope the application of the processes.

1.4 Requirements

The primary design requirements for safety performance management are specified in FAA Orders VS 8000.367A, *Aviation Safety (AVS) Safety Management System Requirements* and VS 8000.370A, *Aviation Safety (AVS) Safety Policy*. These requirements are summarized in Table 1

Table 1 - Design Requirements

Design Requirement	Reference
FAA Order VS 8000.367A, Aviation Safety (AVS) Safety Management System Requirements	
AVS and AVS services/offices must establish and document organizational safety objectives that are measurable	Chapter 3 Section 2.a
AVS and AVS services/offices must monitor those safety objectives and accompanying metrics to ensure that the safety objectives are being met	Chapter 3 Section 2.a
AVS and AVS services/offices must develop and maintain plans to meet national and organizational safety objectives	Chapter 3 Section 2.c
AVS services/offices must monitor their systems to measure the effectiveness of safety risk controls	Chapter 4 Section 1.b.3
AVS services/offices must monitor their systems to: Assess the safety performance of AVS and enable continuous improvement	Chapter 4 Section 1.b.5
AVS and AVS services/offices must perform system assessments to determine whether organizational safety objectives have been met	Chapter 4 Section 2.c.1
The AVS Management Team must conduct regular reviews of AVS to assess the safety performance of AVS	Chapter 4 Section 2.a.1
Management reviews must include assessing the need for changes to the AVSSMS	Chapter 4 Section 3.a.3
FAA Order VS 8000.370A, Aviation Safety (AVS) Safety Policy	
Service and Office Directors are held accountable by AVS-1 to: implement, operate, integrate, and continually improve the AVSSMS	Section 7.b.(1)
AVS uses the AVSSMS to continually improve the level of safety performance throughout the aerospace system	Section 6.c
AVS Services and Offices with safety oversight responsibility must: Set annual safety objectives using FAA strategic planning and business planning processes	Section 14.a

Design Requirement	Reference
AVS Services and Offices with safety oversight responsibility must: Establish measurable safety performance targets, with an emphasis on quantitative data over qualitative information.	Section 14.a
AVS Services and Offices with safety oversight responsibility must: Document safety objectives and safety performance targets in FAA strategic plans (e.g., Destination 2025), the AVS Business Plan, and the individual Service or Office Business Plans. To the extent possible, AVS links individual employee performance plans to the organization's safety objectives and performance targets.	Section 14.c
At a minimum, the AVSMT must assess its safety performance, relative to its safety performance targets, on a quarterly basis.	Section 15.a
At a minimum, individual Service and Office Directors must assess their Service or Office safety performance, relative to its safety performance targets, each month.	Section 15.b

(Note: *Some* of these design requirements will be satisfied through the safety performance management process. Others inform the *how* the safety performance management process will be designed. Both types of requirements have been included to assure that the Order requirements will be met.)

The Safety Performance Design Team established the following additional design requirements to guide its development:

- Results from the safety performance measurement processes should inform business planning activities and establishment of strategic objectives, as well as support management decision-making and resource allocation.
- Safety performance measurement processes developed in AVS will align with the safety performance measurement materials developed by the SM ICG to the greatest extent that is practical.
- Safety performance measurement processes will not rely on information technology (IT) for initial introduction into AVS. The extent to which IT systems can support safety performance measurement processes will be determined after the business processes have been developed, tested, and put into operations.

The design requirements will be used to guide the development of safety performance measurement processes and validate that they meet the intent of AVS policy. These design requirements may be modified as a result of learning during process development. Finally, it is important to note that SM ICG safety performance materials have been drafted, but not finalized. Once they are finalized, this document may need to be modified in order to better align with the final product.

1.5 Assumptions

The Safety Performance Design Team made the following assumptions when establishing its workplan:

- An AVS-level SRM process will be developed as identified in the *AVSEMS Implementation Plan*, which will standardize application of SRM across AVS. It will include:
  - Standard methodologies for comparing risk across AVS,
  - Risk acceptance processes,
  - Development of risk controls, and

  - Requirements for AVS Services/Offices to monitor risk controls to ensure their effectiveness.
- There will be AVS-level processes, as well as processes used with AVS Services/Offices for safety performance measurement.
- Organizational changes might be possible to support safety performance management. For instance, establishing a dedicated group responsible for managing/operating safety performance measurement processes might be the most effective and efficient way to accomplish the objectives.
- AVS management is committed to safety performance management and will expend resources to develop and apply safety performance management processes. Safety performance management will entail performing different activities, which will likely require some number of AVS personnel shifting their time and focus. Further, outcomes of these processes will likely impact how management applies resources. It is assumed that management will support this allocation of resources.
- Necessary skills to identify effective and actionable ways of measuring safety performance exist in AVS. If enhanced competencies are required to implement safety performance measurement processes, they will be defined and included in the safety performance management implementation plan.

2 Framework to Measure Safety Performance in AVS

2.1 Overview

Safety performance management is an essential characteristic of *Safety Assurance* in AVSSMS. Safety Assurance is one of the four components of the SMS that enable the FAA to manage safety within the aerospace system. Safety Assurance includes processes to determine the effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information.

It is important to understand how SRM and Safety Assurance work together to understand the context in which Safety Performance is managed. The SRM process provides a system analysis, the identification of hazards, and the analysis and assessment of safety risk. As a result, safety risk controls are developed and, once they are determined to be practicable in reducing safety risk to an acceptable level, these controls are employed operationally. Safety Assurance is used to ensure that safety risk control strategies are in place, assess whether they are achieving their intended safety risk reduction objectives, and monitor for unintended consequences. If the controls are not adequately reducing safety risk, they are modified and/or additional safety risk controls are developed through SRM. This is one way SRM and Safety Assurance are integrated.

Another way these functions work together is through the identification of potential new hazards or ineffective controls through Safety Assurance measures, which are then analyzed and assessed using SRM. Figure 5 depicts the SRM and Safety Assurance processes and their relationship to one another. It shows the most obvious and frequent interactions between the SMS components of Safety Assurance and SRM. There are three basic findings in the system assessment within Safety Assurance:

- In conformance with requirements.
- Not in conformance with requirements.
- Identification of a new hazard or ineffective control.

When a new hazard or ineffective control is identified, the SRM process is used to further investigate. When a non-conformance to requirements is found, correction or corrective action is typically taken. Management is involved in both SRM and Safety Assurance. In SRM, risk controls are approved and risk is accepted by management. In Safety Assurance, management establishes expectations and allocates resources for further activity based on reviews of insufficient risk control or when non-conformities are found.

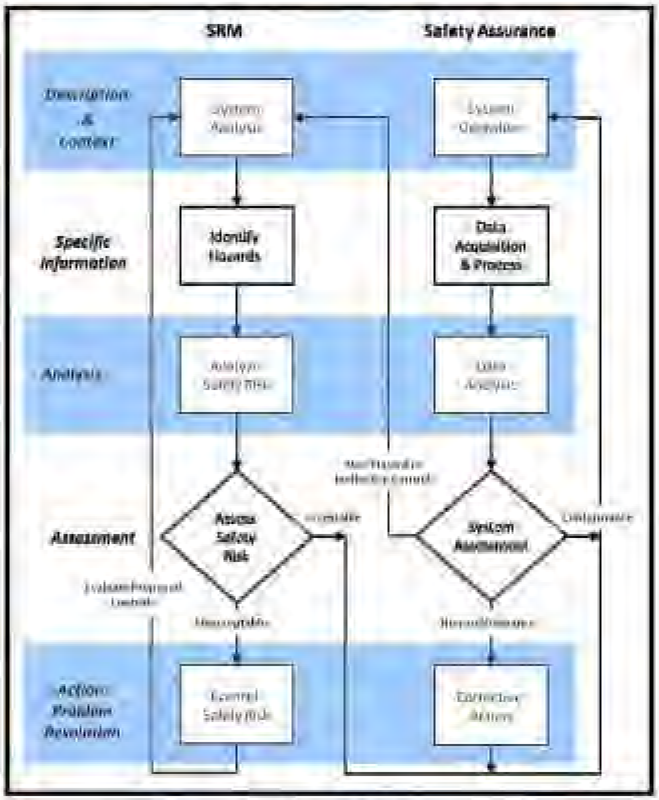
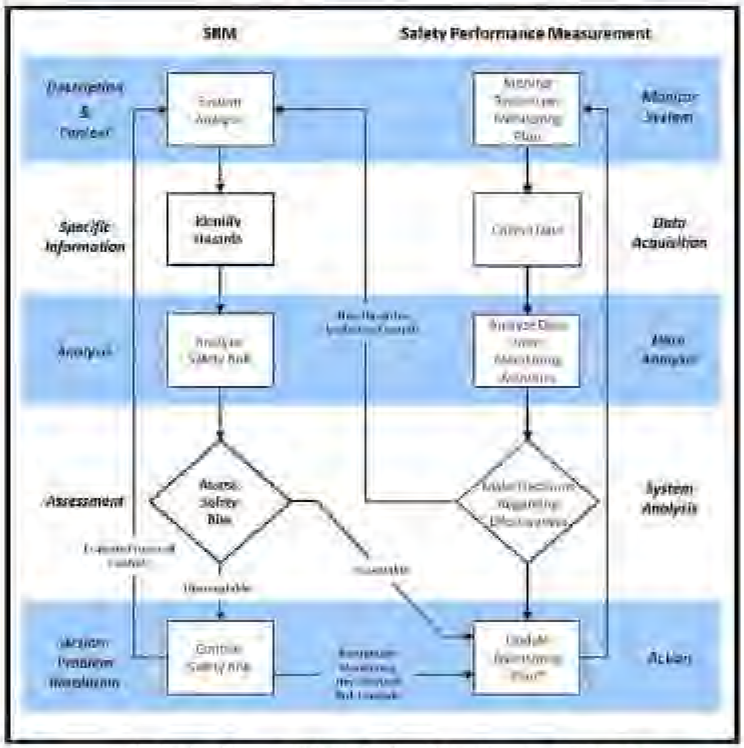


Figure 5 - SRM and Safety Assurance

2.2 Framework

As stated earlier, safety performance management is an essential characteristic of Safety Assurance in AVSSMS. As such it must interface with SRM. Figure 6 illustrates safety performance measurement and how it will work with SRM in safety performance management.



* The first time through the process, will establish the initial monitoring plan in this step.

Figure 6 – SRM and Safety Performance Measurement

The sections below will identify the objectives and provide a description of each step. Please note that this framework is intended to provide the high-level picture of safety performance management in AVS. As the Safety Performance Design Team develops supporting details, these details will be documented in subsequent products. For more information regarding the

Safety Performance Design Team activities and the strategy for development and implementation of safety performance management in AVS, please see Section 3.

Before jumping into a review of the process, it is important to understand the difference between *monitoring* and *measurement*. *Monitoring* is observing the operation of a machine or system typically for the purpose of detecting and correcting problems. Monitoring is done on a continuum with a range of monitoring robustness levels. Robustness driven by various factors such as risk. More robust monitoring uses measurement. This is illustrated in Figure 7.

Figure 7 - Monitoring Continuum

Measurement is an observation or set of observations that reduces uncertainty with quantitatively expressed results. Please note that measurement can be resource-intensive and should be done only when appropriate.

2.2.1 Monitor System

The objective of monitoring the system is to maintain situational awareness regarding the operations and the safety performance of the system. At the AVS-level, the system that is monitored is the components of the aerospace system for which AVS has oversight responsibility. AVS Services/Offices monitor the components of the aerospace system for which they individually have oversight responsibility. Divisions within AVS Services/Offices will do the same. The breakdown continues to the level that is appropriate in order to manage safety performance.

The first step to monitoring is determining the areas to monitor. It is not possible to monitor everything all of the time, so organizations must determine the appropriate areas to monitor. SRM is used to determine what areas are monitored. At the corporate AVS-level, these areas will be identified as *Significant Safety Issues*. The next product that the Safety Performance Design Team will develop is a process to identify the *Significant Safety Issues*. These *Significant Safety Issues* will have direct line of sight with high-level safety goals and objectives identified in existing documents such as *Destination 2025*. The *Significant Safety Issues* will also likely be an aggregation or consolidation of the lower level areas identified by AVS Services/Offices.

AVS Services/Offices will also identify the areas to monitor within the component of the aerospace system for which they have oversight responsibility. The Safety Performance Design Team will develop materials to ensure that these areas are identified in a consistent repeatable manner. Again, these areas should be based on the outputs of SRM within the applicable component of the aerospace system. SRM could be conducted by AVS organizations or product/service provider organizations. Either way, the outputs of SRM will include plans to monitor the effectiveness of the resultant safety risk controls. These plans become the basis for the monitoring plans identified in the safety performance measurement process illustrated in Figure 6. When risk is determined to be acceptable in SRM, the Monitoring Plans may be updated to remove or change what is monitored.

Monitoring plans will include indicators as described in Figure 4, Safety Performance Indicator Framework. The structure of individual monitoring plans describe the relationship to the Tier 1 Integrated Civil Aviation System Level, the desired behaviors of the product/service provider at Tier 2 and the activities that AVS will undertake to influence the behavior of product/service providers. Appropriate safety performance targets will be established to assist in the System Analysis step. Safety performance targets are typically a predetermined risk reduction objective that brings risk within acceptable levels.
The first time through the process, the initial monitoring plan is developed in the *Update Monitoring Plan* step/box. While this is a little confusing, it is important to start with SRM to create and then update the monitoring plans based on the outputs for SRM.

Monitoring plans will be developed at the AVS-level and within the Services/Offices. These plans must take into account existing data sources from within and outside of the FAA. Monitoring plans must also ensure that the requirements in FAA Order VS 8000.370A regarding the periodicity for reviewing safety performance targets are met. Management must assess safety performance relative to safety performance targets at least quarterly at the AVS-level and at least monthly within AVS Services/Offices.

2.2.2 Data Acquisition

The monitoring plan identifies the data to monitor. At the AVS-level, the data may be an aggregate of data collected at a lower-level and tools such as the Aviation Safety Information Analysis and Sharing (ASIAS) System will be leveraged. Similarly, within AVS Services/Offices there are many data sources and tools that will be leveraged to collect the data necessary to implement the monitoring plan.

2.2.3 Data Analysis

In the next step, data is analyzed and turned into information such that decisions can be made in the following step. Data analysis is not an automated (IT-based) activity. It requires an individual or individuals conducting the analysis and putting it in a format and structure that is understandable and manageable by decision-makers. This information must be presented in a consistent format. Therefore, part of the safety performance process development effort will be the establishment of consistent methodologies for presenting information to decision-makers.

2.2.4 System Analysis

In this step, decisions are made regarding the effectiveness of safety management activities at the AVS-level and within AVS Services/Offices. Specifically, determinations are made regarding whether the safety performance targets are being met. If safety performance targets are met, it is presumed that safety risk controls are effective and are having the desired effect.

If safety performance targets are not met, additional analyses are necessary to determine if a potential new hazard exists and/or if there are ineffective controls. If potential new hazards exist and/or if there are ineffective controls, SRM is applied to identify additional actions necessary.

2.2.5 Action

There are basically two paths in this step. First, if it was determined that there are potential new hazards and/or if there are ineffective controls and SRM was conducted, the monitoring plan is updated to take into account this change. The other, more positive path is that the performance targets were met in the step above, and a decision is made regarding whether the monitoring plan should be updated as a result. For instance, at the AVS-level, the AVS Management Team (AVSMT) may decide to change the *Significant Safety Issues* to move an issue off the list in favor of a safety issue that has become a higher concern.

The important characteristic of this step and the whole process, in general, is that safety performance management is a dynamic activity. System changes, whether planned or unplanned may result in changes to what is monitored and measured. The focus is on continuous improvement to continually drive risk out of the aerospace system.

3 Development and Implementation

3.1 Overview

The *AVSSMS Implementation Plan* describes the high-level plan for establishment of safety performance management in AVS. FAA has many documents that list safety objectives and describe strategies for achieving its objectives (e.g., *Destination 2025*, Next Generation Air Transportation System (NextGen) goals and performance measures, Business Plans at various levels). However, these do not fully meet the needs for AVSSMS to determine how effective AVS is in managing safety. Safety performance measurement should encapsulate national and organizational safety objectives and should be considered in the acceptance of safety risk in the aerospace system components that AVS Services/Offices oversee.

Therefore, AVS established the Safety Performance Design Team to develop a process and measures for measuring safety performance in the aerospace system. Please note that this team is called the *Safety Performance Team* in the *AVSSMS Implementation Plan*. Understanding the safety performance of the aerospace system, will allow AVS to enhance its management of safety. The Safety Performance Design Team will develop processes that support management decision making and facilitate change within AVS and industry. The team is starting with the development of this document, which builds on the SM ICG's work. By using the work done by the SM ICG, safety performance across AVS will align with safety performance in other Civil Aviation Authorities (CAAs) and their State Safety Programs (SSPs).

The next product the team will develop is a process to identify *Significant Safety Issues* (called *Significant Risk Areas* in the *AVSSMS Implementation Plan*). *Significant Safety Issues* describe the hazards or events that are expected to have a considerable impact on the accident rate and are therefore candidates for measurement. The team, working with stakeholder Services/Offices and industry, will use the process it developed to conduct system-level assessments to specifically identify the *Significant Safety Issues* in the aerospace system. The team will then decompose these safety issues to establish safety performance indicators for the *Significant Safety Issues*. The safety performance indicators will consider both outcome and process measures as described in Figure 4. These safety performance indicators will include indicators for the FAA, as well as the affected product/service provider organizations.

The Safety Performance Design Team will work with Services/Offices to establish measures for the effectiveness of their safety management processes. While AVS Services/Offices may have or are developing Service-level safety objectives and measures, it is important that they are coordinated and consistent. Therefore, AVS Services/Offices will work with the Safety Performance Design Team to ensure alignment of safety process and performance measures. The team will also make sure that the measures focus on the measurement of the effectiveness of these processes (e.g., the positive affect the processes have on safety performance). Service/Office-level safety measures must also support the higher-level aerospace system-level safety objectives, including those described in *Destination 2025*. With the measures in place, AVS can implement the necessary processes to measure safety. These measures must also be communicated to management and used to determine the need for system changes.

The final activity for the Safety Performance Design Team will be to develop an implementation plan for AVS to fully incorporate safety performance management processes. The Safety Performance Design Team will also facilitate implementation of this plan within AVS. These activities are summarized in the table below.

Table 2 - Development Activities

Safety Performance Design Team Activity	Due Date
Establish Strategy and Framework to Measure Safety Performance in AVS	June 30, 2013
Develop Process to Identify *Significant Safety Issues*	December 31, 2013
Determine *Significant Safety Issues* and Establish Safety Performance Indicators	June 30, 2014
Establish Measures to Determine Effectiveness of Safety Management Processes	December 31, 2014
Develop Implementation Plan to Incorporate Safety Performance Measurement in AVS	June 30, 2015

3.2 Strategy

It is expected that aspects of the safety performance measurement system will be implemented in phases or stages. As elements are developed, they will be tested and prototyped. Based on lesson learned from this testing, they will be refined and more broadly applied. Implementation of processes will be iterative and evolve while adhering to the general outline and timeline described above (and in the *AVSSMS Implementation Plan*).

Full implementation, which will lead to continual improvement (Phase 4, as described in the *AVSSMS Implementation Plan*), is expected in 2016. The implementation plan to incorporate safety performance measurement in AVS will establish more specific activities, milestones, and due dates for full implementation.

Appendix E

EASA

Embodiment of Level of Involvement (LOI) and

Safety Management System (SMS) Requirements

into Part 21

European Aviation Safety Agency — Rulemaking Directorate

Terms of Reference

for a rulemaking task

Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21

RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 project) — Issue 1 — 27/09/2013

Applicability		Process map	
Affected regulations and decisions:	Commission Regulation (EU) No 748/2012 and its Annex I (Part 21), ED Decision 2012/020/R (AMC & GM to Part 21)	Rulemaking lead:	R4
		Concept Paper:	Yes
		Rulemaking group:	No*
		Review group:	No*
Affected stakeholders:	Applicants for EASA Part-21 design approvals, Part-21 Design and Production organisations, NAAs of EU Member States performing POA oversight	**RMT.0262 — LOI NPA 1 (IR):**	
		RIA type:	Light
		Technical consultation during NPA 1 drafting:	Yes
		Publication date of NPA 1 (IR):	2013/Q?
		Duration of NPA 1 consultation:	3 months
Driver/origin:	Legal obligation	Focused consultation:	Yes
Reference:		Publication date of the Opinion:	2014/Q2
		RMT.0611 — LOI NPA 2 (AMC/GM):	
		RIA type:	Light
		Technical consultation during NPA 2 drafting:	Yes
		Publication date of NPA 2:	2014/Q2
		Duration of NPA 2 consultation:	3 months
		Focused consultation:	Yes
		Publication date of the Decision:	2015/Q2
		RMT.0550 & RMT.0612 — SMS NPA (IR + AMC/GM):	
		RIA type:	Full
		Technical consultation during NPA 3 drafting:	Yes
		Publication date of NPA 3:	2014/Q4
		Duration of NPA 3 consultation:	3 Months
		Focused consultation:	Yes
		Publication date of the Opinion:	2015/Q4
		Publication date of the Decision:	2016/Q4
		* NOTE: While the working method is formally 'Agency', the Agency will be supported by two groups (for LOI and SMS) with industry/NAA representatives to steer and monitor a set of pilot projects to test the concepts.	

[illegible]

1. Issue and reasoning for regulatory change

In order to further improve the already good safety records of the civil aviation industry ICAO developed and adopted between 2001 and 2009 in a number of ICAO Annexes the concept of 'Safety Management' (SM). These new SM provisions require implementation of a State Safety Programme (SSP) by the Contracting States and a Safety Management System (SMS) by aviation industry organisations (service providers). As part of its SSP, each State shall require that service providers under its authority implement an SMS in their organisation.

On 25 February 2013, ICAO adopted a new Annex for 'Safety Management' (Annex 19, Edition 1). Annex 19 consolidates all the general SSP and SMS provisions currently spread across Annexes 1, 6, 8, 11, 13 and 14. Annex 19 has adopted the frameworks for SSP and SMS which are generally applicable to all aviation domains, including the domain of Annex 8 'Airworthiness of aircraft'. Annex 19 will become applicable in all aviation domains on 14 November 2013. EU MS will be requested to notify ICAO of any differences that will exist on 14 November 2013 between their national regulations or practices and the provisions of the Standards in Annex 19. Such notifications are to be made before 14 October 2013, and, thereafter, the States shall notify ICAO of any further differences that arise.

To reflect these ICAO developments and in line with the generally accepted EASA principle of Total System Approach, the Agency is in the process of implementing, in a modified form, the ICAO provisions for Safety Management in all the aviation domains within the scope of the Regulation (EC) 216/2008[1] (hereinafter referred to as the 'Basic Regulation'). It is an obligation that stems from the provision of the Basic Regulation which requests to ensure that the provisions of the ICAO Chicago Convention and its Annexes are duly taken into account (ref. Article 2(2)(d)). In addition, the Basic Regulation in its essential requirements for airworthiness, pilot licensing, air operations, ATM/ANS, and aerodromes (see the annexes to the Basic Regulation) requires aviation organisations to implement and maintain a Management System relating to safety, and aim for continuous improvement of this system. The Agency has, recognising its potential for safety improvement, endorsed the Safety Management concept and is actively introducing it across all the aviation domains. Related actions were introduced into the European Aviation Safety Plan (EASp) in order to support the Member States to implement their SSPs and foster implementation of SMS by industry.

The domain of initial airworthiness is the last domain for which rulemaking for the implementation of the Safety Management provisions has to be launched, and EASA Part-21 implementing rules have to be amended accordingly. Related rulemaking tasks RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (formerly all under the MDM.060 project) are part of the EASA 2014-2017 Rulemaking Programme to address the EASp actions SYS1.3a and SYS 2.2a.

2. Objectives

The principal objective of this rulemaking project is to ensure a full compliance of Part-21 with the framework of Safety Management provisions of ICAO Annex 19. This means to check the existing Part-21 rules and add, as necessary, the missing Safety Management provisions so that the Design & Manufacturing (D & M) organisations approved under EASA Part-21 are ICAO SMS compliant, and the competent authorities granting them approvals and performing their continuing oversight are supported with the regulatory provisions to meet their ICAO SSP obligations.

[1] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1). Regulation as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

Closely linked with the above objective related to Part-21 organisations and their approvals is the objective of implementation of performance-based oversight in product certification. This means introduction in Part-21 of a risk-based approach and setting clear criteria for the determination of the Level of Involvement (LOI) of the Agency when it verifies the applicant's demonstrations of compliance of the product with the applicable type certification basis.

The ultimate objective is to further improve the safety performance in the field of initial airworthiness, among others, through:

- systematic risk management (hazard identification, risk assessment and mitigation);
- safety performance measurement of the management system in support of its continuous improvement;
- safety performance-based oversight allowing to focus on areas of greater risk;
- safety awareness and promotion among all staff involved; and
- improved effectiveness and efficiency of Part-21 implementing rules achieved by their streamlining and improved consistency.

Besides the objective of improved safety for D & M organisations and the competent authorities, the other objective is to reduce, in the long term, the cost of the product certification processes and the cost of maintaining the Part-21 organisation approvals.

3. Activities

In the course of the project conduct, the following activities are envisaged:

- Set up steering groups with stakeholders tasked to select, launch, and monitor a number of pilot projects to test the LOI and SMS concepts, and get experience to support the Agency in its related rulemaking activity for Part-21 and AMC/GM material;
- Conduct a thorough gap analysis between the existing Part-21 implementing rules and ICAO Annex 19 SM framework to identify those SM elements currently missing in Part-21. In completion of this action, take into account the EASA SM model framework as implemented (or going to be implemented) in other domains, in particular Air Crew/Air Operations and Continuing Airworthiness (task RMT.0251 (MDM.055));
- Evaluate and improve as much as possible and without resulting excessive administrative cost the overall consistency of Part-21 organisation approvals; take into consideration the recommendations of Advance-NPA 15-2006 and related CRD on 'Consistency of Organisation Approvals' (COrA);
- Evaluate and, if practicable, improve Part-21 implementing rules to better reflect the EASA generally accepted principle of performance-based rulemaking with rules focussed on safety objectives, leaving prescriptive implementation means and interpretations to the AMC/GM level;
- Introduce into Part-21 Human Factors as adapted from the other aviation domains to fit D & M organisations;
- Draft amendments (NPAs) to Part-21 rules and related AMC/GM material to implement the LOI and SMS concepts while providing flexibility, by means of application of the

concept of Alternative Means of Compliance (AltMoC), and proportionality, by means of AMCs/GMs tailored to complex and non-complex D & M entities; and

— Develop Regulatory Impact Assessments (RIA) for LOI and SMS implementation.

Due account should be taken of the experience gained from SMS implementation in the other aviation domains as well as the lessons learned from the previous Agency's attempts to implement LOI and SMS in the domain of initial airworthiness.

4. Deliverables

— **NPA 1** with draft amendments to Part 21 rules to implement LOI;

— **NPA 2** with draft amendments to AMC/GM to Part-21 to support implementation of LOI;

— **NPA 3** with draft amendments to Part-21 rules and AMC/GM to Part-21 to support implementation of SMS;

— **Opinion 1 + CRD** with resulting draft amendments to Part 21 rules to implement LOI;

— **ED Decision 1** with amendments to AMC/GM to Part-21 to support implementation of LOI;

— **Opinion 2 + CRD** with resulting draft amendments to Part-21 rules to implement SMS; and

— **ED Decision 2** with amendments to AMC/GM to Part-21 to support implementation of SMS.

5. Interface issues

— Interface with the other EASA Safety Management related activities, namely with rulemaking under RMT.0251 (MDM.055) task to embody Safety Management System (SMS) requirements into Regulation (EC) No 2042/2003 with the purpose to ensure consistency in principles and frameworks of the SM implementation in both domains; and

— Interface with the international and national Safety Management related activities (ICAO Safety Management Panel (SMP), ICAO Airworthiness Panel (AIRP), Safety Management International Collaboration Group (SM ICG), FAA 21/SMS Aviation Rulemaking Committee (ARC) project etc.) in order to assure equivalency of EASA Part-21 SM concept implementation with corresponding concepts of non-EASA ICAO Contracting States to facilitate mutual understanding and support mutual recognition of related organisation approvals.

6. Focussed consultations

— Consult RAG/TAG and D & M SSCC advisory bodies (meetings and/or written consultations).

— Hold technical workshops as felt appropriate.

7. Profile and contribution of the rulemaking group

As explained above, RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 are 'Agency' tasks so formal rulemaking groups will not be set up. However, the Agency will ensure proper stakeholder's involvement by other, more flexible means using pilot projects (one set for

LOI and one set for SMS) monitored by their dedicated steering groups composed of the involved Agency staff and representatives of stakeholders (D & M organisations and NAAs).

The profile of these pilot projects and participating D & M organisations will ideally include fields as follows:

- CS-25 aeroplane (TC/significant/major change project);
- CS-23/VLA/LSA aeroplane (TC/ significant/major change project);
- Engine (TC/ significant/ major change project);
- Rotorcraft (TC/ significant/ major change project);
- Non-TC holder major change (STC project);
- Part or Appliance project.

8. Annex I: Reference documents

8.1. Affected regulations

Commission Regulation (EU) No 748/2012 and its Annex 1 (Part-21)

8.2. Affected decisions

AMC & GM to Part-21 (ED Decision 2012/020/R)

8.3. Reference documents

- EASA Concept Paper 'Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21' (RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 PROJECT));
- ICAO Annex 19;
- ICAO Annex 8;
- ICAO Doc 9859 (Safety Management Manual);
- ICAO Doc 9734 (Safety Oversight Manual);
- ICAO Doc 9760 (Airworthiness Manual);
- Annex III (Part-ORO) to Commission Regulation (EU) No 965/2012 of 28 October 2012 and ED Decision 2012/017/R;
- Annex II (Part-ARO) to Commission Regulation (EU) No 965/2012 of 28 October 2012 and ED Decision 2012/016/R;
- Annex VI (Part-ARA) to Commission Regulation (EU) No 290/2012 of 30 March 2012 and
  ED Decision 2012/006/R;
- Annex VII (Part-ORA) to Commission Regulation (EU) No 290/2012 of 30 March 2012 and ED Decision 2012/007/R;
- Commission Regulation (EC) No 2042/2003 of 20 November 2003 and its Annexes I & II (Part-M, Part-145);
- NPA 2013-01 (A, B, C) Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003;

- Advance NPA 15-2006 and related CRD on 'Consistency of Organisation Approvals' (COrA);
- FAA Part 5;
- FAA Part 21; and
- Guidance documents of the Safety Management International Collaboration Group (SM ICG).

European Aviation Safety Agency RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060)

European Aviation Safety Agency

Annex to ToR RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 PROJECT)

CONCEPT PAPER

Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21

EXECUTIVE SUMMARY

This Concept Paper presents a top-down, systemic approach to the issues related to the adaptation of the implementing rules for initial airworthiness in order to comply with the Safety Management principles introduced by ICAO Annex 19. It deals with two closely related topics – Level of Involvement (rulemaking tasks RMT.0262 & RMT.0611) and Safety Management System (rulemaking tasks RMT.0550 & RMT.0612). The tasks aim at amending Commission Regulation (EU) No 748/2012 and its Annex I (Part-21), as well as related AMC & GMs in order to add the missing, ICAO compliant Safety Management provisions for applicants for EASA design approvals as well as applicants/holders of Part-21 organisation approvals. The tasks have been classified as complex. Both tasks, formally separated, are seen as parts of one project which aims at:

(A) introducing a risk-based approach to determine Level of Involvement (LoI) of the Agency in product certification, and

(B) reviewing Part-21 to check its compliance with the Safety Management provisions of ICAO Annex 19 and add, as necessary, the requirements for Design & Manufacturing (D & M) organisations related to the Safety Management System (SMS), as well as requirements for competent authorities granting them approvals and performing their continuing oversight to support their State Safety Programme (SSP).

The key elements of the ICAO Safety Management concept which are new to Part-21 regulation are:

- safety risk management (hazard identification, risk assessment and mitigation);
- safety performance measurement and continuous improvement;
- performance-based oversight; and
- safety promotion.

Implementation of Safety Management principles in product certification and D & M organisations has a potential to bring significant safety and cost benefits to both D & M organisations and competent authorities due to better allocation and use of resources and rigorous universal application of a proactive/predictive approach to safety allowing focus on safety critical issues. It will also help maintain a level playing field with competitors since the ICAO Safety Management principles are going to be implemented worldwide in all aviation domains. However, Safety Management implementation will certainly require investment from stakeholders.

The domain of initial airworthiness is the last domain within the scope of Regulation (EC) 216/2008 (hereinafter referred to as the 'Basic Regulation'[1]) where the compatibility of existing implementing rules with the Safety Management principles laid down in Annex 19 still needs to be assessed and full compliance needs to be established, as needed.

This Concept Paper is intended to facilitate discussion, among all parties involved, in order to find the best way forward.

[1] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1). Regulation as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

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1. Identification of the issue

The Agency is in the process of implementing the ICAO provisions for 'Safety Management' (SM) in all the aviation domains within the scope of the Basic Regulation. This stems from the provision in the Basic Regulation related to the Chicago Convention (and its Annexes) which requests to ensure that '... its provisions are duly taken into account in this Regulation and in the rules drawn up for its implementation' (Article 2 (2) (d)).

The ICAO 'Safety Management' (SM) concept, which was introduced in the past years in several Annexes to the Chicago Convention, consists of two main components – the State Safety Programme (SSP) with safety management responsibilities of Contracting States, and Safety Management System (SMS) to be implemented by specified aviation service or product providers in support of the safe operation of aircraft.

Based on the ICAO SSP/SMS frameworks, the Agency has developed its own EASA SM framework which is the adaptation of the ICAO frameworks to fit the specific needs of EU/EASA rules and EU legal environment. The implementation of the EASA SM framework has been completed in the domains of Air Crew and Air Operations. These two domains are fully ICAO compliant[1]. The process has been completed for the domain of ATM/ANS, but additional rulemaking effort will be needed to bring this domain into full compliance with the ICAO SM provisions in Annex 19. The rulemaking process has been launched and is in various levels of progress in the domains of Aerodromes and Continuing Airworthiness.

Initial airworthiness is the last remaining domain in which SM implementation has to be evaluated for compliance with ICAO Annex 19. Certain rulemaking attempts were made in the past but they were unsuccessful (details below). The main issue and objective of this remaining rulemaking task is, therefore, to amend Commission Regulation (EU) No 748/2012 and its Annex I – Part-21 in order to introduce therein the ICAO compliant EASA SM framework.

This rulemaking activity will build on the results achieved and experience gained from the SM implementations in the other domains, in particular the domains of Continuing Airworthiness, Air Crew and Air Operations. The EASA SM framework developed and adopted there will be considered as a model for SM implementation in the field of Initial Airworthiness.

However, its implementation in this domain will require adaptations to fit the specific needs of Part-21. Many organisations already hold a Design Organisation Approval (DOA) and/or a Production Organisation Approval (POA) issued under Part-21. These organisations have already embedded a number of the SM principles, as required by Part-21, and this approach has resulted in a good safety record from these organisations. It is, therefore, important that the introduction of the full SM principles does not detract from the current effective framework or result in unnecessary costs for no safety benefit. Previous attempts to change the current Part-21 system proved difficult due to misunderstandings and resulting opposition on the side of both stakeholders and some of the Agency staff involved. Therefore, we considered useful to describe and explain now, before the rulemaking starts, all the main issues and their possible solutions. Then the subsequent rulemaking activity needs to be embedded into a well-managed change management process to support a smooth SM full implementation. The main

[1] Since EU is not an ICAO Contracting State, the Agency can neither prepare on behalf of the EU MS a common EU State Safety Programme (SSP), nor can it mandate [illegible]. The MS are accountable to ICAO [illegible] EU/EASA [illegible] (EASp) developed for that purpose.

reason for and objective of this Concept Paper is to facilitate a discussion between all parties in order to define the best solution and implementation plan.

This Concept Paper:

- identifies the core issues driving this rulemaking effort (see Section 1);
- provides background to ICAO developments in the Safety Management domain (see Section 2);
- provides background on the EASA approach to the introduction of the ICAO Safety Management principles in all the domains within the scope of the Basic Regulation (see Section 3); and
- identifies specific implementation issues in the domain of initial airworthiness, and describes parameters and open issues on the concepts of implementation of LOI (Section 4) and SMS (Section 5).

2. ICAO background

In order to further improve the already good safety record of the civil aviation industry, between 2001 and 2009, ICAO developed and adopted for a number of ICAO Annexes the new concept of Safety Management (SM).

These new SM provisions require the implementation, from a date specified in each applicable Annex, of a State Safety Programme (SSP) by the Contracting States and of a Safety Management System (SMS) by aviation industry organisations (service providers). As part of its SSP, each State shall require that service providers under its authority implement an SMS in their organisation. This involves the following service/product providers:

- Approved training organisations and medical assessment centres (Annex 1);
- Operators of aeroplanes or helicopters (Annex 6);
- Approved maintenance organisations (Annex 6);
- Air traffic services providers (Annex 11);
- Accident investigation bodies (Annex 13)[7];
- Organisations of certified aerodromes (Annex 14); and
- <u>Organisations responsible for type design or manufacturers of aircraft (Annex 8).</u>

The SSP/SMS provisions, including their frameworks, were originally developed and adopted separately in each of the above ICAO Annexes (except framework for SMS in Annex 8) and made applicable only within the scope of each Annex. The required applicability/compliance dates were different for each Annex.

Annex 19

In 2010 the ICAO High-Level Safety Conference decided that a new annex should be developed on Safety Management. This new annex – Annex 19 'Safety Management' – has been developed in a very short time by the Safety Management Panel (SMP) consisting of

[7] Annex 13 [illegible]

representatives of a number of Contracting States as well as representatives of some international industry organisations (e.g. ICCAIA) and the EU. The Agency, representing the EU, participated (and continues to participate) in the SMP work.

The new Annex 19 (Edition 1) that was adopted by the ICAO Council on 25 February 2013, becomes effective in July 2013 and shall be applicable in all aviation domains on 14 November 2013.

Annex 19 consolidates all the general SSP and SMS provisions currently spread across Annexes 1, 6, 8, 11, 13 and 14 and adds elements on the collection and use of safety data and State safety oversight duties. Annex 19 defines two frameworks, one for SSP (see Attachment A of Annex 19) and one for SMS (see Appendix 2 of Annex 19). These frameworks are generally applicable to all aviation domains, including the domain of Annex 8 'Airworthiness of aircraft'.

The general SM provisions of Annex 19 will be complemented, as necessary in each Annex, by domain specific SM provisions. The Annexes will contain appropriate cross references to the general provisions of Annex 19. All affected annexes will shortly undergo revisions to remove the general provisions now contained in Annex 19 in order to avoid duplications. By creating Annex 19 with Safety Management provisions applicable to all aviation domains, ICAO has created a new hierarchical structure of SSP/SMS provisions.

Immediately after the new Annex becomes effective (July 2013), the Contracting States, including the EU MS, will be requested by the Secretary General to notify ICAO of any differences that will exist on 14 November 2013 between their national regulations or practices and the provisions of the Standards in Annex 19. Such notification is to be made before 14 October 2013, and thereafter the States shall notify the Organization of any further differences that arise.

Further, the Contracting States will also be invited to notify ICAO of any differences between their own practices and those established by the ICAO Recommended Practices, when the notification of such differences is important for the safety of air navigation. The Contracting States will also be requested to notify ICAO, before 14 October 2013, of the date or dates by which they will have complied with the provisions of the Standards in Annex 19.

3. EASA background

3.1. *General*

As explained in section 1 above, the Agency, being responsible for aviation rulemaking in the EU, is obliged to ensure that all the implementing rules within the scope of the Basic Regulation take due account of ICAO provisions, including the provisions for Safety Management specified in Annex 19 and the other affected Annexes.

In addition, the Basic Regulation itself, in its essential requirements for airworthiness, pilot licensing, air operations, ATM/ANS and aerodromes (see the annexes to the Basic Regulation) requires aviation organisations to implement and maintain **a Management System** relating to safety, and aim for continuous improvement of this system.

To implement the above provisions of the Basic Regulation, the Agency has developed its own concept and model framework for Safety Management which is fully ICAO compliant and adapted to the specific EU legal environment.

This model, adapted in its form to fit each domain, is gradually being introduced into the implementing rules for all the domains within the scope of the Basic Regulation. In different domains, the work is in different status of progress (see Figure 1). Below you can find brief information on the implementation status in each domain.

Figure 1: The status of SMS implementation in EU/EASA implementing rules

3.2. *Air Crew*

The rulemaking process has been completed with the adoption of Commission Regulation (EC) No 290/2012[8] which defines, among other things, the Authority and Organisation Requirements for civil aviation aircrew.

Requirements for competent authorities are contained in **Annex VI 'Part –ARA', Authority Requirements for Air Crew.** The SSP related provisions are contained in Sections I (General), II (Management), & III (Oversight, certification and enforcement). Supporting AMC and GMs are contained in ED Decision 2012/006/R[4] (**AMC and GM to Part-ARA**), Subpart GEN, Sections I, II, and III.

The organisation requirements are contained in **Annex VII 'Part ORA', Organisation Requirements for Air Crew.** The SMS related provisions are contained in Sections I (General) and II (Management). Supporting AMCs and GMs are contained in ED Decision 2012/007/R[5] (**AMC and GM to Part-ORA**), Subpart GEN, Sections I and II.

The organisation requirements, encompassing the SMS elements apply to:

– approved training organisations (ATOs), i.e. all organisations providing training for commercial and/or private licences in accordance with the EASA rules on flight crew licensing, as well as organisations engaged in flight test training;
– all holders of a Flight Simulation Training Device (FSTD) qualification certificate; and
– all aero-medical centres (AeMCs).

A text comparison between the ICAO Annex 6 SMS framework and the EASA management system provisions is available in the Explanatory Note to the Decision 2012/007/R (AMC and GM to Part-ORA)[6].

3.3. Air Operations

The rulemaking process for implementing rules for Air Operations has been completed with the adoption of Commission Regulation (EU) No 965/2012 of 5 October 2012 defining Authority, Organisation and Technical Requirements for air operations. It entered into force on 28 October 2012.

Requirements for Competent Authorities are contained in **Annex II 'Part-ARO' Authority Requirements for Air Operations.** The SSP related provisions are contained in Subpart GEN, Section I (General), Section II (Management) and Section III (Oversight, certification and enforcement). Supporting AMC and GMs are contained in ED Decision 2012/016/R[7], Subpart GEN, Sections I, II, and III.

The SMS related provisions for organisations of air operators are contained in **Annex III 'Part-ORO' Organisation Requirements for Air Operations,** Subpart GEN, Sections I (General) and II (Management). The supporting AMC and GMs are contained in ED Decision 2012/017/R[8], Subpart GEN, Sections I and II.

The organisation requirements, encompassing the SMS elements, apply to:

– all operators who are required to hold an AOC/organisation certificate under the new EU rules for air operations; and
– all operators who will be required to declare their activity under the new EU rules for non-commercial operations of Complex Motor Powered Aircraft.

3.4. ATM/ANS

SM related requirements have been adopted and are contained in:

[illegible]
[illegible]
[illegible] [illegible]
[illegible]
[illegible]

Commission Implementing Regulation (EU) No 1034/2011 of 17 October 2011 on 'Safety oversight in air traffic management and air navigation services' with the corresponding requirements for competent authorities in the field of ATM/ANS. This Regulation sets out specific requirements for annual safety oversight reporting and monitoring and assessment of the levels of safety achieved.

- Commission Implementing Regulation (EU) No 1035/2011 of 17 October 2011 on 'Common requirements for the provision of air navigation services', which mandates Air Traffic Services and Communication, Navigation and Surveillance (CNS) providers to have a Safety Management System and all Air Navigation Service providers to implement a Quality Management System (QMS). For the QMS requirement, the Regulation recognises an EN ISO 9001 certificate covering the air navigation services of the provider as a sufficient means of compliance. Under this Regulation, service providers may integrate safety, security and quality management systems.

However, the SM requirements contained in these Regulations are not compliant with ICAO Annex 19. Therefore, it is necessary to align Safety Management Systems (SMS) requirements in Commission Implementing Regulation (EU) No 1035/2011 with SMS requirements within the ICAO SMS framework, and to align Management Systems requirements in Commission Implementing Regulation (EU) No 1034/2011 with SSP requirements required by ICAO. NPA 2013-08 on 'Requirements for ATM/ANS providers and the safety oversight thereof' was published on 10 May 2013.

3.5. Aerodromes

The draft implementing rules on 'Authority, Organisation and Operations Requirements for Aerodromes' have been published in Opinion 01/2013. The rules foresee that aerodrome operators shall implement and maintain a management system that includes a safety management system. The organisation and authority requirements of Opinion 01/2013 are largely based on the organisation and authority requirements developed for air crew and air operations, but inconsistencies exist.

3.6. Continuing Airworthiness

The rulemaking process under task RMT.0251 (MDM.055) was recently started by publication on 21 January 2013 of NPA 2013-01 'Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003'. The NPA was published in 3 parts: 2013-01 (A) (Explanatory Note), 2013-01 (B) (Part-M), and 2013-01 (C) (Part-145). The main objective is to amend Commission Regulation (EC) No 2042/2003 and the implementing rules of Part-145 and Part-M to incorporate the ICAO SMS framework and support the implementation of SSP/EASP by the EU Member States. The frameworks of the SMS/SSP requirements in Commission Regulation (EC) No Regulation 2042/2003 are based on the EASA Management System framework originally developed with a view to be generally applicable across all aviation domains and which was later adopted for Air Crew and Air Operations (Parts ARX/ORX). The embodiment respects the existing structure of Part-145 and Part-M. The changes are extensive and address, as part of SMS/SSP implementation, some specific subjects such as Human Factors and consider the recommendations of the Consistency of Organisation Approvals (COrA) Report (see Advance NPA No 15-2006[15] and the related CRD). A second NPA containing changes to Part-147 and Part-66 is expected to be published in the second quarter of 2013. The objective is to apply the same basic management system provisions and authority requirements for all certified organisations within the scope of Commission Regulation (EC) No 2042/2003. The Opinion & draft Decision is planned for the first Quarter of 2014 (the regulation one year later).

3.7. Initial Airworthiness

Implementation of SM principles in Initial Airworthiness is focussed on two core Part-21 processes:

(1) The product certification process with the idea of introducing a risk-based approach for the determination of the Level of Involvement (LOI) of the Agency in product certification projects.

(2) The process of approval and oversight of Design & Manufacturing (D & M) organisations with the idea of complementing the related organisation requirements with ICAO compliant SM elements, as well as adding these elements to the requirements for the competent authorities granting them approvals and conducting continuing oversight.

Both the LOI and SMS issues are interrelated because the Agency, the design organisation, and the production organisation participate in the same certification and post-certification activities. The organisation SMS requirements and the requirements for performance-based oversight by the competent authorities are complementary with each other and support implementation of SMS and LOI. Therefore, the LOI and SMS frameworks should be compatible and apply the same SM principles.

3.7.1 History of LOI

One of the key elements of the SM concept is the performance-based oversight supported by a performance-based regulatory system. Performance-based oversight can be applied by authorities in various aviation domains for the initial approval, as well as the continuing oversight of aviation organisations, which provide 'service' (aircraft operation, maintenance, ATM/ANS, aerodromes, etc.). In the domain of initial airworthiness, it can be also applied by the authorities when granting the initial design approval to the product itself (i.e. a type certificate) as well as when approving post -TC design changes and repairs during the life cycle of the product. The term 'Level of Involvement' (LOI) has been chosen for product related performance-based oversight.

The implementation of this approach has now been discussed within the Agency for several years. The work started as early as 2004 under task 21.024 'Subpart J'. The original objective of this task was to remove the conflict between the privileges of the DOA holder (see 21.A.263(b)) and the rights of the Agency (see 21.A.257(b) and 21.A.33 (c) and (d)) in respect of the Agency's involvement in the certification process. Under the 21.A.263(b) privileges, the DOA holders' compliance documents shall be accepted by the Agency without

[15] http://easa.europa.eu/rulemaking/docs/npa/2006/NPA%2015-2006.pdf

further verification. At the same time, the applicant for design approval is (under 21.A.257(a) and 21A.33 (c) and (d)) obliged to allow the Agency to review any report, make any inspection, perform or witness any flight and ground test necessary to check the validity of the DOA compliance statements. The task aimed to resolve this conflict and provide upfront, at the stage of approval of the certification programme, a greater legal certainty on the level of Agency involvement in the certification process.

The task was contentious from the outset, with different views being expressed both internally within the Agency and in the wider aviation community. Following the publication and comments received on NPA No 16/2006, some fundamental changes in the concept were introduced, requiring significant internal debate. The ESC participated to this debate on many occasions between the period 04 May 2007 – 06 May 2008. The external Review Group set up in accordance with the rulemaking procedure did not support the proposal.

Even the amended proposal, covered by CRD No 16/2006, which attempted to establish a balance between the organisation and product approval processes by adopting a risk-based approach with a clearer demarcation of responsibilities between the applicant and the Agency, was not agreed. Among the main concerns were:

- The lack of clarity regarding the respective roles and responsibilities of design approval applicants/holders, DOA, product certification teams and DOA oversight teams may lead to overlaps or gaps in the overall certification role of the Agency;

  The perception that the approach will reduce safety (product certification considered more efficient in safety terms than auditing organisations). Experience has shown that compliance documentation may not always be of the standard expected by the Agency. This has led to a general lack of confidence in DOA by certification teams who view DOA as too remote and that assessing a design organisation should be in addition to and not a substitute for assessing the product itself;

  The limited confidence in some DOAs (due to reorganisations, instability and lack of resources);

- The concern that a limited Agency involvement will lead to a loss of Agency technical competence, product specific knowledge, standardisation between projects and credibility;
- The concern that the proposal requires greater coordination between the DOA team and specific PCMs and certification experts. Procedures would need to be developed to ensure this coordination is effective; and
- The possible impact on bilateral agreements which could result in the need for an increased level of involvement from the validating authority....

The final outcome of the rulemaking activity was contained in Opinion No 03-2010 which only addressed the non-controversial part of the proposal. This part, later adopted into Commission Regulation (EU) No 748/2012, introduced limited changes to Part-21 related to the obligation of the applicant for a design approval to present to the Agency a certification programme detailing the means of compliance demonstration, and to keep this document updated as necessary during the certification process. Additionally, DOA holders were given the privilege to approve minor revisions to the Aircraft Flight Manual and its supplements. The rest of the proposal on LOI was put on hold. This sequence of events emphasised the need for proper change management for such a rule change.

However, the effort to progress the subject of LOI was pursued. Since the first rulemaking attempt, the situation has evolved, as the risk-based approach has been promoted worldwide. Consequently, the concept of LOI is viewed positively today.

3.7.2 Start of MDM.060

MDM.060 task has also faced a series of difficulties since its start. MDM.060 was first introduced in the EASA rulemaking programme for 2009-2012 under the title 'New structure for Commission Regulation (EC) No 1702/2003' (later amended to add introduction of SMS). The title suggested that the primary objective of this task was to reorganise the existing structure of Commission Regulation (EC) No 1702/2003 (predecessor of Commission Regulation (EU) No 748/2012) and its Annex — Part-21 in order to align it with the new, 'horizontal structure' of EASA/EU aviation rules proposed by the draft authority and organisation requirements for Air Crew and Air Operations. This was in line with the ICAO direction (Annex 19 was being drafted) and the FAA direction (Part 5 was being drafted) to have the SM related provisions in the 'horizontal structure'.

AGNA and the SSCC were consulted on the Pre-RIA and TOR Issue 1 developed in 2010 (at that time the LOI issue was not highlighted in the scope of the task but the subject was included under 'performance-based oversight') and both industry and NAA groups provided feedback as follows:

(1) The proposed 'horizontal structure' of the EASA/EU aviation rules was seen to lead to no safety benefit whilst imposing a great administrative burden. On the other hand, the structure and content of the existing Part-21 was considered good, providing good safety results. There were concerns about an envisaged adverse impact of SMS implementation on DOA and POA holders who had invested a lot of resources in the implementation of existing and well-performing systems (Quality and Design assurance systems). There were concerns that the existing systems were to be abandoned when the full SMS would be implemented.

(2) SMS implementation in D & M was not at all clear at the ICAO level. Because of a strong opposition from D & M Industry, no framework for SMS was adopted for Annex 8. Discussions on the very need to implement SMS in D & M were under way between the ICAO secretariat and some D & M Industry associations for a long time.

(3) There was disagreement with the proposed working method and a strong recommendation to change it from 'Agency' to 'Group' in order to properly involve industry and NAA stakeholders.

(4) There were complaints that too many rule changes were under way in many aviation domains and that time should be given to stakeholders to first 'digest' the first extension rules.

(5) It was clear from the comments that there was a lack of confidence that the safety benefits, the new SM approach was designed to produce, would, in fact, result.

The above comments led to the decision to postpone the start of MDM.060 task until the issues were clarified. Early in 2011, the task was put on hold, following the decision not to implement the horizontal rule structure.

In March 2012, the MDM.060 task was re-started after the issue of rule structure was definitively clarified with the adoption of Commission Regulation (EU) No 290/2012 and Commission Regulation (EU) No 965/2012.

A new version of the ToR (version 2) was prepared. This time the LOI element was explicitly stated in the ToR and seen as a benefit by all. The AGNA and SSCC were again consulted on the revised ToR. Preliminary regulatory material was drafted by the Rulemaking Directorate accompanied with a concept for LOI. The decision to proceed was taken. The deliverables for the LOI topic were due for December 2012.

The new feedback on the ToR showed, however, the following:

(6) The stakeholders were concerned that Part-OR/ORO. Subpart GEN requirements, although designed with a view to ensuring general applicability, were tailored to operators and not suitable for Part 21 organisations.

(7) Opposition was expressed against combining the LOI and SMS issues under the umbrella of a single task. They were seen as two separate processes, one related to the product, the other to the organisation.

(8) A request was made to review and clarify DOA privileges with the possibility to extend them if justified by the results of the risk/performance based oversight. A wish was expressed to grant stakeholders the DOA privilege to issue STCs and major changes approvals if in the approved scope.

(9) A request was made to harmonise the EASA SM framework with the FAA and TCCA and accept assistance from D & M associations (ICCAIA).

(10) A request was made to address Human Factors.

(11) Stakeholders disapproved of the Agency's rejection of the proposal to change the working method from 'Agency' to 'Group'.

At this stage (June 2012), the issue was transferred to the Certification Directorate to develop a new concept and test it in pilot projects. However, there were no convenient pilot projects available. The Certification Directorate concentrated on developing the new concept with support material provided by the Certification Strategy Group which has D&M industry participation.

4. LOI concept for Part-21

4.1. LOI concept parameters

In collaboration with industry and the EASA DOA Section, the Certification Directorate has developed a concept for LOI which addresses the majority of the issues not progressed during the previous rulemaking attempts. The concept has been agreed internally within the Agency and the initial discussions with stakeholders have been favourable.

The key elements of the concept for LOI are:

(a) It builds on the introduction of the certification programme by Commission Regulation (EU) No 748/2012;

(b) It formally introduces a risk-based approach both in product certification and design organisation approvals;

(c) It enables the Agency to determine its level of involvement in product certification on the basis of consistent clear criteria, associated with safety risk, linked to:

(1) the novelty and criticality of the certification item, including means of compliance, and

(2) the level of performance of the design organisation.

(d) It introduces the possibility of extending, under certain conditions, the DOA privileges to approve major changes to the Type Design (including changes to associated required manuals/data), major repairs and STC;

(e) It establishes product certification and design organisation approvals as two processes sharing the same common risk-based elements;

(f) It improves the clarity of the Part-21 text, by separating the requirements applicable to product certification and those applicable to design organisation approvals;

(g) It clarifies the responsibilities of the applicant and the Agency in the product certification process. The applicant remains fully responsible for the compliance of its design with the certification basis;

(h) It better defines the responsibilities of the Agency in product certification. In particular, the contradiction of the present text in 21.A.33 (d), 21.A.257 (b) and 21.A.263 (b) is resolved. The current privilege 'compliance documents shall be accepted by the Agency without further verification' is replaced by a risk-based determination of the level of involvement;

(i) It is consistent with and extends the current DOA concept with all the new elements introduced, as appropriate, including the description of the privileges;

(j) It supports innovations by enabling the industry to safely discharge their responsibilities in a manner appropriate with the extended supply chain models used by industry;

(k) It introduces a consistent and proportionate demonstration of capability for all design organisations (including those applying for ETSOA);

(l) It has the potential to make the DOA concept attractive and proportionate for Small and Medium Enterprises (SMEs), in terms of complexity and privileges.

It is assumed that the LOI concept will be applicable to:

- applicants for TCs and APU ETSOA; and
- applicants for major/minor changes and major/minor repairs, STCs (Subparts D, M, and E) and ETSOAs (Subpart O).

In the first phase, the focus will be on LOI implementation in certification projects of DOA applicants/holders. The applicants for/holders of design approvals designing under Alternative Procedures to DOA (APDOA) and under certification programme only will be addressed later.

The concept does not change the accountability of the applicant for demonstrating full compliance with the type-certification basis. It also does not change the respective roles and division of work in the certification process within the Agency team (i.e. between the Certification staff and DOA staff) or within the applicant team (i.e. between their Certification staff & DOA staff) but should improve the collaboration between the teams, the exchange of information and encourage timely interaction.

For further details about the LOI concept by the Certification Directorate, see Attachment A to this Concept Paper. The concept is accompanied with the detailed initial proposal for Part-21 rule changes.

4.2. Rulemaking process for LOI

The first step is to initiate rulemaking for Part-21 to introduce there the necessary rule changes for the implementation of LOI. The draft rule changes developed by the Certification Directorate will be used as an input for the content of the first NPA (NPA 1). The draft rule changes will be accompanied by an Explanatory Note and a light qualitative RIA only. The draft NPA proposal will undergo focused internal consultation and immediately after that it will be published for external comments. This first phase will be progressed as fast as possible leading to an Opinion.

In the meantime, the second phase will be launched with the objective of developing AMC/GM material. This material will be published in the second NPA (NPA No 2) leading to a draft Decision. The development of AMC/GM material will be supported by pilot projects.

4.2.1 Working method

The working method will formally be 'Agency', so that a rulemaking group will not be set up, but adequate involvement of the industry will be assured by other means, namely by direct monitoring of the pilot projects (see below) and participation in the development of AMC/GM material. In addition, consultations with the D & M Sub-SSCC and TAG advisory bodies, workshops, focused consultations, etc. will take place as necessary.

4.2.2 Pilot projects

To avoid similar difficulties to those experienced in the first attempt, it was agreed to use several current certification projects as pilot projects to test and validate the LOI concept as proposed by the Certification Directorate. The pilot projects will also inform the drafting of AMC/GM material to the proposed rules to allow a smooth implementation of LOI. The LOI pilot projects are ready to start. In April 2013, a Steering Group for LOI pilot projects (LOI SG) was set up. It consists of the Agency staff involved and representatives from leading D & M industry companies. The role of the LOI SG will be to monitor the pilot projects, collect experience and exchange views between the Agency and industry to achieve a good mutual understanding to facilitate smooth implementation. The main group's deliverable will be draft AMC/GM material and, if necessary, a proposal for further adaptations of the implementing rules drafted in phase one.

The profile of these pilot projects and participating design organisations will ideally include fields as follows:

- CS-25 aeroplane (TC/significant/major change project);
- CS-23/VLA/LSA aeroplane (TC/significant/major change project);
- Engine (TC/ significant/major change project);
- Rotorcraft (TC/significant/ major change project);
- Non-TC holder major change (STC project); and
- Part or Appliance project.

4.2.3 Deliverables

The main deliverables will be an Opinion with draft rule changes to Part-21 and a draft Decision with AMC/GM material. If needed, a proposal for further adaptations of the implementing rules drafted in phase one will be delivered.

4.2.4 Time schedule for LOI

4.2.4.1 Time schedule for implementing rules

The time schedule for the IRs is proposed as follows:

April 2013	Start of the LOI SG for pilot projects
May 2013	Adoption of this Concept Paper (both on LOI and SMS) by ISC/IETC
June 2013	RAG/TAG/SSCC are consulted on the Concept Paper + draft ToR
June/July 2013	TOR is published, NPA 1 (IRs only) internal consultation
August 2013	NPA 1 (IRs only) is published (shortened consultation period will be considered)
Q2/2014	Opinion (+ CRD + draft Commission Regulation) is published
Q4/2015	Commission Regulation is adopted (estimate)

NOTE: *Full implementation of LOI is planned to be synchronised with SMS implementation expected in 2017. However, in individual certification projects LOI can be applied earlier, based on Certification Memos and updated certification procedures. Before the applicability date of the Part-21 rule changes, certain details, such as the envisaged extended DOA privileges, cannot be applied.*

4.2.4.2 Time schedule for AMC/GM material

The time schedule for AMC/GM is proposed follows:

Q2/2013	Start of pilot projects, the Concept Paper and ToR are approved
Q3/2013	Start drafting NPA 2 (for AMC/GM material) based on the output from pilot projects
Q2/2014	NPA 2 published
Q1/2015	Draft Decision ready
Q4/2015	Decision adopted (concurrent with Commission Regulation adoption)

4.3. LOI concept open issues

4.3.1 Applicability issue

It needs to be considered whether and how the LOI concept should be applied to SMEs designing and modifying ELA 2 and ELA 1 aircraft under the Alternative Procedures to DOA

(AMDOA) or, for ELA 1 only, by presenting the certification programme. The issue also includes applications for ETSOAs.

4.3.2 Content of AMC/GM material

The Certification Directorate envisages in their concept for LOI that a significant amount of AMC and GMs will need to be produced, in particular in the following domains:

- Content and level of detail of the certification programme;
- Criteria for determining the level of performance of design organisation;
- Criteria for determining the criticality of an item of the certification programme; and
- Criteria for determining the novelty of an item of the certification programme.

There are other candidates for AMC/GMs such as :

- Definition of a mechanism which will ensure a smooth cooperation of and timely interactions between the different parties involved in the product certification activities to be established (applicant, EASA DOA team, and EASA Product certification team);
- Definition of a mechanism for the management of certification programmes (how they are established, on what basis, in which form, how they are approved, how they can be amended, etc.);
- Criteria for the determination of the depth of involvement. For a specific item of the certification programme, the determination of the LOI may not be just "Yes/No" but "how deep";
- Criteria and conditions for granting the privilege to a DOA holder to approve major changes, major repairs and/or STC under their DOA;

NOTE: Before formal adoption of the Commission Regulation with the related LOI Part-21 rules and synchronised adoption of related ED Decision with supporting AMC/GM material, Certification Memos may be used to allow the LOI process to be applied to individual certification projects. However, DOA holders will only be entitled to the LOI related privileges after the Commission Regulation is formally adopted.

- Access of the Agency certification team to all compliance documents whether or not the agency is involved in the task;
- Reporting obligations of the Applicant for significant events that occur during the certification process; and
- Criteria and procedure for reconsidering the LOI for a specific item or items of the certification programme.

4.3.3 Output from FAA 21/SMS ARC project

The details of the LOI concept may be influenced by the outcome of the FAA 21/SMS Aviation Rulemaking Committee (ARC) project which has been set up to provide FAA with recommendations on how to amend FAR Part-21 and Part-5 to implement performance-based oversight (Level of Involvement) in product certification and SMS in D & M organisations. There is a need to align the results of the work on each side to support harmonisation and mutual recognition of performance-based oversight (Level of Involvement) based on their equivalency.

4.4. Interfaces

4.4.1 Interface with tasks RMT.0550 & RMT.0612 (SMS)

The activity under tasks RMT.0262 & RMT.0611 on LOI should be closely coordinated with the activity under tasks RMT.0550 & RMT.0612 for the implementation of SMS, in particular to address the design organisations whose safety performance will be a factor considered when determining a LOI in certification projects.

4.4.2 Interface with the FAA 21/SMS ARC project

The LOI SG should maintain contacts with and monitor the work of the FAA 21/SMS ARC group on the implementation of the performance based oversight and LOI in FAA.

5. SMS concept for Part-21

5.1. SMS concept parameters

5.1.1 Part-21 SMS and compliance with ICAO

The framework of the SMS implementation in Part-21, including its oversight, must be ICAO compliant. This will be assured by conducting a thorough gap analysis between the criteria of Annex 19 and Part 21 to identify SMS/SSP elements that will need to be added.

5.1.2 Part 21 SMS framework and its consistency with other domains

The framework of the SMS implementation in Part-21 should be consistent with the EASA model framework as implemented (or going to be implemented) in the other domains within the scope of the Basic Regulation. This is required by the principle, generally accepted in EASA, of a Total System Approach. This system requires that aviation system components (organisations, systems, services, products, regulations, etc.) are addressed in a uniform or, at least, consistent way as they are all part of a single aviation network. Such system facilitates interoperability of the system components and improves its overall performance. It eliminates or minimises room for safety gaps, conflicting or overlapping requirements, confused responsibilities, misinterpretations etc. Applied to a single organisation holding multiple EASA organisation approvals, it supports smooth integration of these approvals under their company integrated management system. Therefore, internally (within Part-21) and externally (against the other EASA domains) the SMS/SSP frameworks should be consistent. However, a consistent approach does not mean that all implementation aspects must be the same. Differences, where supported by an appropriate rationale, can be accommodated. It is not intended to rigorously enforce a specific framework aspect where it is inappropriate for DBR (see also 5.3.1 below).

5.1.3 Structure

When introducing the SMS/SSP requirements into Part-21, its existing structure (its division to Sections and Subparts) will be respected as far as possible, unless justified otherwise.

5.1.4 No stand-alone SMS organisation approval

The existing organisation and authority requirements of DOA and POA approvals will be amended to embody those SMS/SSP elements which are currently missing there. The existing approvals will be amended but the Agency does not foresee a separate 'SMS' approval.

5.1.5 EASA SMS scope vs ICAO SMS scope for D & M

The ICAO SARPs, as in Annex 19, apply to organisations designing or manufacturing aircraft only. ICAO has already communicated its plan for Edition 2 of Annex 19 to extend its scope to include engines, propellers, and some other safety critical aircraft components. The Agency's approach is based on the essential requirements of the Basic Regulation and requires implementation of a Management System with safety aspects from all holders of or applicants for EASA organisation approvals while applying it to the full scope of these approvals. In the initial airworthiness domain, the implementation of SMS will be required from design organisations designing under DOA and production organisations producing under POA and will cover their full approved scope which may cover:

- products and/or their changes and repairs, and
- parts and appliances (including ETSO articles).

SM principles will also need to be implemented, in some proportionate form to be explored, by those designing under Alternative Procedures to DOA (APDOA) or under presentation of certification programme only. In the manufacturing field, the SM principles will need to be implemented by holders of or applicants for a letter of agreement under Subpart F of Part-21 to produce products, parts, or appliances without POA. But how exactly SMS will be implemented in these fields is an open issue.

5.1.6 Consistency of SMS frameworks between DOA and POA

It is recognised that organisations wholly or partly involved in aviation D&M are likely, as with the Agency, to have a total system approach to safety management and as such will have one Management System framework for their complete organisation, which may extend beyond D&M and, indeed, beyond aviation. It is a principle of the EASA SM implementation rulemaking that every attempt will be made to allow easy integration of Part-21 SM processes into a broader framework, while making no compromises on adhering to the ICAO Annex 19 requirements (see also 5.1.2 above).

Consequently, as far as their contents is concerned, the resulting DOA and POA SMS/SSP frameworks need to be consistent. The exact way how these frameworks will be incorporated in the relevant Part-21 Subparts (J, G, F) is an open issue. Another open issue is if and how to improve, apart from SMS, the overall consistency of the DOA an POA requirements (see also 5.4.1 below).

5.1.7 Regulation of State Safety Programme (SSP)

SSPs of the EU MS fall within their authority and are currently not directly regulated by the EU/EASA aviation rules, and there is no plan to change this. This decision has been taken for all aviation domains and it is due to legal reasons as well as due to a wish not to interfere with the current SSPs recently implemented in the MS. Certainly the SSPs of the EU MS need to reflect the existing EU/EASA aviation legislative framework as well as the European Aviation Safety Programme (EASP) and plan (EASp) designed to support the SSPs of the MS. Consequently, the requirements for competent authorities (for Section B of Part-21) will not directly refer to the SSP but will support their implementation by the States.

5.1.8 Alternative Means of Compliance

The SMS/SSP concept for D & M organisations will incorporate the EASA concept of voluntary use of alternative means of compliance (altMoC) with the Implementing Rules, as adopted in other domains within the scope of the Basic Regulation (e.g. Air Crew and Air Operations). This is to offer D& M organisations the same flexibility as provided to the other service providers (Total System Approach). However, as in case of the alternative MoC proposed by the applicant for a design approval (as alternative to the AMC published in CS), these altMoCs must be found acceptable by the approving competent authority (the Agency for DOA, the applicable NAA for POA). Therefore, the published Part-21 AMC remain the only means of compliance with the corresponding rule unless an altMoC is approved by the competent authority. To be approved, it must provide an equivalent level of safety. The requirements for Section B of Part-21 will specify for the competent authorities the procedure and conditions for the use of altMoCs.

5.1.9 Human factors

The scope of MDM.060 task will include the embodiment into Part-21 of Human Factors as adapted from the other aviation domains(e.g. Part-145) to fit Part-21 and the D & M organisations. Human Factors are currently missing in Part-21 and their inclusion is in response to comments on the initial ToR and a recommendation of the European HF Advisory Group.

5.2. Rulemaking process for SMS

5.2.1 Working method

The working method will formally be the 'Agency' but adequate involvement of the industry and NAA stakeholders will be assured by various means. The Agency will set up an SMS Steering Group with industry and NAA representatives which will be primarily tasked to launch and monitor a number of the SMS pilot projects (see below) and gather implementation experience. Based on the pilot projects results, the SMS SG or its dedicated sub-groups will prepare draft SMS rules for Part-21and related AMC/GM material. In addition, consultations of the TAG & D & M Sub-SSCC, workshops, focused consultations etc. will be considered as necessary. This will be stated in the project ToR.

5.2.2 Pilot projects for SMS

In a similar way to LOI, the Agency plans to launch a set of pilot projects for testing the implementation of SMS in D & M organisations. The pilot projects are means for development of the rules and AMC/GM material, and the SMS SG in charge of the pilot projects will support the Agency in their drafting. The exercise will require involvement of the Agency's POA and Standardisation (Initial Airworthiness) expert staff. Because national POAs in the EU MS are within the remit of EU NAAs, their staff will also be invited to participate in the pilot projects.

The profile of these pilot projects and participating D & M organisations will ideally include fields as follows:

– CS-25 aeroplane (TC/significant/major change project);
– CS-23/VLA/LSA aeroplane (TC/significant/major change project);
– Engine (TC/ significant/major change project);
– Rotorcraft (TC/ significant/major change project)
– Non-TC holder major change (STC project); and
– Part or Appliance project.

5.2.3 Deliverables

One Opinion for Part-21 implementing rules and one Decision for AMC/GM material will be delivered. The draft rule changes and related AMCs/GMs will be developed simultaneously to be contained in a single NPA leading to the Opinion and Decision.

5.2.4 Time schedule for SMS

The time schedule proposal for the SMS implementation is as follows:

May 2013	Adoption of the Concept Paper by ISC/IETC
June 2013	TAG/SSCC consulted on the Concept

	Paper + draft ToR
June/July 2013	TOR published
Q3/2013	Start of pilot projects for SMS
Q1 /2015	NPA (with IR & AMC/GM) published
Q1 /2016	Opinion + CRD + draft Commission Regulation + draft ED Decision published
Q2/2017	Commission Regulation adopted (estimate) + ED Decision adopted
2017	Full implementation of SMS (synchronised with ICAO implementation).

5.3. SMS concept open issues

5.3.1 Form of SMS implementation in Part-21

The form of implementation of SMS into Part-21 may differ from other domains because of the specific structure of Part-21. Since DOA and POA already contain a number of elements upon which to build SMS (e.g. competent and trained personnel, facilities, a feedback to accountable manager, compliance monitoring system, etc.) the embodiment must be such that there will be no superfluous or contradicting requirements. To ensure this, a thorough gap analysis will be performed with the Annex 19 framework. It will need to be decided whether to only complement the existing requirements of the relevant Part-21 Subparts (J, G, and F) with missing SMS/SSP provisions piece by piece or to introduce (e.g. into Subpart A – General Provisions common for all the other Part-21 Subparts) a full set of basic high-level requirements on the Management System and adapt Subparts J, G, and F to avoid obvious duplications.

5.4. Other open issues

5.4.1 Consistency of Part-21 organisation approvals

The need for SMS implementation in DOA and POA organisations offers again the opportunity for implementation of the old JAA initiative of restoring consistency of various aviation organisation approvals. In the framework of Part-21 field, it would apply to the requirements of DOA & POA approvals and production without POA (contained currently in Subparts J, G, and F). The aim would be to make these three approvals more consistent in terms of their structure, contents and terminology. These approvals were originally developed for JAR-21 by the JAA progressively and more or less independently (as were the other organisation approvals for other JARs) so that the regulatory material varies in many aspects. Inconsistencies in organisation approvals became apparent while implementing them. The JAA recognised this issue by setting up a WG to address this issue. The WG produced a final report 'Consistency of Organisation Approvals' (COrA report) and the Agency later, based on the COrA report, progressed the issue with an Advance NPA (A-NPA No 15-2006) followed by a

CRD. However, the implementation of the idea was deferred. For the purpose of this rulemaking project there are two options:

Option 1: Use the opportunity of RMT.0550 task with the aim to introduce the SMS related requirements in a consistent way and amend also the existing remaining requirements in Subparts J, G, and F to achieve the overall consistency of the DOA and POA approvals.

Advantages of Option 1

Consistency, well implemented, should improve transparency and clarity of requirements and reduce room for misinterpretations. Both the D & M industry and the competent authorities may profit if the potential for safety and cost benefits is realised, particularly where organisations hold more than one approval. It is likely to support integration of both design and production management systems as consistent pillars under a single 'integrated management system' of the organisation.

Disadvantages of Option 1

It extends the scope of the tasks and scope of the necessary changes to Part-21. When not implemented sensitively, it could have an administrative impact on DOA and POA communities for both stakeholders and the competent authorities.

Option 2: Limit the task to strictly necessary changes to Part 21 for introduction of SMS principles.

Advantages of Option 2

It might simplify conduct of MDM.060 task and limit changes to Part-21 to what is strictly requested by ICAO Annex 19. It might avoid industry stakeholders having to make changes in their established organisations based on administrative rather than safety related reasons.

Disadvantages of Option 2

Leaving the issue of consistency of organisation approvals for (a) future rulemaking task(s) might result in more work for D&M organisations to align their internal single SMS with inconsistent requirements. It might result in a situation not optimised for safety, given that Option 1 was seen as having potential to improve safety.

5.4.2 Part-21 review to introduce performance based rulemaking principles

The need to introduce rule changes and potentially transfer rules within the structure of Part-21 to implement SMS raises the question of whether to use the opportunity to make a full review of Part-21 and related AMC/GM in order to check and, if needed, improve its quality by introducing the principles of performance-based rulemaking (Option 1). The objective would be to clearly distinguish between the essential safety elements to be kept in Part 21 and the non-essential implementation aspects that should be transferred to the AMC/GM to Part-21. The alternative option (Option 2) would be to defer this exercise to (a) future rulemaking task(s).

Preferred option:

Option 1, including Part-21 review, to introduce performance-based rulemaking principles.

The extra work for organisations with existing DOA and POA approvals needs to be mitigated by ensuring the revised, consistent rule and guidance material is no more prescriptive than it needs to be. The basic style and approach of Part 21 should not be changed.

5.5. Interfaces

5.5.1 Interface with tasks RMT.0262 & RMT.0611 (LOI)

The activity under tasks RMT.0550 & RMT.0612 on SMS should be closely coordinated with the activity under tasks RMT.0262 & RMT.0611 on LOI. For example the level of involvement of the Agency in certification projects of Design Organisations that have achieved SMS compliance is relevant to both tasks.

5.5.2 Interface with task RMT.0251 (MDM.055) - SMS for Commission Regulation (EC) No 2042/2003 organisations)

The activity under tasks RMT.0550 & RMT.0612 on SMS implementation should be coordinated with the activity under task MDM.055 on implementation of SMS by organisations within the scope of Commission Regulation (EC) No 2042/2003. The aim is to implement consistent SMS systems, in particular, in organisations having multiple approvals and to allow competent authorities to streamline and rationalise their procedures.

5.5.3 Interface with the FAA 21/SMS ARC project

The future SMS SG should establish contacts and monitor the work of the FAA 21/SMS ARC group on the implementation of SMS and performance-based oversight in FAR Part 21. European D & M industry will profit if both the US and EU SMS systems (and ultimately the SMS systems of other countries) are as close as possible, providing that the consistent systems are appropriate.

6. Conclusions

(To be completed with conclusions for the open issues and, if needed, changes to the assumptions.)

7. Attachments

A. Level of involvement (LOI) project – Descriptive note

B. Comparison of the Annex 19 SMS framework with EASA SMS framework

ATTACHMENT A

LEVEL OF INVOLVEMENT (LOI) PROJECT
DESCRIPTIVE NOTE

1. Rationale for the proposed changes

The recent publication of the revised Part 21 included as the Annex to Commission Regulation (EU) No 748/2012 has clarified the duties of applicants in product certification activities (type certificates, restricted type certificates, changes to TC, supplemental type certificates, repair design approvals, European technical standard orders).

The proposed revision of Part-21 aims at improving the current regulation in the following domains:

- Formal introduction of a risk-based approach both in product certification and design organisation approvals;
- Enabling the Agency to determine its level of involvement in product certification on the basis of consistently tangible criteria, based on safety risk;
- Introduction of the possibility to approve major changes, major repairs, and STC under a DOA privilege, under certain conditions;
- Establishment of product certification and design organisation approvals as two separate processes sharing the same common risk based elements; and
- Improvement of the clarity of Part 21 text, by separating the requirements applicable to product certification and design organisation approvals.

2. Scope of the proposed changes

2.1. *Principle of the proposed changes*

The proposed changes do not change the roles and repartition of the tasks between the applicant and the Agency for product certification activities when an EASA certificate has to be issued.

The principle is that the Agency will review and verify the demonstrations of compliance proposed by the applicant according to a predefined level of involvement (LOI):

- When the Agency does not verify, or, alternatively, when it is satisfied after its verification (which may need completion of several iterations), it does not issue any statement, nor any endorsement. The applicant proceeds with its final declaration of compliance, in response to which the Agency issues the approval certificate. This is the current Part-21 process and it is not modified; and
- When, on the other hand, the Agency is not satisfied after its verification, it shall issue a formal rejection of demonstration of compliance, which automatically results in a DOA finding and blocks the issuance of the certificate until the demonstration is modified and can be accepted by the Agency. This element is new.

Additionally, to avoid unnecessary administrative burden without any added technical value, a new privilege is introduced to allow design organisation approval (DOA) holders to issue themselves major design change or repair approval or STC, when the Agency has decided not to be involved in the verification of the demonstrations of compliance.

2.2. Impact on the chronology of certification projects

Certification projects typically comprise the following chronological phases:

(1) Familiarisation,

(2) Establishment of the type certification basis,

(3) Establishment of the certification programme,

(4) Compliance demonstration,

(5) Declaration of compliance, and

(6) Final report and issuance of the certificate.

The LOI project builds on the introduction of the certification programme by Commission Regulation (EU) No 748/2012. It does not, therefore, modify the chronology except for the establishment of the certification programme phase which also includes the determination of the LOI by the Agency.

2.3. Scope of the changes in Part 21

This project fully takes advantage of the structure of Part-21 and essentially comprises two main symmetrical paragraphs:

- Elements related to requirements set on the applicant for product certification are essentially contained in paragraph 21.A.20. For this purpose, two new clauses have been added, one of which coming from an existing paragraph, and
- Elements related to requirements set on the Agency for product certification activities are essentially contained in a new paragraph 21.B.20.

An additional clause is added to paragraph 21.A.21 to prevent the issuance of the certificate when the Agency is not satisfied with the demonstrations of compliance.

Another additional clause has been added to 21.A.258 to introduce an automatic link (a DOA finding) between type certification and design organisation approval when a demonstration of compliance is formally rejected by the Agency.

Finally, paragraph 21.A.263 has been modified to introduce the new DOA privilege, and adaptations are proposed to paragraphs 21.A.103, 21.A.115 and 21.A.437.

2.4. Acceptable means of compliance and guidance material

A significant amount of AMC and GM will need to be produced, in particular in the following domains:

- Content and level of detail of the certification programme;
- Criteria for determining the level of performance of design organisation;
- Criteria for determining the criticality of an item of the certification programme; and
- Criteria for determining the novelty of an item of the certification programme.

This soft law material is likely to be dependant on the type of product and the experts' discipline (or group of disciplines). It is proposed to develop the soft law material in cooperation with industry. It will be based on the current best practices augmented by the results of 'pilot projects'. These may consist of elements of ongoing projects on which the concepts are retrospectively tested, or completely new projects (or elements of projects) on which the LOI concept will be applied.

2.5. Compatibility with OSD

The proposed changes have been tested and found compatible with the OSD requirements which are on the process to be incorporated in Part-21 according to the most recent version of the OSD opinion.

3. Proposed changes to Part-21

Section 3.1 contains the typographical conventions used to describe the proposed changes to Part-21. The following sections respectively address:

– changes to section A implementing the LOI concept for type certificates and restricted type certificates;

– changes to section B implementing the LOI concept for the Agency;

– changes to section A extending the LOI concept to Subparts D, E, M, and O; and

– changes to section A implementing the additional privilege described in the proposed modified paragraph 21.A.263(c) (8).

3.1. Typographical conventions

The following conventions are used in this part of the document:

– Unchanged text is in this font,

– *Changed or additional text is in this font, and*

– [illegible]

3.2. Proposed changes to section A implementing the LOI concept for TC and RTC

21.A.20 Compliance with the type-certification basis and environmental protection requirements

(a) The applicant for a type-certificate or a restricted type-certificate shall demonstrate compliance with the applicable type-certification basis and environmental protection requirements and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant shall provide the Agency with a certification programme detailing the means for compliance demonstration. This document shall be updated as necessary during the certification process.

(c) The applicant shall record justification of compliance within compliance demonstration documents according to the certification programme established under point (b).

(d) The applicant shall declare that it has demonstrated compliance with the applicable type-certification basis and environmental protection requirements, according to the certification programme established under point (b).

(e) Where the applicant holds an appropriate design organisation approval, the declaration of point (d) shall be made according to the provisions of Subpart J.

(f) The Applicant shall timely allow the Agency to review any report and make any inspection and perform or witness any flight and ground test necessary to check the validity of its compliance demonstrations and to determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested, as defined by the level of involvement specified under point 21.B.208 (b).

(g) The Applicant shall regularly inform the Agency of the progress and of any significant difficulty encountered whilst demonstrating compliance.

21.A.21 Issue of a type certificate

The applicant shall be entitled to have a product type-certificate issued by the Agency after:

(a) demonstrating its capability in accordance with point 21.A.14;

(b) submitting the declaration referred to in point 21.A.20(d); and

(c) demonstrating that:

(1) the product to be certificated meets the applicable type-certification basis and environmental protection requirements designated in accordance with points 21.A.17 and 21.A.18;

(2) any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety;

(3) no feature or characteristic makes it unsafe for the uses for which certification is requested; and

(4) the type-certificate applicant has expressly stated that it is prepared to comply with point 21.A.44.

(d) In the case of an aircraft type-certificate, the engine or propeller, or both, if installed in the aircraft, have a type-certificate issued or determined in accordance with this Regulation.

(e) [illegible]

(f) All demonstrations of compliance subject to Agency verification according to point 21.B.208 (b) have been verified to the satisfaction of the Agency.

21.A.23 Issue of a restricted type certificate

(a) [illegible]

(b) [illegible]

(c) All demonstrations of compliance subject to Agency verification according to point 21.B.208 (b) have been verified to the satisfaction of the Agency.

21.A.33 Inspections and tests

(a) [illegible]

(b) [illegible]

[illegible]

[illegible]

(d) For tests performed or witnessed by the Agency to verify the demonstration of compliance of the applicant according to point 21.B.208 (b):

[illegible]

[illegible]

21.A.257 Investigations

The design organisation shall make arrangements that allow the Agency to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

[illegible]

[illegible]

21.A.258 Findings

[illegible]

[illegible]

[illegible]

[illegible]

(e) The rejection of a demonstration of compliance made by the Agency in accordance with 21.B.208 (c) shall result in a DOA finding classified according to point (a) and (b).

21.A.263 Privileges

[illegible]

[illegible]

[illegible]

[illegible]

(8) When, pursuant to 21.B.208(b), the Agency has concluded that it is not involved, the design organisation approval holder shall be entitled to issue the design approval.

3.3. Proposed changes to section B implementing the LOI concept

21.B.14 Level of performance of the design organisation

When acting in accordance with Subparts B, D, E, M and O, the Agency shall establish the level of performance of the design organisation.

21.B.208 Level of involvement

When acting in accordance with Subparts B, D, E, M, and O:

(a) The Agency shall notify the applicant once it has accepted the certification programme provided according to 21.A.20(b).

(b) For each item in the certification programme established under point 21.A.20 (b), the Agency shall determine its level of involvement in the verification of the demonstration of compliance and in determining that no feature or characteristic makes the product unsafe for the uses for which certification is requested, based on a combination of:

(1) the novelty and criticality of the certification item, including means of compliance and

(2) the level of performance of the design organisation, as established under 21.B.14, complemented as necessary by elements resulting from the circumstances listed under 21.B.208 (c).

(c) The following circumstances may be used by the Agency to complement or revise its level of involvement:

(1) accident, incident or unsafe condition related to the concerned item of the certification programme, or its technology, on any product, or

(2) change in the performance of the design organisation, or

(3) demonstration of compliance rejected by the Agency whilst verifying the demonstrations of compliance provided by the Applicant, for any ongoing certification project with this applicant, or

(4) revision of the certification programme established under point 21.A.20 (b), or

(5) technical or operational evolution in the field of the concerned item of the certification programme, its technology, or in the means of compliance identified in the certification programme, or

(6) information provided by the applicant under 21.A.20 (g).

(d) According to point (b), the Agency shall verify the demonstrations of compliance submitted by the applicant and determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested. For this purpose, it may require further clarifications from the applicant.

(e) When the Agency is not satisfied with the demonstration of compliance of the applicant and all attempts to resolve the situation have failed, it shall notify the rejection of the demonstration of compliance to the applicant, and the reasons thereof.

3.4. Proposed changes to section A extending the LOI concept to Subparts D, E, M, and O

3.4.1 Extension to major changes and STC

21.A.97 Major changes

(1) [illegible]

(2) [illegible]

(3) comply with points 21.A.20 (b), (c), (d), (f) and (g), and

(4) [illegible]

(5) [illegible]

(c) [illegible]

Note: [illegible]

3.4.2 Extension to repair design approvals

21.A.433 Repair design

(a) [illegible]

(1) [illegible]

(2) comply with points 21.A.20 (b), (c), (d), (f) and (g), and

(3) [illegible]

(b) [illegible]

3.4.3 Extension to ETSO

21.A.605 Data requirement

(a) [illegible]

(b) [illegible]

(c) [illegible]

(d) [illegible]

(e) [illegible]

(f) *for all other articles, the procedures referred to in point 21.A.602B(b)(2) and the certification programme referred to in 21.A.20(b).*

21.A.615 Verification by the Agency

The applicant for an ETSO approval shall comply with 21.A.20(f) and (g).

3.5. Proposed changes to section A resulting from the new privilege

Changes are introduced to 21.A.103, 21.A.115 and 21.A.437 to introduce approval by DOA holder when the Agency has concluded that it is not involved.

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Concept Paper

3.5.1 Extension to major changes

21.A.103 Issue of approval

(c) By derogation to this paragraph, a major change to the type design may be approved by the appropriately approved design organisation of the applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.208(b) and given that conditions (a) and (b) of this paragraph are met.

3.5.2 Extension to STC

21.A.115 Issue of a supplemental type certificate

(g) By derogation to this paragraph, the supplemental type certificate may be issued by the appropriately approved design organisation of the applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.208(b) and given that conditions (a) to (d) of this paragraph are met.

3.5.3 Extension to repair design approvals

21.A.437 Issue of a repair design approval

(c) for minor repairs only, by an appropriately approved design organisation under a procedure approved by the Agency, or

(d) For major repair design approval, by the appropriately approved design organisation of the Applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.208(b).

ATTACHMENT B

COMPARISON OF ANNEX 19 SMS FRAMEWORK WITH THE EASA SMS FRAMEWORK

European Aviation Safety Agency

RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060)
Concept Paper

ICAO Annex 19 SMS Framework	EASA SMS Framework
1. Safety policy and objectives	**– Safety policy, organisation and accountabilities**
1.1 – Management commitment and responsibility	• Organisational commitments for safety
1.2 – Safety accountabilities	• Lines of responsibility and accountability
1.3 – Appointment of key safety personnel	• Key safety personnel and roles
1.4 – Coordination of emergency response planning	• Safety objectives and performance standards
1.5 – SMS Documentation	• Resources for safety implementation
	• Organisation management system documentation
	• Emergency response plan (ERP)
2. Safety risk management	**– Safety risk management**
2.1 – Hazard identification	• Hazard identification
2.2 – Risk assessment and mitigation process	• Risk assessment and mitigation
3. Safety assurance	**– Safety assurance**
3.1 – Safety performance monitoring and measurement	• Compliance monitoring system
3.2 – The management of change	• Safety reporting procedure
3.3 – Continuous improvement of the SMS	• Internal occurrence reporting scheme
4. Safety promotion	
4.1 – Training and education	
4.2 – Safety communication	

- Internal safety investigation
- Safety performance and measurement
- Management of change
- Continuous improvement

— Personnel - Safety promotion
- Safety training
- Safety communication

ICAO Annex 19 SMS Standards	EASA Management System Implementing Rules
1. Safety Policy and Objectives **1.1 Management commitment and responsibility** The service provider shall define its safety policy in accordance with international and national requirements. The safety policy shall: (a) reflect organizational commitment regarding safety; (b) include a clear statement about the provision of the necessary resources for the implementation of the safety policy; (c) include safety reporting procedures; (d) [illegible] (e) be signed by the accountable executive of the organization;	**ORA.GEN.200 Management System** (a) The organisation shall establish, implement and maintain a management system that includes: (1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct safety accountability of the accountable manager; (2) a description of the overall philosophies and principles of the organisation with regard to safety, referred to as the safety policy; (3) the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;

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(f) [illegible]

(g) [illegible]

1.2 Safety accountabilities

[illegible]

a) [illegible]

b) [illegible]

c) [illegible]

d) [illegible]

e) [illegible]

1.3 Appointment of key safety personnel

[illegible]

1.4 Coordination emergency response planning

[illegible]

(4) [illegible]

(5) [illegible]

(6) [illegible]

(7) [illegible]

(b) [illegible]

ORX.GEN.205 Contracted activities

(a) [illegible]

(b) [illegible]

[illegible]

and services.

1.5 SMS documentation

1.5.1 The service provider shall develop an SMS implementation plan, [illegible]

1.5.2 The service provider shall develop and maintain SMS documentation that describes its:

a) safety policy and objectives;

b) SMS requirements;

c) SMS processes and procedures;

d) accountabilities, responsibilities and authorities for SMS processes and procedures; and

e) SMS outputs.

1.5.3 The service provider shall develop and maintain an SMS manual as part of its SMS documentation.

2. Safety risk management

2.1 Hazard identification

2.1.1 The service provider shall develop and maintain a process that ensures that hazards associated with its aviation products or services are identified.

2.1.2 Hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection.

2.2 Risk assessment and mitigation

The service provider shall develop and maintain a process that ensures

work under the approval of the organisation. The contracting organisation shall ensure that the competent authority is given access to the contracted organisation to determine continued compliance with the applicable requirements.

ORX.GEN.210 Personnel requirements

(a) The organisation shall appoint an accountable manager, who has the authority for ensuring that all activities can be financed and carried out in accordance with the applicable requirements. The accountable manager shall be responsible for establishing and maintaining an effective management system.

(b) A person or group of persons shall be nominated by the organisation with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager.

(c) The organisation shall have sufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements.

(d) The organisation shall maintain appropriate experience, qualification and training records to show compliance with point (c).

(e) The organisation shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.

ORX.GEN.215 Facility requirements

The organisation shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.

ORX.GEN.220 Record keeping

(a) The organisation shall establish a system of record keeping that analysis, assessment, and control of the safety risks associated with identified hazards.

3. Safety assurance

3.1 Safety performance monitoring and measurement

3.1.1 The service provider shall develop and maintain the means to verify the safety performance of the organisation and to validate the effectiveness of safety risk controls.

3.1.2 The service provider's safety performance shall be verified in reference to the safety performance indicators and safety performance targets of the SMS.

3.2 The management of change

The service provider shall develop and maintain a process to identify changes which may affect the level of safety risk associated with its aviation products or services and to identify and manage the safety risks that may arise from those changes.

3.3 Continuous improvement of the SMS

The service provider shall monitor and assess the effectiveness of its SMS processes to enable continuous improvement of the overall performance of the SMS.

4. Safety Promotion

4.1 Training and education

4.1.1 The service provider shall develop and maintain a safety training programme that ensures that personnel are trained and competent to perform their SMS duties.

4.1.2 The scope of the safety training programme shall be appropriate to [illegible]

allow adequate storage and reliable traceability of all activities developed, covering in particular all the elements indicated in [illegible].

(b) The format of the records shall be specified in the organisation's procedures.

(c) Records shall be stored in a manner that ensures protection from damage, alteration, and theft.

[illegible]

[illegible]

European Aviation Safety Agency — RMT.0262 & RMT.0611 and RMT.0550 & RMT.0613 (MDM.060)

[illegible]

each individual's involvement in the SMS.

3.2 Safety communication

The service provider shall develop and maintain a formal means for safety communication that:

a) ensures personnel are aware of the SMS to a degree commensurate with their positions;

b) conveys safety critical information;

c) explains why particular safety actions are taken; and

d) explains why safety procedures are introduced or changed.

[illegible]

[illegible]

Appendix F

Responses to Oversight / Assessment Relevant Questions

Oversight / Assessment Relevant Questions:

1. What FAA organizational changes have to be implemented to support robust oversight? Will the FAA need to have Centers of Excellence? Yes. Addressed in report.
2. What is the appropriate intent level of the oversight function? The intent of oversight is to validate the development of the defined system and verify compliance to the requirements. The level of oversight is determined by the risk level of the organization and activity (see risk section).
3. How will "one" oversight process be designed for AVS? Single surveillance model between engineering and production? Should the oversight be implemented for AIR initially with AFS to follow? Single centralized FAA Oversight organization.
4. Is it necessary to differentiate the oversight approach based on organization size, certificates, maturity, etc? If so what are the oversight criteria? The oversight approach is the same, however, the privileges / functions will vary, as will the depth and interval of surveillance based on organization size, maturity, certificates, etc (see surveillance section).
5. How will oversight be aligned to appropriately match the privilege and responsibility level of the organization? The level of oversight is determined by the risk level of the organization and activity (see risk section).
6. How is systems approach organizational oversight differentiated from level of involvement (LOI) at a project level? Organizational surveillance will be conducted by the Oversight organization, while LOPI will be conducted at local ACO level.
7. If ongoing oversight is based on performance and not compliance how can it be normalized by company and scalable? Oversight will be based on privileges / functions (defined by the Organization WG), and scale will be determined by the risk level of the organization and activity.
8. How important is it that the US model is harmonized, or at least recognized as fully equivalent, with other authorities' DOA/DO systems – today and in the future as they evolve? It is important and is addressed in report.
9. How does oversight change from overseeing a delegated organization (ODA holder) to an applicant showing organization? DO oversight is not over a delegated entity. See Section 5.
10. Should there be routine FAA oversight and audit of the design organization's processes or should this be accomplished via self-audit and reported to the FAA? Should it be a combination of both? It would be a combination of both. A DO's routine internal surveillance results will be fed into the risk model to determine interval and scope of FAA oversight. The FAA oversight will sample DO processes and products to validate strengths and potential gaps or 'blind spots' in the organization.
11. What safety risk-based structure will be imposed for assessed deviations to procedure? Assessed deviations to procedure will follow corrective action procedures defined in FAA Order 2150.3. The risk based evaluation of these will follow the principles established in the SMS.
12. How does AS9100, or equivalent, outside auditing equate to the FAA oversight system? (Compare actual FAA Approved Production QMS audit versus AS9100 findings.) Not addressed in report.
13. Should internal FAA QMS audits be used as a model? If not, what best practices can be benchmarked to develop framework? (Consider other industries.) Not addressed in report.
14. Should a system be generated to allow FAA resources to perform maintenance of organizations instead of a formal audit process (i.e., review of internal audits with a focus on verification and validation)? (Audit the management system elements not the findings.) Addressed with performance based oversight approach.

Implementation Relevant Questions:

1. What metrics / measures need to be established to ensure a successful implementation of organizational showing oversight? Recommending a separate activity to develop performance measures (Included in section 6)

2. What is the impact on oversight model / approach if any part of today's delegation system (individual or organization) authorization is retained? No impact to oversight approach. Retained items (e.g. LOPI) are handled separately and independently from oversight. If areas of a delegation are still necessary, the single oversight model must be addressed.
3. Can FAA accept Third-Party certification in lieu of FAA audit? Yes in some cases. Addressed in sections 4 and 6.
4. What critical criteria will be used to identify frequency and scope of oversight activity? Addressed in sections 4 and 5.
5. What are the other "triggers" that would cause additional FAA oversight? Addressed in section 5.

APPENDIX I—TSO SUBTEAM REPORT

GAMA TSO Sub-team Report
to the
Part 21/SMS Aviation Rulemaking Committee

TSO Design Approval Clarification and Program Enhancement

January 31, 2014

I. INTRODUCTION

This report summarizes the activities and recommendations developed by the General Aviation Manufacturers Association (GAMA) Technical Standard Order (TSO) Sub-team, chartered to support the deliberations of the FAA Part 21/SMS Aviation Rulemaking Committee (ARC) and its Design Organization (DO) Working Group (WG).

The report is intended to clarify the FAA TSO Design Approval processes, identify practical TSO implementation issues from both the FAA and industry perspectives, and recommend specific actions to resolve them. It is not intended to address the question of DO applicability to TSOA applicants or holders, which remains the responsibility of the Design Organization WG. Similarly, questions related to Safety Management Systems and Oversight requirements have been assigned to other ARC Working Groups and are not considered here.

The objective of this report is to present the background material and specific rulemaking proposals to be considered by the ARC in making its recommendations to the FAA regarding the clarification and enhancement of the current TSO program, as well as the establishment of an effective, efficient and globally recognized TSO program within the future DO accountability framework envisaged and to be proposed by the ARC.

Taken in its entirety, this report constitutes the TSO Sub-team recommendations detailing the guiding principles and attributes necessary to prepare regulatory language for the drafting of any NPRM, Policy and/or Guidance materials. While not a complete listing, recommended rule and preamble language is provided in the respective sections.

Note:
This report utilizes the content structure and formatting created by the Part 21 SMS ARC Design Organization Working Group in the Design Organization Concept Report, for consistency, ease of reference and incorporation in the final ARC report if as applicable.

II. BACKGROUND

II. A. FAA Part 21/SMS ARC and Design Organization Working Group Charter

On October 5, 2012, the FAA Administrator chartered an Aviation Rulemaking Committee for Part 21/Safety Management Systems (SMS). The Part 21/SMS ARC was tasked to recommend improvements to the effectiveness and efficiency of existing certification procedures for products and parts, along with incorporating SMS in the design and manufacturing environments. The ARC was tasked with making recommendations, including proposals for rulemaking, suggested processes, policies, and guidance as well as other actions the agency should take in support of its goal.

In addressing its charter, the ARC further chartered the Design Organization Working Group on March 17, 2013 to assist it in developing details associated with FAA recognition of Design Organizations in 14 CFR Part 21. The Working Group was tasked to define and address the details necessary for the FAA to recognize a Design Organization that meets organizational and system requirements sufficient to ensure that a Design Organization is capable of making compliance determinations upon which the FAA may rely.

The Design Organization WG adopted, as part of its charter, the task to recommend the types of organizations and product/part thresholds above which the application of Design Organization, and SMS, requirements should be considered mandatory.

II. B. TSO Sub-team Charter

The FAA Part 21/SMS ARC charter requests "consideration of proposed revisions to clarify and update design-oriented regulatory requirements in Part 21", including **"clarifying TSO design approval processes"**

In early planning discussions, the ARC directed that Design Organization applicability to TSO parts suppliers should be considered by the ARC's Design Organization WG. Other, practical TSO implementation issues were to be drafted as problem statements for consideration by a separate TSO Sub-team, within the ARC's overarching objectives for continuing improvement in safety, incorporating SMS/Continued Operations Safety (COS) processes and increased efficiency in the certification processes, as well as transitioning to a systems oversight framework that does not require FAA delegation.

GAMA's Technical Policy Committee approved the formation of the TSO Sub-team, which met initially on July 25, 2013, to consider the TSO problem statements brought forward by the FAA and industry and to recommend solutions in the form of Rulemaking, Policy and/or Guidance that, to the extent possible, support harmonization with international airworthiness authorities. The TSO Sub-team comprises FAA and industry representatives for multiple categories of TSO articles, including Avionics, Aircraft Instruments, APUs, Oxygen Systems, Seats, Cabin Safety and Cargo Handling Systems.

A copy of the GAMA Project Charter and a list of TSO Sub-team members are contained in Appendices A and B to this report, respectively.

While this document is the TSO Sub-team's final report to the ARC, the Sub-team has also identified topics for further discussion beyond the scope of the ARC. As such, the group will continue to operate as a GAMA Sub-team to serve as an industry forum for recommending and supporting ongoing improvements to the FAA TSO program, via stand-alone policy and guidance.

III. SUMMARY OF ACTIVITIES

III. A. Sub-team Work Plan

Following its initial meeting, in the course of three additional meetings – August 27, October 2-3 (Industry only) and November 13-14, together with an October 16 online meeting and several subsequent FAA coordination and editing meetings, the TSO Sub-team reconfirmed both the FAA's and industry's views of the continuing value and relevance of a sub-aircraft level approval process that installation developers can take credit for and can be reused across multiple installations.

A brief summary of the Sub-team's discussion of the TSO Program value and challenges is contained in Appendix C to this report. It is noteworthy that there was very close alignment in the views of the FAA and industry members representing the multiple categories of TSO articles.

The Sub-team reviewed all open items in the FAA's Part 21 Clean-up Matrix carried forward from the Part 21 (Production) re-write, including clarification of TSO Holder Part 21.3 responsibilities, clarification of TSO Deviation and acceptable Equivalent Level Of Safety (ELOS) procedures, as well as clarification of TSO design changes, part marking and integrated non-TSO functions. In addition, the problem statements identified by the Part 21/SMS ARC members and additional issues raised by industry during the 2013 FAA Parts Approval Workshop were considered for potential resolution by rulemaking, policy and/or guidance.

A list of the TSO issues and problem statements from the Part 21/SMS ARC members and from industry during the 2013 FAA Parts Approval Workshop is contained in Appendix D to this report.

It was reported at the October 2-3 meeting that the Design Organization WG had determined TSO will fall below the threshold for mandatory application of Design Organization, and SMS, requirements. The Sub-team proceeded to develop its recommendations on this basis but without precluding the possibility of a TSO organization voluntarily adopting DO, and SMS, requirements in a scalable fashion, consistent with its technical capabilities and the scope of TSO privileges envisaged.

Assumptions:

The TSO Sub-team assumes the following regarding broader ARC recommendations and related FAA policy activities.
1. The ARC will recommend that TSO organizations fall "below the threshold" of any mandatory requirement to become a Design Organization.

2. The ARC will recommend that an SMS will only be required for those organizations that fall "above the threshold" of any mandatory requirement to become a Design Organization.

3. The ARC will provide recommendations for DO organization requirements, whether applicability is mandatory or voluntary. The FAA is expected to adopt a subset of these DO organization requirements as TSO organization requirements under 14 CFR 21.605.

4. The ARC is expected to clarify that "substantiation data" does not need to be FAA approved. As such, the TSO Sub-team has tabled recommendations that would grant privileges to appropriately qualified TSO organizations for the approval of substantiation data (e.g., identification of "approved" DO-178 data, DO-160 data, flammability data, or other forms of data).

III. B. Product

With regard to the TSO Program value and challenges identified in Appendix C, the TSO Sub-team reviewed the list of issues and problem statements from the three sources (FAA, ARC Members and FAA-Industry Workshop), to distill the key issues that, if appropriately addressed, would lead to material improvements in the effectiveness and efficiency of the TSO program. These key issues are:

- Acceptance/approval of integrated Non-TSO functions
- Management of post-TSOA design discrepancies
- Definition of substantiation data and data submittal items
- Minimizing re-review of TSOA substantiation data at installation approval
- Elimination of unnecessary TSO deviation requests

The TSO Sub-team continued to develop six Rulemaking recommendations and proposals for related Policy & Guidance, for consideration by the Part 21/SMS ARC in its final report to the FAA. While Recommendation 1 below is written with reference to a "Certified TSO Organization", these recommendations are generally intended to be implementable by either a Certified TSO Organization or an expanded FAA (ODA) delegation system incorporating TSO Design functions.

Each of the following recommendations is supported with a Discussion Paper/draft narrative for a Background/Preamble section describing the issue being addressed; and a Recommendation/Proposed Rule section outlining the proposed rule or rule revision, and any related policy & guidance. In some instances a Benefits/Metrics section is provided, summarizing the expected benefits to the FAA and industry, together with associated metrics.

Summary of Recommendations:

1) Allowance for TSO Organizations to issue their own TSO authorizations, relative to scalable privileges for particular types of TSO standards

Alternate approaches via a Certified TSO Organization or expansion of TSO ODA functions

2) Clarifying the types of data that can be approved under TSOA (Type design of the article, and declared performance of the article including Non-TSO functions & Incomplete TSO), and expectations for acceptance of approved TSO data for installation

Require and approve Declaration of Design and Performance (DDP) via revision to 21.601(b)(2) and proposed new 21.603(a)(3)

3) Requirement to declare Non-TSO functions

Proposed new 21.603(a)(3) and 21.619(d) for subsequent design changes. Additional guidance to include a "decision table" to assist in differentiating between TSO Supporting Features and Integrated Non-TSO Functions

4) Rule revision to remove the term "model number" from TSO rules and replace it with a requirement for a "unique identifier"

Revision to 21.603(b) and 21.619 for subsequent design changes

5) Change to Part 21 to establish the effective TSO revision level at the beginning of the project, not at the end

Revision to 21.603(a)

6) Process for TSO Holder to continue marking TSO articles following a determination of "a design discrepancy that does not result in an unsafe condition"

Revision of 45.10(b) and proposed new 21.616(i)

Summary of Parking Lot Topics: Proposals for Future Policy and/or Guidance

1) Maintain privilege for TSO Holders to make minor and insignificant (sub-minor) changes to articles without further approval

2) Clarify TSO Application Data, Manufacturer Data and Furnished Data requirements (Ref. Sub-team Discussion Paper – "TSO Documents")

3) Develop expanded guidance to promote the uniform definition and treatment of Integrated Non-TSO Functions by applicants, installation developers and the FAA (Ref. Sub-team Discussion Paper – "Non-TSO Functions")

IV. RECOMMENDATIONS

IV. 1) Self-issuance of TSOA

Part 21 ARC
GAMA TSO Subgroup

Subject: Self issuance of TSO Authorizations by Certified TSO Organizations

Tasking: Determine if the FAA's statutory authority permits the FAA to change Part 21, Subpart O to allow TSO organizations to issue their own TSO authorizations with no FAA involvement.

Background: The TSO system has been described as a "self-certification" process, but in reality, it currently requires FAA involvement to verify the manufacturer's compliance statement and issue an authorization to apply TSO marking for each article. The FAA could better manage its resources and streamline the TSO process by allowing the traditional FAA review portion to be performed by Certified TSO Organizations or appropriately delegated organizations, up to and including issuance of the TSO authorization letter. The FAA already has a rule-basis to qualify TSO organizations under 21.605. But Part 21 Subpart O currently requires an application to be submitted to the ACO (under 21.603) and the FAA to issue the authorization (under 21.611).

Recommendation: Rule changes to § 21.603 and 21.611 should be considered to allow for TSO organizations to apply for the privilege of issuing their own TSO authorizations. The expectation is that this privilege would require specific capabilities that may not be required of all TSO organizations under 21.605. As such, 21.605 would also be amended to specify expectations for organizations seeking the privilege of self-issuance. The FAA, via policy, would be expected to use these new regulatory capabilities to describe a scalable system of organizational privileges. For example, the FAA may specify organizational capabilities necessary for an organization to receive the privilege for each TSO standard, or for groups/classes of TSO standards. The FAA would specify oversight requirements to monitor use of this privilege, and to take action against improper use of the privilege.

Proposal: Based on the above, the following changes are proposed for the committee's consideration to address self-issuance of TSO authorizations.

§ 21.601 Applicability and definitions. *(Proposed)*

(a) This subpart prescribes—

—

(b) For the purposes of this subpart—
(1) A TSO issued by the FAA is a minimum performance standard for specified articles used on civil aircraft;
(2) A TSO authorization is an FAA design and production approval issued to the manufacturer of an article that has been found to meet a specific TSO;
(3) A letter of TSO design approval is an FAA design approval for an article that has been found to meet a specific TSO in accordance with the procedures of §21.621;
(4) An article manufactured under a TSO authorization, an FAA letter of acceptance as described in §21.613(b), or an article manufactured under a letter of TSO design approval described in §21.621 is an approved article for the purpose of meeting the regulations of this chapter that require the article to be approved; and
(5) An article manufacturer is the person who controls the design and quality of the article produced (or to be produced, in the case of an application), including any related parts, processes, or services procured from an outside source;
(6) A Certified TSO Organization is an FAA operating certificate for the issuance of TSO authorizations.

§ 21.603 Application *[Proposed]*

(a) ***Other than as described under 21.603(d), an*** applicant for a TSO authorization must apply to the appropriate aircraft certification office in the form and manner prescribed by the FAA. The applicant must include the following documents in the application:

—

(d) An applicant for a Certified TSO Organization certificate must apply by submitting an application to the appropriate aircraft certification office in the form and manner prescribed by the FAA.

§ 21.605 Organization. *[Proposed]*

(a) Each applicant for or holder of a TSO authorization must provide the FAA with a document describing how the applicant's organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

(b) Each applicant for or holder of a Certified TSO Organization certificate must provide and maintain documentation describing the applicant's organization and system for managing safety and compliance of TSO authorizations issued under its approval.

§ 21.611 Issuance. ***[Proposed]***

(a) If the FAA finds that the applicant ***for TSO authorization*** complies with the requirements of this subchapter, the FAA issues a TSO authorization to the applicant (including all TSO deviations granted to the applicant).

(b) A Certified TSO Organization certificate holder may issue a TSO authorization when it determines that an article complies with the requirements of this subchapter and may be approved in accordance with the Certified TSO Organization operating certificate issued under 21.6xx. (See Note 2 below).

NOTES:

1. This recommendation suggests the FAA will maintain 2 systems for TSOA, i.e. The Certified TSO Organization and the traditional, FAA managed TSOA project. Certified TSO Organizations will not be authorized to act as TSOA Agents for third party TSOA projects.

2. TBD. Will need an explicit rule describing the FAA's additional responsibility for issuing Certified TSO Organization operating certificates and retained responsibility for the review and approval of TSO Deviation requests.

3. TBD. Will need an explicit rule describing the FAA's authority to oversee Certified TSO Organizations and to revoke a Certified TSO Organization's Certificate.

Parking Lot Question: Would the FAA directly oversee Certified TSO Organizations or would it be possible for the FAA to assign oversight responsibilities to a third-party industry organization? The latter approach may diminish the reusability of the "FAA TSOA" credentials, especially with regard to acceptance by foreign authorities.

IV. 2) Require and Approve Declaration of Design and Performance (DDP)

Part 21 ARC
GAMA TSO Subgroup

Subject: Incorporate a Declaration of Design and Performance as a Required Element for FAA TSO Approval

Background: Under current rules, the holder of a TSO authorization is expected to maintain the performance of the TSO article relative to the TSO standard. However, in order to support airworthiness or contractual requirements, TSO manufacturers are typically required by their customers to maintain performance of the article relative to requirements that are not part of the TSO standard. The TSO system could be modified to allow manufacturers to better align their requirements under the TSO system with those requirements they are electing to meet as part of airworthiness or contractual obligations. EASA's system supports the declaration of this type of manufacturer-defined performance by requiring the submission of a declaration of design and performance, and expects TSO manufacturers to control the article's performance relative to that DDP.

Recommendation: The FAA should require submission of a DDP as part of a TSO application. TSO manufacturers should be required to maintain the performance of the article relative to the DDP. Except where required by other FAA policy (e.g., see Section IV.3, discussion of required declaration of non-TSO functions), the manufacturer should not be required to declare any performance that goes beyond the minimum requirements of the TSO. Instead, the manufacturer may elect to align their DDP with the TSO requirements, or they may elect to include additional requirements or performance levels that go beyond the minimum requirements of the TSO. This approach affords flexibility to the TSO manufacturer so they can align their regulatory responsibilities under the TSO system with any external contractual or airworthiness requirements that also apply to the TSO article. But no additional burden is added in requiring the TSO article to maintain performance that exceeds the minimums required by the TSO, unless the performance declared in the DDP exceeds the minimum TSO requirements.

Proposal: Based on the above, the following changes are proposed for the subcommittee's consideration to address the incorporation of a DDP into the TSO system:

§ 21.601 Applicability and definitions. *(Proposed)*

(b) For the purposes of this subpart—
(1) A TSO issued by the FAA is a minimum performance standard for specified articles used on civil aircraft;
(2) A TSO authorization is an FAA design and production approval issued to the manufacturer of an article that has been found to meet ***applicable TSO standards. Any data specified in the TSO authorization's declaration of design performance is considered to be approved;***

§ 21.603 Application. *[Proposed]*

(a) An applicant for a TSO authorization must apply to the appropriate aircraft certification office in the form and manner prescribed by the FAA. The applicant must include the following documents in the application:
(1) A statement of conformance certifying that the applicant has met the requirements of this subpart and that the article concerned meets the applicable TSO that is effective on the date of application for that article.
(2) One copy of the technical data required in the applicable TSO.
(3) One copy of a declaration of design and performance for the article and supplementary data, if needed to support any declaration of performance exceeding the minimum TSO requirements.

NOTES:

1. Minimum required DDP content should be defined in a revision to AC21-46 (Reference EASA AMC 21.A.608 for minimum DDP content).
2. If this proposal to require and approve a DDP is not accepted, another solution will be needed to address the question of what TSO approval actually approves. This may require further definition that any data specified in the TSO authorization is approved data.

IV. 3) Requirement to Declare Non-TSO Function

Part 21 ARC
GAMA TSO Subgroup

Subject: Non-TSO functions included in a TSO article

Tasking: Determine if Part 21, Subpart O, changes are necessary to address added non-TSO functionality in a TSO article, or can it be handled by TSO policy only (i.e. Order 8150.1C).

Background: Non-TSO function(s) have become more and more prevalent in avionics systems mainly due to added processing capabilities in newer integrated circuits as well as larger and cheaper memory capabilities. However, mechanical systems TSOs, such as seats, can also contain provisions to host non-TSO functions (e.g., embedded passenger entertainment devices). These added non-TSO functions are mainly market or OEM driven to optimize installation capabilities while minimizing certification costs. Added non-TSO functions have historically been handled through FAA policy, since Part 21 Subpart O does not specifically address or codify their embedded existence. This has resulted in a problem with some ACOs who feel that current Part 21 Subpart O does not allow for a more detailed evaluation of the non-TSO function(s) at the time of TSO approval, even though in reality, the added non-TSO function(s) is/are inseparable from the hosting TSO article design at the time of manufacture.

Recommendation: A rule change to § 21.603 should be considered to address added non-TSO function(s) incorporated in a TSO article approval. Building under a TSO design and manufacturing approval is a privilege. Since the TSO label is affixed at the time of final inspection it represents the final approved configuration, which may include embedded non-TSO functionality. For this reason the FAA should have the authority to require the manufacturer to declare, at the time of TSO application, all non-TSO functionality contained in the final approved configuration that is intended to be acknowledged in the TSO authorization. It should be noted that the non-TSO function(s), once acknowledged by the FAA, are considered inseparable in the approved design. Design changes (minor/major) to the TSO function are addressed by § 21.619, however, a minor change to the non-TSO function(s) still requires an analysis of its impact on the required performance of the hosting TSO.

Proposal: Based on the above, the following changes to § 21.603 are proposed for the committee's consideration to address added non-TSO functionality.

§ 21.603 Application ***[Proposed addition of new subparagraph (a)(3) and minor revision to subparagraph (b) in accordance with Recommendation 4)]***

(a) An applicant for a TSO authorization must apply to the appropriate aircraft certification office in the form and manner prescribed by the FAA. The applicant must include the following documents in the application:
(1) A statement of conformance certifying that the applicant has met the requirements of this subpart and that the article concerned meets the applicable TSO that is effective on the date of application for that article.
(2) One copy of the technical data required in the applicable TSO, ***and;***
(3) The applicant must also submit one copy of the technical data for any additional declared function(s) not required for the performance of the TSO function. This data must include the manufacturer's declared performance and design assurance level of the added function(s).
(b) If the applicant anticipates a series of minor changes in accordance with Sec. 21.619, the applicant may set forth in its application the basic ***unique identifier*** of the article and the part number of the components with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.
(c) If the application is deficient, the applicant must, when requested by the FAA, provide any additional information necessary to show compliance with this part. If the applicant fails to provide the additional information within 30 days after the FAA's request, the FAA denies the application and notifies the applicant.

§ 21.619 Design changes ***[Proposed addition of new subparagraph (d)]***

(a) Minor changes by the manufacturer holding a TSO authorization. The manufacturer of an article under an authorization issued under this part may make minor design changes (any change other than a major change) without further approval by the FAA. In this case, the changed article keeps the original model number (part numbers may be used to identify minor changes) and the manufacturer must forward to the appropriate aircraft certification office, any revised data that are necessary for compliance with Sec. 21.603(b).
(b) Major changes by the manufacturer holding a TSO authorization. Any design change by the manufacturer extensive enough to require a substantially complete investigation to determine compliance with a TSO is a major change. Before making a major change, the manufacturer must assign a new type or model designation to the article and apply for an authorization under Sec. 21.603.
(c) Changes by persons other than the manufacturer. No design change by any person (other than the manufacturer who provided the statement of conformance for the article) is eligible for approval under this part unless the

person seeking the approval is a manufacturer and applies under Sec. 21.603(a) for a separate TSO authorization. Persons other than a manufacturer may obtain approval for design changes under part 43 or under the applicable airworthiness regulations of this chapter.

—

(d) If additional functions are declared in accordance with 21.603(a)(3), then the manufacturer must ensure that any design changes to those functions do not:
1) Impact the performance of approved TSO function(s); or
2) Change the declared performance of the additional function(s).

Benefit: *For the TSO applicant* – an initial review of the manufacturer-declared performance can be made, and credit for software, hardware, and environmental testing, in support of installation, can be acknowledged in the TSOA letter. *For the FAA* – more efficient use of engineering resources since the review of the added function(s) can be more thoroughly accomplished with the TSO manufacturer as opposed to attempting to accomplish this review during each subsequent installation approval. It should be noted that both the TSO article as well as the integrated non-TSO function(s) must be appropriate to support the intended installation.

NOTES:

1. The development of additional policy and/or guidance is essential to assist in determining a Supporting TSO Feature vs. an Integrated Non-TSO Function and to promote standardized and unambiguous interpretation. Table 1 below may be used as basis for developing additional common policy and/or guidance in Order 8110.4, Order 8150.1, AC 21-46 and/or AC 21-50.

2. The minimum DDP content definition noted in Recommendation 2) above should include, for any additional declared function(s) not required for the performance of the TSO function, appropriate reference to i) An analysis showing that the added function(s) will not interfere with required TSO performance in the article, and ii) Any limitations or continued maintenance and preventive maintenance actions necessary to ensure that the added function(s) continues to meet the manufacturer's declared performance.

3. Proposed new subparagraph § 21.603(a)(3) would become new subparagraph § 21.603(a)(4) following adoption of Recommendation 2) above, which also adds a new subparagraph § 21.603(a)(3).

Table 1.

Determination of a Supporting TSO Feature vs. an Integrated Non-TSO Function

Identifying any Integrated Non-TSO Function within a TSO article is necessary to assure the function is properly evaluated as part of the TSOA and for installation approval. The following table will help you distinguish between a supporting TSO feature and an integrated non-TSO function hosted within the TSO article[1]. Keep in mind that whether a "supporting TSO feature" or an "integrated non-TSO function", both require an installation approval to evaluate compatibility and intended function.

Step	Does...	Considerations	If yes...	If no...
1	It directly support the usability, performance, or design assurance of the hosting TSO?	In many cases the TSO manufacturer may add features to improve the utility of the article, to differentiate their product from a competitor's, or to support a design assurance level. Examples of such features include the flip-flop of the active and standby frequency in a VHF radio; providing supplemental airport information in an FMS database; or adding an electrically operated recline to a passenger seat. If you are having difficulty making this determination, then ask the reverse question: "*Would it have any useful purpose if the hosting TSO did not exist?" In the example of a built-in-test-equipment (BITE) check in a transponder, the answer would be no, since the BITE check has no purpose beyond supporting the hosting TSO and it should be considered a feature.*	It should be treated as a "**supporting feature**" of the hosting TSO.	Go to Step 2
2	Another TSO cover this function?	If the function is covered by another TSO, the applicant should comply with that TSO's performance requirements as, by definition, it can no longer be considered a "Non-TSO Function". It should be noted that a TSO authorization is *not* the only means to achieve an article approval—an applicant can also use the TC or STC process and then, using the approved data, seek manufacture authority for the article under a 14 CFR §21.303 PMA authorization. Therefore, the applicant may choose to either comply with the applicable TSO for the function, or approve the entire article under the TC/STC process as appropriate.	Comply with the performance requirements of the applicable TSO, or use the TC/STC process to achieve article approval.	TSO applicant should declare this as an "**Integrated Non-TSO function**".

[1] Whether a supporting TSO feature or an integrated Non-TSO function, the manufacturer must demonstrate neither will adversely impact the required performance of the TSO(s) included in the article.
[2] Depending on the complexity of the integrated Non-TSO function, a concurrent TC or STC evaluation may be necessary to properly evaluate the integrated Non-TSO functionality.

IV. 4) Replace Model Number with Unique Identifier

Part 21 ARC
GAMA TSO Subgroup

Subject: Replace "Model Number" requirements with "Unique Identifier" requirement

Background: Current regulations require the use of model numbers to maintain configuration control of TSO authorizations. But from a practical perspective, model numbers are frequently used as marketing identifiers; they do not consistently provide a meaningful reference for configuration control of TSO article designs.

Recommendation: The Group recommends eliminating the requirement to use a model number, but should not preclude the use of a model number. Group recommends making the rule require a "unique identifier". Policy and guidance can specify that base part number is the recommended means of compliance. Policy or guidance is needed to clarify that "sub-approval level" changes do not need to be documented as a "minor change" under the rule. The current rule language structure is appropriate (keep the current definition for major changes but better define what constitutes a minor change… require new application for major changes and allow flexibility for minor changes).

The intent of the rule is to maintain configuration control of the approved descriptive data and approved performance of the article. Any change to the approved descriptive data for the article or approved performance of the article must be documented as either a major or minor change. Changes that do not affect approved descriptive data (e.g., sub-assembly, MRB, lower-level design drawing changes) are addressed under production configuration control requirements in 21.137, are not considered a change to the TSOA, and do not require a change to the unique identifier for the article. Changes to an article that do not affect approved performance for the article (e.g., re-substantiation to verify that sub-minor changes yield the same approved performance level) are not considered a change to the TSOA, but may require resubmittal of furnished data. Changes to the approved performance level of all articles covered by the TSOA (e.g., new substantiation to qualify existing and future articles to a higher performance level) are considered to be a change to the TSOA but do not require a change to the unique identifier for the article.

Proposal: Based on the above, the following changes are proposed for the committee's consideration to address replacement of model number configuration control requirements with unique identifier requirements:

§ 21.603 Application [Proposed]

(b) If the applicant anticipates a series of minor changes in accordance with §21.619, the applicant may set forth in its application the basic ***unique identifier*** of the article and the part number of the components with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.

§ 21.619 Design changes [Proposed]

(a) *Minor changes by the manufacturer holding a TSO authorization.* The manufacturer of an article under an authorization issued under this part may make minor design changes (any change other than a major change) without further approval by the FAA. In this case, the changed article keeps the original ***unique identifier*** (part numbers may be used to identify minor changes)~~***and the manufacturer must forward to the appropriate aircraft certification office, any revised data that are necessary for compliance with §21.603(b)***~~.

(b) *Major changes by the manufacturer holding a TSO authorization.* Any design change by the manufacturer extensive enough to require a substantially complete investigation to determine compliance with a TSO is a major change. Before making a major change, the manufacturer must assign a new ***unique identifier*** to the article and apply for an authorization under §21.603.

IV. 5) Establishing the Effective TSO Revision Level

Part 21 ARC
GAMA TSO Subgroup

Subject: Change to TSO Application Process in Part 21 to establish the effective TSO revision level at the beginning of the project, not at the end.

Tasking: Determine language changes to Part 21, Subpart O, to establish the Effective TSO Revision Level at the beginning of a TSO development project.

Background: Current regulation (14 CFR 21.603(a)(1)) implies that application for TSO is made after all design and development is completed. Designing and developing a TSO article is a lengthy process especially for complex articles. During this time, TSOs could be revised or new TSOs could be introduced. Current policy, as defined in FAA Order 8150.1C, section 6-1.b., allows an applicant six (6) months from release of a newer revision to apply with the previous revision. Although six (6) months seems to be a reasonable timeframe, many complex system developments take significantly longer and the six (6) month grace period is not sufficient. The two (2) current options to address this situation are:

1. Request a petition for exemption (per 14 CFR 11) which an applicant is required to submit at least 120 days before the exemption is needed. After submission, approval can take many months due to the requirement of publication in the Federal Register and a public comment period.
2. Comply with the newer revision TSO or add a newly released TSO.

If a new revision of a TSO or newly introduced TSO provides no benefit or does not impact flight safety, this additional work to submit a petition for exemption or complying with the latest TSO during an in-process development project could be a large burden on an applicant, potentially driving re-redesign and/or re-test and preventing expeditious introduction of safety enhancing products to market.

Since TSOA is a self certification based upon a statement of conformance, the responsibility of reviewing and ensuring any new or revised TSO(s) does not affect the certification basis or design is the burden of the TSO applicant regardless of when application is made.

Recommendation: A rule change to 14 CFR 21.603(a) should be considered to address the allowance of declaring the effective TSO revision at the beginning of a design and development project, in the same manner of Type Certificate applicants (reference 14 CFR 21.17(c)). When a TSO project is started, the applicant submits a Project Specific Certification Plan (PSCP) or equivalent. The PSCP or equivalent would be used to define the effective TSO revision level and the agreed upon time period for which it will remain effective.

§ 21.603 Application *[Proposed]*

(a) An applicant for a TSO authorization must apply to the appropriate aircraft certification office in the form and manner prescribed by the FAA. ***The application must declare the effective TSO revision level(s) that describe the certification basis and a unique identifier for the article. In addition, the applicant must propose and the FAA must accept the deadline by which the development project will be completed and the following documents submitted to the aircraft certification office.***

Benefit: If the applicant is allowed to declare the effective TSO revision levels at the beginning of a project, FAA/Applicant communication on complex certification issues could be improved. Presently, when application is submitted, there could be several iterations due to certification basis disagreements causing potential applicant design rework and weeks to months of delay in issuance of a TSOA letter. Based upon the regulation change, adoption of the new or recently revised TSO(s) would be voluntary unless the change is due to a safety of flight issue or required for other reasons, such as interoperability, and deemed mandatory by the FAA.

The benefits of this change can be tracked through improved turnaround time of TSOA Letter issuance from the FAA, upon final submittal of a statement of conformance certifying that the applicant has met the requirements of the subpart and that the article meets the applicable TSO(s).

NOTES:

1. Develop specific guidance for declaring the effective TSO revision level basis and agreed upon time period for the application, for inclusion in Order 8150.1 and/or AC21-46. The Sub-team anticipates developing a more specific set of expected time frames for the development of different types of TSO articles, for inclusion in future Policy/Guidance. Both of these initiatives would also benefit from review and coordination with foreign authorities.

2. If adopted as drafted, this Recommendation does not conflict with other changes to §21.603(a) resulting from Recommendations 1, 2, 3 and 4.

IV. 6) Continued Marking of TSO Articles

Part 21 ARC
GAMA TSO Subgroup

Subject: Marking of an article upon discovery of a post-TSO approval design discrepancy.

Tasking: Determine if recent Part 21, Subpart O, changes, implemented with Amendment 21-92, dated 4/16/2011, now allows TSO holders the flexibility to continue to mark TSO articles that are found, "post-TSO approval" to contain a design deficiency that does not result in a unsafe condition.

Finding: The requirement that the article must meet all applicable TSO performance standards in order to be marked is still in effect, but was moved to § 45.10(b).

Background: Prior to the Part 21 and 45 changes implemented by Amendment 21-92, dated 4/16/2011 and Amendment 45-26, dated 4/16/2011, respectively, the requirement that an article meet applicable TSO performance standards in order to be so marked was defined in § 21.603 as shown below:

> **§ 21.603 TSO marking and privileges**
>
> (a) Except as provided in paragraph (b) of this section and Sec. 21.617(c), no person may identify an article with a TSO marking unless that person holds a TSO authorization and the article meets applicable TSO performance standards.

With the Part 21 and 45 Amendment changes implemented in 4/16/2011, the previous § 21.603(a) requirements were recodified into § 45.10(b) as shown below, which still requires the article to meet applicable performance standards before marking can be applied:

> **§ 45.10 Markings**
>
> No person may mark a product or article in accordance with this subpart unless--
> (a) That person produced the product or article --
> (1) Under part 21, subpart F, G, K, or O of this chapter, or
> (2) For export to the United States under the provisions of an agreement between the United States and another country or jurisdiction for the acceptance of products and articles; and
> (b) That product or article conforms to its approved design, and is in a

condition for safe operation; and, for a TSO article, that TSO article meets the applicable performance standards.

Currently, when a TSO holder identifies a design deficiency, the holder must stop shipment (i.e., stop marking per § 45.10(b)) and report the deficiency to the ACO. If the ACO determines that the deficiency does not result in an unsafe condition (i.e., does not require a 14 CFR § 39.1 action), then to resume shipping of articles the TSO holder must either correct the deficiency immediately (which may not be practical), or, more typically, request a deviation under § 21.618. However, the intent of the § 21.618 provision was to provide a means for the TSO "applicant" to propose a true "equivalent level of safety" to a TSO performance requirement, and was not meant to forgive a design deficiency or oversight of the TSO holder. Therefore, in an effort to apply a "managed risk" approach, it is recommended that a revision to § 45.10(b) and the addition of a new paragraph to § 21.616, "Responsibility of holder", be proposed by the Part 21 ARC to allow a TSO holder to resume shipping with the TSO marking when an ACO-accepted corrective action plan has been proposed and implemented.

Proposal: Based on the above, the following change to § 45.10(b) and the addition of a paragraph (i) to § 21.616 are proposed for the committee's consideration.

§ 45.10 Markings ***[Proposed deletion in paragraph (b)]***

No person may mark a product or article in accordance with this subpart unless--
(a) That person produced the product or article --
(1) Under part 21, subpart F, G, K, or O of this chapter; or
(2) For export to the United States under the provisions of an agreement between the United States and another country or jurisdiction for the acceptance of products and articles; and
(b) That product or article conforms to its approved design, and is in a condition for safe operation~~; **and, for a TSO article, that TSO article meets the applicable performance standards.**~~

§ 21.616 Responsibility of holder ***[Proposed new paragraph (i)]***

(c) Ensure that each manufactured article conforms to its approved design, is in a condition for safe operation, and meets the applicable TSO;

—

(i) Notwithstanding paragraph (c) of this section and § 21.3, a holder of a TSO authorization may, upon discovery of a discrepancy in the approved design, continue to manufacture a TSO article if:

(1) The discrepancy is reported to the FAA;
(2) The FAA determines that the discrepancy does not result in an unsafe condition; and
(3) The TSO holder implements a corrective action plan that is accepted by the FAA.

Benefit: Provides for a risk-based approach to handle TSO design deficiencies that do not rise to the level of an "unsafe" condition. May also be in the public's interest in the case where the stop shipment could result in a major economic burden to the end-user of the article.

Appendix A
GAMA TSO Sub-team Charter

General Aviation
Manufacturers Association
[illegible]

April 24, 2013

Project Charter: Technical Standard Order (TSO) Program Improvement

Sponsor: GAMA Avionics & Electronic Systems Subcommittee (AVI) & FAA Part 21/SMS ARC

Objective: The project group will consider TSO Problem Statements brought forward by the FAA and industry, and recommend solutions in the form of Rulemaking, Policy and/or Guidance.

Background: The FAA's Part 21/SMS ARC charter requests "consideration of proposed revisions to clarify and update design-oriented regulatory requirements in Part 21", including "clarifying TSO design approval processes".
In early planning discussions, the ARC determined that Design Organization (S)MS and Oversight applicability to TSO Suppliers should be considered by the ARC's Organization WG. Other, practical TSO implementation issues should be drafted as Problem Statements for initial consideration by a supplementary WG to be formed later. Such consideration shall be within the ARC's overarching objectives for continuing improvement in safety, incorporating SMS/GOM and increased efficiency in the certification processes, as well as transitioning to an overall systems oversight framework that does not require FAA delegation.

Tasks: The project group will develop recommendations for use by the Part 21/SMS ARC, and the FAA directly for any recommendations not requiring rulemaking, over the next 6-8 months. The project group will identify and review existing regulatory requirements, policy, guidance, industry practice, specific TSOs as necessary, and any other available sources of pertinent information relating to the following three objectives:

- 14 CFR Part 21. In particular, all open items in the FAA's Part 21, Subpart O (21.6XX) Clean-up Matrix carried forward from the Part 21 (Production) re-write, should be addressed in accordance with the ARC's charter to "Clarify the TSO design approval process". These include, without limitation, clarification of TSO Holder Part 21.3 responsibilities, clarification of TSO Deviation (and acceptable ELOS) processes, and clarification of TSO design changes, part marking and integrated non-TSO functions.

- Develop and address the initial TSO Problem Statements submitted by the FAA and industry, identifying areas of overlap with the FAA's Clean-up Matrix for rulemaking action, as well as areas that could be addressed through policy and/or guidance.

- Describe the transition plans and timescales for recommendations, including applicability to existing/legacy products.

Product: The project group shall develop any recommendations for rulemaking for use by the Part 21/SMS ARC in its final report to the FAA, early 2014. The project group shall also develop any recommendations for policy and/or guidance to advocate directly with FAA for nearer-term improvements, as well as obtaining endorsement through the Part 21/SMS ARC. All recommendations should support harmonization of the approach, to the extent possible, with appropriate national authorities.

Membership: The project group shall consist of representatives from the industry and FAA, representing the interests of Avionics and other categories of TSO articles, e.g. Cabin Equipment, Wheels/Brakes, Life Rafts or APUs.

Schedule: The project group shall commence no later than May 2013 and complete activity as soon as practical with final recommendations submitted to the FAA and the Part 21/SMS ARC by December 2013.

Resources: 10-15 people, 2-4 project meetings, teleconferences/webmeetings and email coordination.

Approval: The project was proposed to/approved by the TPC and AVI in April 2013.

Appendix B
GAMA TSO Sub-team Members

NAME	ORGANIZATION
Industry Representatives:	
Anderson, Tom	EVAC UTAS, UTC & SAE S-9
Barber, Fred	Avidyne
Boullay, Edmond	US Crest Group
Chevrel, Cedric	Thales
Garner, Robert	Odyssey II Solutions & SAE A-10
Islam, Raki	Zodiac Aerospace & SAE SEAT
Mahone, Bruce	SAE International
Moynihan, Pat	UTAS, UTC & SAE A-4
Neeld, Jonathon	CSafe Global & SAE AGE-2A
Parelon, Eric	Thales
Rogozinski, Tom	Honeywell
Ruggles, Van	Garmin
Sambiase, Joe	GAMA
Spross, Tim	L-3
Southgate, Roger	Rockwell Collins
Tew, Paul	Universal Avionics
FAA Representatives:	
Brockmann, Matthew	AIR-130
Greer, Paul	AGC-200
Jennings, Richard	AIR-130
Law, Douglas	AIR-120
Linegang, Michael	AIR-120
Powell, Victor	AIR-110

Appendix C
TSO Program Values and Challenges

FAA Team Members' Perspective

Value:

- TSO reduces duplicate use of FAA resources to evaluate the same article multiple times for different installations (e.g., fewer designees)
- TSO supports simplification of after-market installation approvals (e.g., facilitates field approval process for simple modifications & replacement) and changes to type design (e.g., major/minor)
    - Note: does not apply well to things like slide rafts, fly-by-wire, EICAS etc. because the TSO article is highly integrated with the aircraft installation
    - Note: does not apply well to cargo equipment or portable articles because there is no installation approval for the equipment.
- TSO supports interoperability of avionics with the air traffic system
    - Note: primarily applies to Comm, Nav, and Surveillance equipment
- TSO supports approval of designs for equipment that is not installed in the aircraft
- TSO supports establishment of equipment-based operational requirements
- TSO provides production approval for equipment independent of aircraft-level approval
- TSO provides an avenue to identify common-cause COS issues that are tied to a specific article (vs. without TSO, COS issues would be tied to each aircraft individually, but difficult to identify across multiple aircraft)
- FAA recognition of industry consensus standards encourages use of technical standards (and can require the use of the newer standard in the case of TSO)
- FAA recognition of new and updated standards encourages advancement of technology
- TSO encourages the addressing of requirements at the lower level supplier's level (vs. relying only on aircraft-level requirements to trickle down to suppliers)

Challenges:

- Standards become outdated or misaligned with airworthiness requirements
- TSO approval can be misunderstood when TSO standards are outdated
- TSO approval can be misunderstood when the installation requires specific performance from TSO article (beyond the minimum TSO requirements) or the TSO article's performance is highly dependent on the installation
- TSO approval can be misunderstood when the TSO article includes incomplete TSO approval, non-TSO functions, or other performance not specific to the TSO standard
- FAA does not have clear policy / criteria for oversight of TSO article designers
- TSO adds complexity in continued airworthiness/maintenance due to the need to maintain two approval bases for the article and aircraft
- Configuration management – TSO minor changes and aircraft-level changes both need to be assessed

Industry Team Members' Perspective

Value:

- Marketability
- FAA TSO approval provides international recognition
- FAA TSO approval process is relatively harmonized with other international article approval processes
- TSO allows the manufacturer to make minor changes to the design
- TSO supports lower cost / economies of scale for equipment manufacturers
- TSO allows the TSO holder to design, manufacture, and deliver products under a single approved quality system (vs. needing to operate under multiple higher-level quality systems)
- TSO supports the supply of spare parts directly from the TSO holder
- TSO facilitates sharing of design data by the TSO holder with affiliated repair stations, supporting the provision of maintenance/return-to-service actions
- TSO provides reliable "partial credit" for compliance with installation requirements (TSO reduces the burden on the installer)
- TSO approval supports reduction of international authority resources for validation of articles
- TSO provides ability to generate approved data
- Use of industry standard provides accessible understanding of the article's design
- TSO supports after-market customers

Challenges:

- Outdated standards reduce the value of TSO credit towards installation
- Integrated/complex systems are bound by multiple TSO standards which may not be consistent/compatible
- TSO and aircraft-level approval can create ambiguity regarding responsibilities for COS issues and reporting of events under Part 21.3
- Combined design and production approval for APUs limits the TSO holders' ability to take advantage of Part 21.101 changed product rule and other privileges afforded to engine type certificate holders

Appendix D
Issues and Problem Statements Considered

Sources 1 and 2. FAA Part 21 Matrix and ARC Member Discussion

[illegible] TSO Subteam TSO PROBLEM STATEMENTS & RECOMMENDATIONS [illegible] August 201[illegible]

Ref No.	Source & Problem Statement	Rule & Stakeholders	Recommendation	Rationale / Comments	Rule/Policy
18	21 ARC: Consider relevant changes in FAA's Part 21 Draft [illegible]				P
19	21 ARC: Clarity in Policy Guidance re: integrated, dependent, partial, multiple and non-TSO functions			[illegible]	R, P
20	21 ARC: Uniform requirements across different TSO categories		Separate categories of TSOs? Electronic v. Mechanical? Permanently installed v. easily removable?		
21	21 ARC: Combined Design and Production approval		Consider separating	[illegible]	R
22	21 ARC: Design change management, notification and approval	21.619; 21.[illegible]	2005 RAIRC recommendations? Type design data definition?		
23	21 ARC: Major/Minor change determination re: Limited/tested functions in a multiple TSO article				P
24	21 ARC: Value of [illegible] TSO w/ Non-TSO [illegible] TSO			[illegible]	
25	21 ARC: Limitations of APU TSO (C77B) v. Part 21 [illegible]	APU Mfrs		Design approval [illegible]	

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Source 3, 2013 FAA Parts Approval Workshop

P 21 SMS ARC TSO [illegible] TSO PROBLEM STATEMENTS & RECOMMENDATIONS [illegible]

Ref. No.	Source & Problem Statement	Rule & Stakeholders	Recommendation	Rationale / Comments	Rule / Policy
26	Industry: Specific role, responsibilities and privileges of [illegible] approval			Mitigate [illegible] TSO [illegible]	?
27	Industry: Time of TSO application and adoption of new TSO revisions			[illegible]	R, P
28	Industry: [illegible]				
29	Industry: Optional application for all included TSO functions [illegible] (TSO & Non-TSO)			[illegible] Non-TSO [illegible]	
30	Industry: Clarify Data submittal [illegible] TSO [illegible]				P
31	Industry: [illegible] compliance [illegible] TC [illegible]			[illegible] compliance to [illegible]	

31 GAMA TSO Sub-team
Part 21/SMS Aviation Rulemaking Committee

Appendix E
List of Acronyms

AC	Advisory Circular
AEG	Aircraft Evaluation Group
ARC	Aviation Rulemaking Committee
AVS	FAA Office of Aviation Safety
CAA	Civil Aviation Authority of another country
CCA	Common Cause Analysis
COS	Continued Operational Safety
DO	Design Organization
CFR	Code of Federal Regulations
DAR	Designated Airworthiness Representative
DER	Designated Engineering Representative
EASA	European Aviation Safety Agency
FHA	Functional Hazard Assessment
FAA	Federal Aviation Administration
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
JPDO	Joint Planning and Development Office
NAS	National Airspace System
ODA	Organization Designation Authorization
PAH	Production Approval Holder
PMA	Parts Manufacturer Approval
PSSA	Preliminary System Safety Assessment
QMS	Quality Management System
SMS	Safety Management System
SSA	System Safety Assessment
STC	Supplemental Type Certificate
TC	Type Certificate
TSO	Technical Standard Order
USC	United States Code
WG	Working Group

APPENDIX J—COST BENEFIT ANALYSIS WORKING GROUP REPORT

Part 21/SMS Aviation Rulemaking Committee
Cost-Benefit Analysis Working Group

◀▶

Final Report

June 2014

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II. INTRODUCTION

Historically, aviation safety rulemaking cost-benefit analysis (CBA) has focused on the prevention of accidents and lives lost as the benefit justification to offset costs of implementation of new rules. In evaluating the proposed transition to a systems-based approach to new rules, the purpose of this Part 21/SMSARC activity was to create a rule that relies not upon accident prevention as a justification, but rather a rule that can be justified and supported by enhanced improvements to the effectiveness and efficiency for both industry and the FAA. As a result, the Cost-Benefit Analysis Working Group (CBA WG) was tasked to find new ways to capture the benefits and costs associated with such improvements and identify a methodology that supports this.

The CBA WG charter identified five deliverables that have been addressed and are contained in this report. Those deliverables are:

- Benefits associated with moving to a systems-based approach;
- Benefits associated with harmonized regulatory frameworks for organizations with bilateral partners;
- Overall industry benefits related to safety, efficiency, and effectiveness;
- Benefits associated with FAA process changes;
- New and/or alternative cost-benefit methodologies to assist the FAA's required economic analysis of rulemaking.

Data gathered by the CBA WG was intended to be supporting data only and does not represent a formal economic analysis. All data gathered by the CBA WG has been shared with the Economic Analysis Division (APO-300) in the Office of Aviation Policy and Plans at the FAA and will be referenced during the formal economic analysis in the event a rulemaking project takes place.

III. BENEFITS

III.a. BACKGROUND: SYSTEM CONCEPT EVOLUTION

As the aviation industry steadily continues to grow, FAA resources continue to remain level. The increase in design and manufacturing is a clear benefit for the U.S. economy; however, if our system does not adjust with the growth in aviation, the FAA will not be able to provide the same level of oversight and support as is currently provided today. A "systems approach" must be adopted to accommodate the increase in aviation design and manufacturing. Shifting toward a systems approach will enable the industry to continue on its current path while FAA resources can focus on higher risk projects and areas where resources are better utilized.

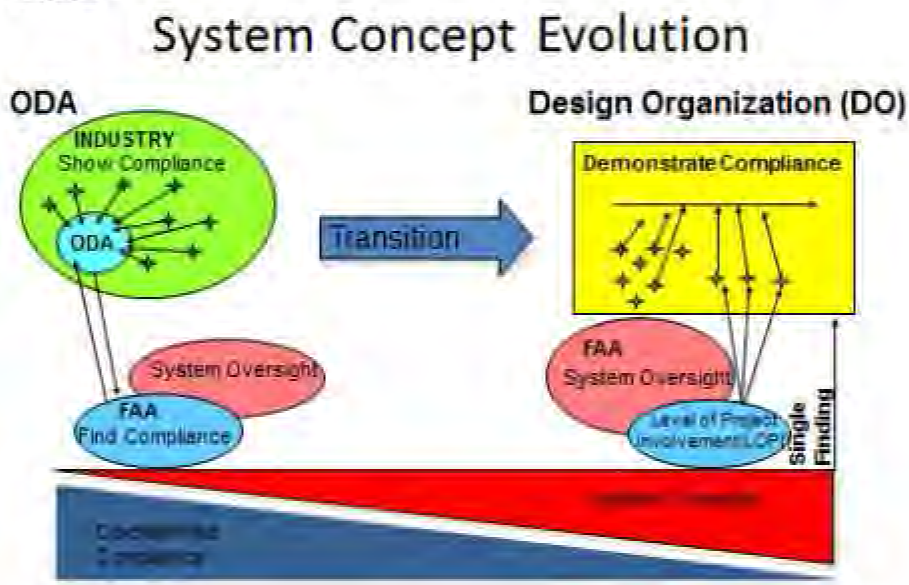
Figure 1 below represents an illustration of the transition from the current Organization Designation Authorization (ODA) system of today to the future state of a "Design Organization (DO)" (as envisioned by the Part 21/SMS ARC).

The left side of the illustration depicts the ODA model as it is intended to function today. Today's system for certification is based on a "showing" (*i.e.*, of compliance) by the applicant and a "finding" by the FAA. For every action by the applicant, there has to be an equal action by the authority on a project-by-project basis. Each star in the image in **Figure 1** represents a "showing" by the applicant and a "finding" by the FAA.

Transitioning to a DO would reduce the amount of FAA involvement and allow the industry to work with more independence and responsibility. Following the transition arrow in **Figure 1** shows how the current ODA model would transition from one using discrete findings of compliance to one that applies systems oversight. A DO is a regulatorily-recognized organization that meets organizational and system requirements sufficient to ensure that it is capable of making compliance determinations upon which the FAA may rely in support of obtaining design approvals under 14 Code of Federal Regulations (CFR) part 21. As such, the DO maintains and follows processes to manage its certification projects as well as the continued airworthiness of its products. This method allows for FAA oversight of the process, less direct project involvement by the FAA, and reduced one-for-one show/find, all while maintaining and, ultimately, enhancing safety for U.S. design and manufacturing organizations.

The CBA WG explored this transition by researching the costs and benefits of moving to a systems approach. The results of our preliminary review have been articulated in subsequent sections.

Figure 1


System Concept Evolution
ODA
Design Organization (DO)
INDUSTRY
Show Compliance
ODA
Transition
Demonstrate Compliance
System Oversight
FAA
Find Compliance
FAA
System Oversight
Level of Project
Involvement(LOPI)
Single
Finding

III.b. INDUSTRY SYSTEM CONCEPTS AND BENEFITS

III.b.i. Mandatory DO with Safety Management Systems (SMS)

The CBA WG approached its methodology under the ARC's original assumption that the optimal organization of the future would be comprised of a mandatory DO with the inclusion of SMS. The specific attributes of a "DO plus SMS" can be referenced in the Organization and the SMS Working Groups' final reports.

A definition of the methodology assumption has been documented below. This definition comes from the Organization Working Group's final report.

> *"A DO is a regulatory-recognized [sic] organization that meets organizational and system requirements sufficient to ensure that it is capable of making compliance statements upon which the FAA may rely in support of obtaining Design Approvals (DA) under 14 Code of Federal Regulations (CFR) part 21. As such, the DO maintains and follows processes to manage its certification projects, as well as the continued airworthiness of its products.*
>
> *A DO will include organizations applying for, supporting the application for, or holding Type Certificates (TC), Supplemental Type Certificates (STC), or Parts Manufacturer Approvals (PMA)."*

In addition to this definition, it was assumed that implementation of SMS would be required of all parties in order to become a DO. Therefore, the CBA WG used this assumption and definition in developing the methodology, conducting surveys, and all other data gathering techniques.

[It should be noted here, however, that, at this point in time, the final conclusion reached by the ARC was that SMS should be mandatory, but that DO should be voluntary. This conclusion was not reached until late into the time frame for which the ARC was chartered. The CBA WG activity and this report are based on the original assumption that both SMS and DO would be mandated based on the definition given above.]

III.b.ii. Certification Concepts for "Below the Risk-Based Threshold"

The ARC has identified three potential options for any applicant falling below the risk-based threshold identified as the requirement for SMS implementation and a DO. The risk-based threshold is based on the potential risks posed by the applicant's products to aircraft safety. If a DO threshold is defined at a later date, the three options will be applicable to that threshold. The risk-based threshold is suggested in this case due to the uncertainty of the DO threshold. The applicability threshold requires SMS for organizations that:

- Design or manufacture products (i.e., aircraft, engines, propellers) or;
- Design or manufacture articles whose failure could directly prevent continued safe flight and landing; or
- Make design changes to a product, through a Supplemental Type Certificate (STC), failure of which could directly prevent continued safe flight and landing.

The objective of having these options is to ensure that small companies that do not meet the above criteria for implementing SMS and becoming a DO have the opportunity to gain the same benefits as the large established companies without incurring the same level of cost and complexity to certificate products. The impact of requiring substantial ramp up cost for those companies falling below the risk based threshold could not only hurt small business, but could negatively impact the economy as a whole. The goal of recommending change to part 21 is to streamline certification so that industry and the FAA are able to continually improve the current high level of safety, while keeping up with industry growth. Three options for organizations "below the threshold" have been identified to encourage small businesses and innovation in the sector. Those three options are:

- Accredited Organization (AO);
- Agent DO; and
- Modified Current Model.

Each option has been articulated below and is designed to reduce the daily involvement of the FAA on low-risk activities while still maintaining or improving aviation safety. Because of time and resource constraints, the ARC was unable to focus on companies falling below the threshold. Therefore, these options have been explored by the CBA WG as a preliminary effort. Further research and definition are required for each option following the conclusion of this ARC.

Accredited Organization:

The Accredited Organization (AO) approach would seek to achieve many of the same objectives as the Mandatory DO/SMS approach, but with an aim toward making such achievements cost effective for smaller businesses while maintaining or improving safety. This would be an optional program, with a goal of voluntary adoption by industry. In order to parallel or harmonize with the international mandate for SMS principles, the AO would implement Continuing Operational Safety (COS) principles or SMS principles. COS incorporates many, but not all, principles of SMS and is a system which many "below the threshold" companies are already familiar with, or have already implemented.

Those companies seeking to export products to SMS-requiring ICAO countries may elect to implement appropriate additional SMS requirements; however, adoption of SMS requirements would not be mandatory for those implementing an AO.

Adoption of certain established COS/SMS principles would be required for accreditation to a voluntary industry standard. The AO approach would be a voluntary industry accreditation program similar to that described in the FAA's **Advisory Circular 00-56A["Voluntary Industry Distributor Accreditation Program"]** for distributors. Under such an approach, one or more industry organizations (e.g., SAE) would develop industry accreditation standards articulating the necessary requirements for an AO system, including implementation of COS/SMS principles. Those "below the threshold" companies successfully accredited to such standards would be identified in an FAA document indicating compliance. The objective of such an accreditation program is to encourage voluntary participation by industry, and for customers to make inclusion in such a program a prerequisite to doing business. As accreditation to the standard becomes an accepted norm, more companies would seek to implement COS/SMS principles under the AO model.

The AO approach may also provide "below the threshold" companies that meet the required accreditation standard with the opportunity to utilize an approved "compliance library." The compliance library could be one that the AO develops on its own and has FAA approval, or one that is developed as part of a consensus standard that is approved by the FAA. If a consensus standard was to be utilized, the AO would use only those standards that are on a list approved for the AO by the FAA. The compliance library would enable below the threshold companies to take advantage of the reliability indicated by accreditation to self-start projects fitting in its compliance library. Self-starting projects from its compliance library permits the AO to avoid the FAA sequencing/project prioritization queue and to more quickly initiate projects, thus bringing products to market more quickly. Projects not within an AO's "compliance library" would still be subject to FAA sequencing/project prioritization. The compliance library could be expanded to demonstrate more competencies that would permit the AO to avoid the FAA queue for additional projects.

The AO approach will also provide for a reduced Level of Project Involvement (LOPI) by the FAA. The extent to which LOPI is reduced or increased will depend upon the complexity of the proposed project. Complex projects will involve more significant LOPI from the FAA in terms of systems oversight and findings, though not rising to the level of the one-for-one show-find process of the current model. Those projects of diminishing complexity will allow for correspondingly reduced LOPI, in some cases almost zero LOPI, reflecting their lower level of complexity and potential effect on safety, thus preserving FAA resources.

Agent Design Organization:

Agent DO is a concept that needs further discussion and understanding by both the industry and the FAA. Persons or companies qualifying as an Agent DO would be similar in nature to current Consultant DERs, though responsibilities would shift in a similar manner as the Accredited Organization approach.

Such Agent DOs would provide cost-effective options for small companies, STC applicants, and small PMA applicants who do not have the resources to implement an Accredited Organization approach, or who have limited needs for FAA resources due to limited applications.

An Agent DO would have authority to provide services to comply with the 14 CFR §21.3 (Reporting of failures, malfunctions, and defects) requirements and COS monitoring on behalf of holder of a type certificate (including amended or supplemental type certificates), a PMA, or a TSO authorization, or the licensee of a type certificate. This would enable small companies to comply with the §21.3 and COS requirements without maintaining the required resources on their own.

As mentioned above, this concept needs further exploration and the Agent DO approach would not be applicable until DOs become voluntary.

Modified Current Model:

The Modified Current Model approach is a simple reflection of the use of designees by small businesses, including PMA companies and STC applicants. Although the process has not been changed, the model is "modified" in the sense that the FAA anticipates a reduction in the number of DERs who would be available to provide services to these small applicants. The number of DERs would be reduced by approximately two-thirds of current numbers by attrition, non-renewal of privileges, and limitations of new DER privileges. Sequencing, Risk-based Resource Targeting (RBRT), and/or Project Prioritization would still be applicable, causing certain applicants to be substantially delayed in the FAA queue based on the perceived value and safety considerations of their application, while giving preference to those applicants whose projects are deemed having a greater impact on safety.

Criteria for applicant-only-showing would be developed by means of a standard (e.g., ISO, SAE) for low risk projects. Specific criteria for applicant-only-showing would include such things as:

- the article being considered low-risk;
- the project meeting criteria of the compliance library; and
- the applicant's ability to issue a §21.20 statement.

If the standard is adopted, there will be privileges gained by doing so. A compliance library would be developed and accessible in a repeatable manner, allowing the applicant to initiate low risk projects independent of the FAA. However, in order for the applicant to take advantage of the privileges, all criteria must be met. If there are deviations from the defined criteria, then there will be stipulations that would potentially involve the FAA or a DER. Additionally, the company would have a system in place to meet the specific criteria and have a process with proper oversight and/or checks in the system. The system would have reporting requirements back to the authority regarding self-disclosures and a corrective action program regarding non-compliances. This system would then provide for additional privileges under applicant only showing program.

This Modified Current Model will encourage those companies that can afford to implement a DO or an Accredited Organization to do so, in order to avoid being subject to increased queue time with the FAA. Smaller businesses unable to establish an Accredited Organization or DO may be subject to delays in compliance findings by the agency in areas of FAA involvement, such as flight testing, software, human factors, noise, test witnessing, and inherently governmental functions, such as exemptions. The FAA would balance the certification needs of applicants producing future products for the National Air Space (NAS) versus maintaining an ever-growing COS responsibility within the same NAS. The majority of FAA resources are currently focused on lower-risk projects due to the sheer number of projects initiated each year. Transitioning smaller business and lower-risk companies to this type of system could decrease product time to market for the individual companies, along with allowing the FAA to focus resources in areas of greater need.

III.b.iii. Industry Benefits

With both concepts, either above or below the threshold, there are a number of overall industry benefits related to safety, efficiency, and effectiveness:

- Decreased product time to market;
- Less time spent in sequencing;
- Increased project authority;
- Reduced time spent guiding the FAA during audits;
- International harmonization;
- Scheduling control;
- Elimination of redundant conformity;
- Increased work efficiency (due to schedule control, less interruption, less wait time); and
- Centralized Oversight Office.

The benefits gained are further described in each of the ARC Working Group reports. Each benefit was identified through the data gathering process during the CBA surveys, presentations and workshops. The benefits were not assumed by the CBA WG, but described by ARC members and survey participants. The CBA WG prefers to see further research be performed on each benefit listed to realize the full worth in cost and efficiencies. Due to the understandable reluctance of many survey participants to provide specific cost data and the late realization of other working group recommendations, the CBA WG did not have sufficient time to fully explore the potential of each benefit. A benefit survey is strongly encouraged as a change in methodology to the commonly applied economic analysis process. Fully understanding the benefits will assist applicants in realizing the true reduction in cost due to benefits, compared to the common survey that only requests information on costs incurred. During the data gathering process, the CBA WG found that it was difficult for survey participants assign a monetary value to benefits. They understood the benefits from an intangible and efficiency perspective, but were unsure how to document them. This was a valuable lesson learned for the CBA WG, emphasizing the importance of a benefits survey.

III.c. FAA NEED FOR CHANGE AND BENEFITS

III.c.i. Industry Growth and the Need for Change

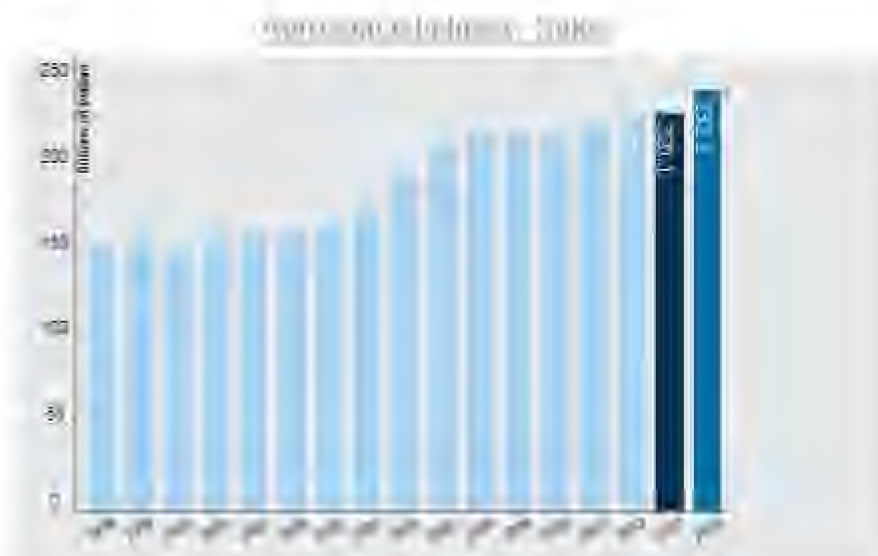
The U.S. civil aviation industry has a crucial role in fostering trade and making any place on the globe easily and quickly accessible. The U.S. industry and travelers depend on the vital services of air transportation to support the U.S. economy. Even with severe fluctuations in the economy and the recent government sequestration, the aviation industry has been able to continually readjust and regain stability.

The following points indicate the importance of the industry:

- In 2009, air carriers operating in U.S. airspace transported 793 million passengers over 1,039.3 billion revenue passenger miles (RPM).[7]
- More than 53 billion revenue ton-miles (RTM) of scheduled freight passed through U.S. airports in 2009.[11]
- The U.S. civil aviation manufacturing industry continues to be the leading U.S. net exporter. According to 2009 data from the U.S. International Trade Commission (USITC), the U.S. civil aviation manufacturing industry supported a positive trade balance of over $75 billion.[7]
- The 2011 FAA Aerospace Forecast projected an average annual growth rates of 3.8 percent per year through 2031 for U.S. airlines.[7]

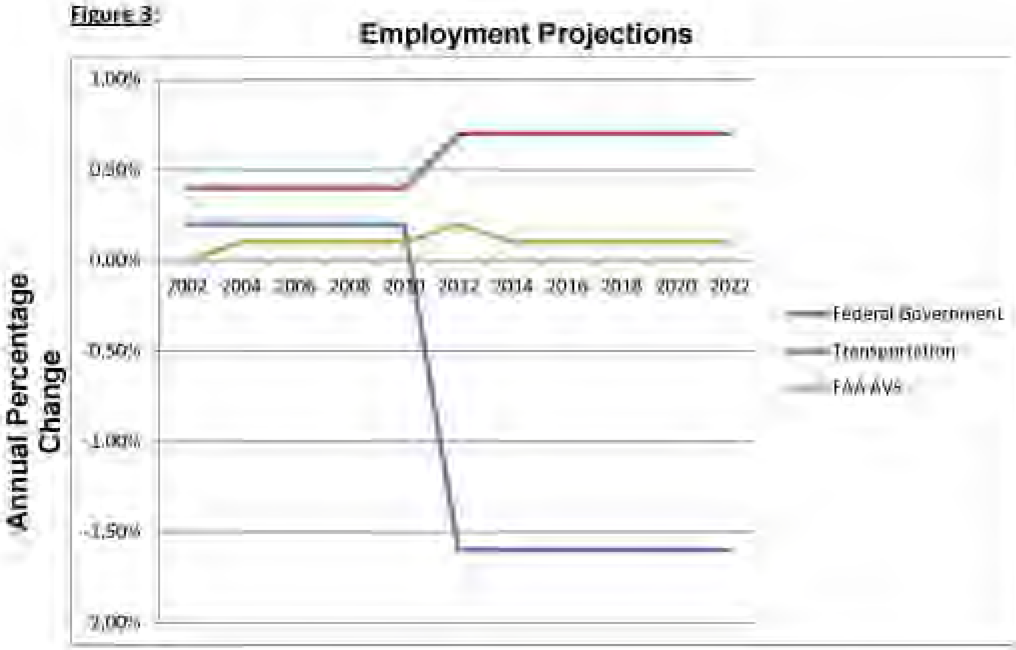
The U.S. aerospace industry may be facing some of its greatest challenges in decades. While weathering several trials in 2013, the industry produced relatively flat results compared with 2012. An overall slight decrease in sales was forecast, reaching $220.1 billion for 2013 – down from $222 billion in 2012 – with only civil aircraft sales showing growth.[1] According to data from the Aerospace Industries Association (**Figure 2**), however, aerospace industry annual sales have increased more or less continuously from 1998 through 2014.

Figure 2:



FAA and industry data show that even through difficult transitions, U.S. aviation continues to innovate and grow. Although this is good news for the industry and the economy, there is increasing concern about the FAA's ability to oversee and support this continuous growth at its current and projected capacity. The Bureau of Transportation Statistics (BTS) projects employment in the broader transportation industry to increase by 0.7% annually through 2022, but conversely projects an annual decline of 1.6% in government employment over the same period. Additionally, the FAA, AVS specific, has maintained a relatively flat increase in hiring. This is due to the slow and steady hiring rate combined with the attrition rate. **Figure 3** illustrates this gap.

Figure 3:



If, as forecast by the FAA, airline passenger services grow at a rate 3.8% per year through 2031, but FAA employment steadily declines by 1.6% each year, then there will be a significant gap between the aviation industry's demands for FAA services, compared with the capacity of the FAA to support. This gap could translate into the stifling of innovation and entrepreneurship and, possibly, even a decline in air travel.

For certification activity specifically, the FAA has devised strategies to mitigate the increasing resource gap. However, strategies like designee programs and sequencing have reached their limits in their ability to mitigate the gap. The result has been an increase in sequencing wait times and the areas of focus of FAA employees. The United States has reached a point where significant change is needed in its aviation certification system. The Design Organization and SMS concepts, if implemented, could provide the solution to address this challenge.

III.c.ii. FAA Benefits

Shifting to a systems approach could provide huge benefits to the FAA. The FAA is rapidly moving to a situation where current resources are unable to support the amount of work being requested at local offices. If the FAA were able to support certification activity through application of a systems approach, then resources would be able to better focus on areas of greater need. In its ***2011 The Economic Impact of Civil Aviation on the U.S. Economy*** report, the FAA found that its rate of hire is equal to or less than its rate of attrition; therefore, even with current levels of hiring, the number of agency employees is decreasing. As long as this trend continues, the growth in industry will always outpace the growth of agency resources.

The CBA WG is aware that the benefits accruing to the FAA are not the types of benefits typically considered when conducting an economic analysis under OMB guidelines for new rules. However, the level of FAA resources is a key contributing factor to the industry growth rate, evolution of technology, and product time to market. Therefore, the CBA WG took FAA benefits into consideration when understanding the impacts of moving to a systems approach for both the industry and the FAA.

If the industry moves toward a DO with the inclusion of SMS, some FAA benefits would include:

- Increased standardization of oversight;
- Accountability Framework;
- Less time spent with new applicants;
- Less time spent on low-risk projects;
- Less time spent on product audits;
- More time spent on new technology, research and development, areas of higher risk (Reallocation of resources); and
- More efficient and streamlined certification processes.

Thus, according to research and the data gathered, multiple benefits would be realized by the FAA, as well as the industry.

IV. INTERNATIONAL HARMONIZATION

All parties recognize that civil aviation authorities and the aviation industry have access to finite and often very limited resources. These governmental and industry resources must be focused to produce the greatest safety benefit possible. Harmonization of aviation safety and regulatory requirements has been a long-standing goal of the United States and, in fact, of all ICAO Member States. However, it is recognized that such harmonization of aviation safety standards must be based on reliable safety data and, ultimately, on the potential for decreased risk. The initial recommendations of this ARC, if accepted, would not only move the FAA toward a certification oversight system that is more harmonized with many of the aviation trading partners of the United States, but could also help to move other ICAO Member States toward similar systems.

More than twenty years ago, the (then) U.S. General Accounting Office (GAO) investigated progress being made in the harmonization of aircraft design standards and found, *inter alia*, that:

1. Varying (non-harmonized) certification processes are inefficient and raise manufacturers' and users' costs because of different interpretations of regulations, which impose additional requirements and duplicate certification activities;
2. Regulatory resources spent on duplicative activities can be better used to address other safety issues; and
3. Common standards and practices lower costs and increase safety.[illegible]

The introduction of risk-based safety management principles to certification systems is a significant change to the existing traditional certification system that relies primarily upon a large corps of government inspectors overseeing each aspect of certification. Unilateral implementation of such a risk-based system, or adoption by only a handful of authorities, could create serious problems due to the diversion of the new and old systems and the resulting problems with lack of mutual recognition and acceptance of product certifications outcomes.

In Europe, EASA has moved ahead in implementing and integrating safety management principles. With the recommendations of this ARC, the FAA is moving in the same direction to maintain harmonization and compatibility. This harmonized effort also aids the international aviation industry, with its increasingly global supply chains – ones that require "interoperability" in their SMS applications.

Harmonized rulemaking on all sides is of utmost importance, not just for national civil aviation authorities, but also for their aviation and aerospace industries. In Europe, for example, certain certification approvals of major type design changes are going to be issued in the EU by the European Aviation Safety Agency (EASA)-approved organizations themselves. This entails minimal (or no) certification involvement of the Agency, except the ongoing checks performed as a part of continuing oversight of the design organization in observance of the Level of Involvement (LOI) principles. If such approvals were not to be accepted by the FAA because of "lack of EASA involvement," it would mean serious problems both for manufacturers and regulators, as it would require two almost entirely separate certification processes (one satisfying FAA requirements and one implementing LOI).

In addition to the expected safety and economic benefits of implemented safety management principles, harmonized rulemaking action by civil aviation authorities worldwide is necessary to maintain a level playing field for their aviation and aerospace industries. Harmonization is critical to the economic health of the worldwide aerospace industry. For example, the FAA and EASA oversee aerospace manufacturers that represent over 60% of the global aviation market. A harmonized EASA/FAA approach to certification would greatly assist ICAO in the further development of this concept as a global standard. The adoption of development of these systems in a timely manner may be critical, as other countries may advocate different and, in many cases less vigorous, systems as the basis for ICAO Standards, which may not be consistent with our approach. As all ICAO Member States need to implement SMS in order to meet ICAO requirements, the pioneers in this area may ultimately dictate the standards by which we will need to abide.

The evolution from the reliance on individuals to the reliance on approved organizations (under continuing oversight) will align the FAA closer to the EASA system, and that of some other ICAO states, with a clear benefit to both U.S. and European industries (among others due to a potentially increased scope of mutually acceptable design changes and repairs). The FAA and EASA systems would certainly be more aligned - adopting the concept of approved organizations granted certain privileges, and their corresponding responsibilities – instead of the current FAA delegation principle, relying on the individual designees (DER, DAR) and/or the ODA concept.

Implementation of a new system of approved design organizations with privileges will support the implementation of compatible DOA/SMS models from which all civil aviation authorities would benefit both mutually and internationally. The FAA, as a certification oversight authority, would benefit in the development of an organization/management system that would enable an environment for more focused attention on areas of concern, and, where necessary and appropriate, enforcement.

If the SMS concept is implemented in a harmonized manner with other civil aviation authorities the industry will benefit from easier mutual recognition of such approved organizations and their resulting SMS systems. Again focusing on the FAA-EASA example, the U.S.-E.U. Bilateral Aviation Safety Agreement (BASA) would not need to deal with substantial system differences on both sides and this would, in turn, have a positive effect on oversight resources required within the scope of BASA activities. Similarly, if the LOI concept in certification projects is implemented on both sides in a compatible way, it would ensure that the traditional "one for one" compliance showing-finding process would be replaced by a risk-based compliance verification process. It will be accepted that the level of authority involvement may vary, depending on the level of performance of approved design organizations and an assessment by the authority of the other safety risks in product certification.

The benefits of the harmonization of certification processes and procedures may best be summarized by a paper that the FAA prepared for an ICAO regional meeting in 2011:

> *"The United States supports a harmonized regulatory system in which airworthiness standards and the certification processes to ensure compliance to these standards are based on universally accepted data and feasible for implementation. Harmonization of rules and processes amongst the increasing number of international aviation regulators should be a goal for all Civil Aviation Authorities (CAA), as common requirements facilitate global acceptance."*[8]

Movement toward adoption of risk-based safety management principles into certification systems, as outlined by this ARC, would not only move the FAA toward a system that would strengthen aviation safety, but one that would be harmonized with that of other major aerospace manufacturing States.

V. CBA METHODOLOGY

V.a. CBA METHODOLOGY OVERVIEW

The methodology identified in this document is only one alternate means of identifying the costs and benefits of rulemaking. This approach includes a number of different data collection tools and options for sampling. Historically, aviation safety rulemaking cost-benefit analysis (CBA) has focused on the prevention of accidents and lives lost as the benefit justification to offset costs of implementation of new rules. The methodology applied in this report focuses on the collection of real data and active interaction with the parties affected (small and large organizations, as well as the FAA). As the industry continues to change, the FAA must maintain adequate skills in promoting change to enhance safety. This methodology approach was chosen as a proactive method to identifying cost and benefits at a preliminary stage of the ARC and rulemaking process. The costs and benefits described have been identified through industry participation and are not the assumptions of one individual.

The CBA WG worked in synch with the full ARC during the development of ARC recommendations. Due to the uncertainty of final recommendations to be made, and the concurrent preparation of this report, the CBA WG was required to make certain assumptions based on the ARC direction at an early stage. The CBA methodology general guidelines that were actively followed throughout the ARC duration included:

1. ***Process Identification*** - This is the area of work where the CBA WG identified the process that would be followed in order to identify costs and benefits for the Part 21/SMS ARC. This process included mapping out subsequent steps.

2. ***Research*** – Performed research of academic, FAA and other government agencies, aviation and other industry cost benefit approaches. Used this research to determine whether approaching a methodology other than the historical approach to CBA by the FAA was feasible, attainable, and something this ARC should consider.

3. ***Data Collection*** – Once research had been performed, the ARC was at a more mature stage in understanding the direction the recommendations would take. Using the recommendations, the CBA WG began the data collection phase. This phase included developing templates for surveys, presentations and workshops. The CBA WG actively worked with ARC participants, external workshops and the other working groups to populate templates, hold discussions, and gather data.

4. ***Analyze the Data*** – Once the data was gathered, the CBA WG met multiple times either through face-to-face meetings or telecons to discuss and analyze the data as a team. This involved reviewing and understanding the responses provided in surveys and discussion, following up with participants when needed, and scheduling future

discussions to gather follow on data as the ARC progressed.

5. ***Conclusions*** – The conclusions of this effort were documented based on the findings of the data gathered. The overall conclusions consisted of identified gaps and findings that required follow on effort or research in the event a rulemaking activity takes place.

Although this methodology is quite high level, this is the process the CBA WG used as guidance throughout the ARC timeline. This methodology served as a tool for organizing the working group as it worked in synch with the ARC and was used as a guide to know what and how data should be gathered. Each guideline required significant effort and, in some cases, took a substantial amount of time. Given the ARC's chartered timeline, each phase of this methodology needed to be shortened to accommodate the full ARC. Working in alignment with the ARC proved to be less streamlined than anticipated; however, the CBA WG adopted these concepts in order to achieve true results of the concepts being explored by the ARC. This report summarizes each phase of the methodology and contains all noteworthy data gathered.

Additionally, calculating efficiencies was a primary goal in this methodology. The CBA WG concluded that in order to calculate efficiencies effectively they must first be defined. In most cases the CBA WG found that efficiencies can be calculated if they are defined in a detailed manner. Requirements that are process oriented tend to be more difficult to calculate, because a process is intertwined with multiple facets of an organization's function. The process must be broken out by physical aspect in order to calculate the cost incurred or reduced. Examples include administrative functions and physical time. Efficiencies often translate into intangible activities that an organization is unable to define from a physical perspective. In this event, qualitative assessments must be made. An educated calculation should be determined through organizational history, research, forecasting, etc.

Calculating efficiencies is an activity that the CBA WG did not have the opportunity to spend adequate time on. This will involve working with the industry on perceived benefits and translating them into cost values.

V.b. PROCESS IDENTIFICATION

The Process Identification step is the area of work that identified the process to be followed in order to identify costs and benefits for the Part 21/SMS ARC goals. The development of a Cost Benefit Analysis Working Group was the first step this in process identification. During the CBA WG's first face-to-face meeting, the team worked to develop its plan of action, identifying how the working group wanted to proceed with accomplishing its charter's goals.

The process identification took into account that the ARC was still in a premature phase and had not agreed upon final recommendations. Given that the CBA WG was assigned to work in synch with the ARC, the working group chose to perform research and to develop methods for gathering cost and benefit data in parallel with the ARC as it explored recommendation concepts.

Some of the methods included performing research, developing templates, and surveys to gather data supportive of the ARC goals. Multiple templates were drafted and presented to the full ARC on how to best gather certification baseline cost. The certification baseline was defined as the cost to industry for conducting certification in today's system. The baseline cost would then be compared with the cost and benefits that would accrue if specific ARC recommendations were to be implemented.

Templates and surveys were drafted for small and large companies to populate. A decision was made very early on by the CBA WG to gather data from all companies, small and large. Once the ARC decided it would be unable to fully address organizations falling "below the threshold," the CBA WG chose to continue including small business in the event the ARC recommendations changed.

Following the development of the templates and surveys for gathering of cost and benefit data, the CBA WG began to fully research other agencies, industries and private organizations for useful methods of gathering cost and benefit data.

V.c. RESEARCH

The benefits of aviation regulations have traditionally been calculated using a "reactive" process – that is, the analysis of past accidents and the calculation of how many lives would be potentially saved and hull losses/accidents potentially prevented by the introduction of corrective actions to prevent the recurrence of an accident event. Because the past decade has been the safest statistically in modern airline history – having the fewest fatalities and accidents – it is becoming increasingly harder to justify the cost of new requirements in traditional safety terms (i.e., the number of accidents prevented or lives saved). New regulations can no longer claim credit for avoiding a past accident that was already addressed in a previous rule.

From the outset, the objective of the Part 21/SMS ARC was not aimed towards new design or operational requirements that would primarily save lives; rather, it was aimed towards requiring enhanced improvements in processes, procedures, and oversight that would promote comprehensive efficiencies to both industry and the FAA, as well as enhancing safety generally. The CBA WG was tasked to find new ways to capture the benefits and costs associated with such changes.

With this objective, the CBA WG started out by conducting a "literature search" for cost-benefit studies that may already have been performed by government agencies, academia, or others, that focused on capturing the costs/benefits of regulations that bring "efficiencies" rather than improved safety specifically. The following discussion describes seven relevant items that were identified and reviewed.

1. FAA's Final Rule on Organization Designation Authorization (ODA)

In the Regulatory Evaluation for this rule, the FAA determined that the cost of compliance with the new rule would entail only the additional costs to apply for and to operate an ODA, over and above the costs for an existing designation authorization. The total costs to operate an ODA are not the costs to comply with the rule. Thus, FAA calculations focused only on those costs involved in transitioning to an ODA from a current organization model.

FAA did break down these compliance costs to two types: (1) initial compliance costs, and (2) annual compliance costs. Initial compliance costs were the one-time costs to develop the procedures and apply to the FAA for an ODA. Annual compliance costs were the yearly incremental costs resulting from any changes in the company's practices, procedures, personnel training and retraining, self-audits, recordkeeping, etc. to fulfill the ODA requirements.

Throughout their final regulatory evaluation, the FAA mentions the "efficiencies" that the ODA rule will bring, both to industry and to FAA. For industry efficiencies, FAA did provide a quantified illustration of the potential benefits by measuring the value of <u>time-savings</u> as an opportunity cost of capital approach. In this example FAA stated:

> *"[I]dle capital equipment ties up investment capital with no return. The opportunity cost of this idle equipment equals the value of the equipment multiplied by the interest rate, multiplied by the time the equipment is not used. For example, the annual value of a new transport category production airplane is about $50 million. Using a 5 percent interest rate, the cost of a one-day increase in manufacturing time would be about $6,850. If the rule were to save an average of one-half a day of manufacturing time, the manufacturer would save $3,425 per airplane. …"*

The FAA does tie these efficiencies back to <u>safety</u> where it states:

> *"By shifting our inspection focus from reviewing test results towards overseeing the designation program, we will more efficiently use our resources while extending our oversight coverage, thereby increasing safety."*

2. EASA's Notice of Proposed Amendment (NPA) 2013-01 (A), Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003 RMT.0251 (MDM.055)

EASA describes its proposed rule as supporting a "holistic approach" towards management systems by incorporating safety management principles into the management systems of organizations as well as the regulating authorities. The rule formally requires the implementation of SMS in a number of types of organizations, including Approved Training Organizations (ATOs), holders of Flight Simulation Training Device (FSTD) qualification certificates, aero-medical centers, and others.

In its formal Regulatory Impact Assessment (RIA) for this proposed rule, EASA described the technical requirements of the rule as mainly focused on:

> *"… the creation of streamlined, consolidated management system requirements that, while built upon existing quality systems, improve consistency in organisation approvals, and introduce additional requirements related to hazard identification, risk evaluation, and effective risk mitigation."*

The working method adopted for the RIA was to perform a *"**<u>qualitative</u>** assessment of possible impacts."*

EASA's assessment contains no quantitative data, but does provide an in-depth analysis of the impact of the rule, as to:

- safety impacts;
- social impacts;
- economic impacts for industry;
- economic impacts for authorities;
- proportionality issues (i.e., size, complexity of organizations); and
- impact on regulatory coordination and harmonization (including ICAO standards).

In its conclusion, EASA found that the need for the regulation was supported on the grounds of safety, increased efficiency, and international harmonization.

3. FAA Report, "Business Case for the Next Generation Air Transportation System (August 2012)"

In this report, the FAA addresses the potential air traffic management requirements of the Next Generation Air Transportation System (NextGen). It considers the shortfalls in the current system that new technologies can help to alleviate, and the "costs and benefits" of doing so.

This business case focuses on the direct benefits to aircraft operators, passengers, and taxpayers from the rollout of NextGen improvements. These benefits include:

- Improvements in system capacity (i.e., reductions in flight and taxi times and corresponding fuel use resulting from less delay; reductions in cancelled flights; additional scheduled flights that are enabled by new capacity); and
- Improvements in system efficiency (i.e., reductions in flight times and fuel use due to more direct routings, and reduced fuel use due to more efficient descent profiles).

FAA was able to monetize these benefits and efficiencies by relying on various inputs to estimate a cost vs. benefit conclusion. As part of the estimating process, they employed an elaborate modeling system – System Wide Analysis Capability (SWAC) – whose methodology involves a fast-time simulation model used to estimate the potential benefits of NextGen improvements in the National Air Space (NAS).

Based on these inputs, FAA was able to show in its analysis that NextGen mid-term improvements will generate $106 billion in benefits for the nation as a whole through 2030.

4. "Aviation Safety Management Systems Return on Investment Study," Center for Aviation Safety Research (CASR), Parks College of Engineering, Aviation and Technology, Saint Louis University; February 2011

This report is a result of FAA's tasking of CASR to develop a model to show the investment benefit of SMS implementation and sustainment vs. the costs of developing the program, as well as costs associated with incidents and accidents. The model is built around the concept that the large costs associated with accidents could be reduced or avoided with the implementation of a safety management system. These reduced or avoided costs could then be seen as a net gain and placed into a *return-on-investment* model for safety management system investment calculations.

The CASR team reviewed how accidents and incidents affect the financial results of an aviation organization at three levels:

- **Macro-level**, where shareholder and market value is lost due to "bad publicity" occurring post-accident/incident. (*Examples of costs*: drop in stock price, or change in public perception of air travel safety.)
- **Mid-level**, where losses are absorbed as part of the regular costs of doing business, most particularly if SMS programs do not exist that would prevent such incidents from occurring. (*Examples of costs*: raised workers compensation premiums, logistical costs of a product recall, or the time that vital equipment is out of service.)
- **Micro-level**, where individual accidents/incidents in a company that incur costs that could have been avoided or mitigated if an appropriate SMS program were in effect. (*Examples of costs*: damage to products or facilities, schedule delay penalties, and parts failures)

Gathering these costs, the CASR team then used the following formula to determine the return on investment (ROI) of implementing an SMS program:

Return on Investment = (Payback – Investment) ÷ Investment

CASR concluded that:

> *"… a properly executed ROI analysis of safety interventions allows organizations to compare safety investments with other competing business investments and assist in decisions regarding financial resources."*

5. U.S. Environmental Protection Agency (EPA)

The CBA WG also looked at cost-benefit and cost-efficiency analyses undertaken by other U.S. government agencies. The U.S. EPA produces an immense volume of regulations annually, and has used cost-benefit analysis for many years as one of several sources of information on the impacts of alternative policy choices.

Typically, the EPA provides three types of analysis:

- estimates of the *net benefits* (benefits minus costs) for each regulatory alternative, along with a discussion of the non-monetized effects;
- a *schedule* showing when the benefits and costs would occur; and
- a *cost effectiveness analysis* of each major alternative for situations when many benefits are not easily monetized or when the governing statute specifies the regulatory objectives.

The cost portion of EPA's analyses normally includes:

- *estimating the expenditures* needed to comply with new regulations (e.g., to install contaminant removal technologies); and
- *determining the market effects* of these expenditures (e.g., the cost increase to the household water bill).

The benefits portion of the analyses generally focuses on the effects of reducing exposure to contaminants, including effects on human health and the environment.

The EPA is authorized to issue regulations under several different acts of Congress, among them:

- Clean Air Act;
- Clean Water Act;
- Safe Drinking Water Act;
- Toxic Substances Control Act;
- Resource Conservation and Recovery Act;
- Comprehensive Environmental Response, Compensation and Liability Act;
- Superfund Amendments and Reauthorization Act;
- Federal Insecticide, Fungicide, and Rodenticide Act;
- Food Quality and Protection Act;
- Pollution Prevention Act; and
- Atomic Energy Act and its amendments, including the Uranium Mill Tailings Radiation Control Act.

Each of these laws includes statutory obligations to conduct economic analyses. Some of them give EPA relatively broad flexibility to use economic criteria in the decision-making process; whereas, others circumscribe EPA's use of economic analysis.

In order to develop *quantifiable* estimates for benefits and costs in compliance with these different statutory obligations, EPA has needed to develop many "non-economic" analyses, such as methods for evaluating dose-response relationships for critical and noncritical effects. The benefits of regulatory action are in some cases required to be reflected in improvements in human welfare or, equivalently, the avoided damages or losses in welfare that humans experience in the absence of regulatory action. These and similar important categories of benefits are often considered in the analyses *qualitatively*, due to the difficulty of quantification and data availability.

It should be noted here that EPA has been criticized by the Government Accountability Office (GAO) in the past for its failure to *monetize* benefits. The GAO indicated that, without monetization, a study probably can provide no more than a "cost-effectiveness" scenario – although that may be adequate in some cases (especially where there is little statutory flexibility).

(In light of the many Acts, Executive Orders, and other policies with which EPA must comply in developing its regulations, EPA has posted on-line extensive guidance for developing and performing regulatory cost-benefit impact analyses.)

6. The U.S. Food Industry: Hazard Analysis and Critical Control Points (HACCP)

The food industry in the U.S. is regulated for the most part by the Food and Drug Administration (FDA) and the Department of Agriculture (USDA), and portions of the industry are required by these agencies to implement "Hazard Analysis and Critical Control Points," or ***HACCP***. HACCP is a systematic preventive approach to food safety and biological, chemical, and physical hazards in production processes that can cause the finished product to be unsafe, and the program includes the development of measurements to reduce these risks to a safe level.

Similar to SMS, the HACCP is referred to as *"the prevention of hazards"* rather than the inspection of finished products. The HACCP system can be used at all stages of the food chain, from food production and preparation processes to packaging, distribution, etc. HACCP emphasizes control of the process as far upstream in the processing system as possible by using operator control and monitoring at critical control points. As such, HACCP *"enhances the responsibility of producers and processors in quality and safety assurance."*

Meat HACCP systems are regulated by the USDA, while seafood and juice are regulated by the FDA. (The use of HACCP is currently voluntary in other food industries.)

Recently, HACCP has been increasingly applied to industries other than food, such as cosmetics and pharmaceuticals. This method, which in effect seeks to "plan out" unsafe practices based on science and risk, differs from traditional "produce and sort" quality control methods that do nothing to prevent hazards from occurring and must identify them at the end of the process.

Based on risk-assessment, HACCP allows both industry and government to allocate their resources efficiently in establishing and auditing safe food production practice. While the application of HACCP systems has been recognized to aid inspection by regulatory authorities and promote international trade by increasing confidence in food safety, those benefits have not been quantified.

7. Office of Management and Budget (OMB) Guidance on Regulatory Analysis

The Office of Management and Budget's *Circular A-4* provides guidance to the Federal executive agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities.

Circular A-4 emphasizes that cost-benefit analysis is the primary tool used for regulatory analyses:

> *"Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society."*

However, it also acknowledges that it will not always be possible to express in monetary units all of the important benefits and costs of a rule. In this case, OMB emphasizes:

> *"When it is not* [possible to quantify costs/benefits], *the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a threshold analysis to evaluate their significance. Threshold or break-even analysis answers the question, 'How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?' In addition to threshold analysis, you should indicate, where possible, which non-quantified effects are most important and why.*

Thus, OMB recognizes that some important benefits and costs may be inherently too difficult to quantify or monetize, given current data and methods. In those cases, Circular A-4 provides lengthy instructions to the agencies on analyzing them qualitatively – presenting a description of the unquantified effects, discussing the strengths and limitations of the qualitative information, and providing a clear explanation of the rationale behind the choice.

8. "Understanding the Nature of Past Corrective Actions and How Safety Management Systems Could Change the Scope of Future Corrective Actions in Aviation," Center for Aviation Safety Research (CASR), Parks College of Engineering, Aviation and Technology, Saint Louis University; March 2013

As stated by the CASR team, "This study was initiated to better understand how implementation and maturation of Safety Management Systems (SMS), particularly at design and manufacturing (D&M) organizations, might change the scope and nature of future AD corrective actions. Considering the already robust safety record of the aviation industry over the last ten years, some D&M industry representatives have questioned the value in pursuing SMS beyond existing levels. Since each AD involves unplanned costs, complexities, and other variables that must be managed while maintaining the aircraft, this study was considered a first step in exploring how implementation and maturation of SMS could benefit the industry in broader terms by reducing the necessity for corrective actions."

The CASR team recommends, "…the FAA consider how industry can gain further insight into improving system safety through review of AD data. A pilot activity may be appropriate to see how FAA and industry could support, and benefit from, regular review of this data at a system level. Consideration should be given to looking at AD follow-up actions to ensure that appropriate updates are made to various controls (processes, practices, standards) to capture system-level learning that could preclude future events."

Additionally, "a large percentage of the ADs (48%) were considered revisions to existing risk controls and were associated with one of six different descriptors related to the AD corrective action. This suggests that existing industry practices are recognizing areas that must be addressed for safe operations. These cases also illustrate that the existing risk controls were not sufficient and the AD action was necessary to achieve an acceptable level of safety. The industry may want to review the effectiveness of existing risk controls and ensure effective safety performance measures are in place. Improved risk controls and safety performance monitoring may significantly reduce the number of AD actions in the future. Thus, these improvements may reduce costs and the potential for unintended consequences associated with unplanned and complex AD compliance actions. The D&M industry and the FAA need to further explore SMS."

After reviewing this study, the CBA WG concluded that if SMS were to require a cost benefit analysis independent of a design organization, this study would be an adequate point of reference. The study recommends additional research, however it is a good indicator of how SMS may prevent unsafe events in the future.

RESEARCH CONCLUSIONS:

Cost-benefit analyses addressing other than quantified items are neither unusual nor untested. While examples are not abundant, those that do exist provide ample informative insight as to how such analyses can be used appropriately to assess the impact of key intangibles.

V.d. COLLECTION AND ANALYZING THE DATA

During this phase of the process, the CBA WG worked actively with ARC participants as well as outside parties to understand the potential impacts to small and large organizations. Data was collected through a series of discussions, meetings, surveys, presentations and workshops. Data collection was a combination of formal and informal methods. The formal methods of collecting data were through three primary avenues:

1. Part 21/SMS ARC face-to-face meetings;
2. 2013 Modification and Replacement Parts Association (MARPA) conference;
3. Distribution of the Cost Benefit Survey for Large Organizations to seven design and manufacturing companies.

V.d.i. COST BENEFIT SURVEY OF SMALL ORGANIZATIONS

The small company survey was developed by the CBA WG and delivered by representatives of the CBA WG to small business members and other interested parties at the 2013 Modification and Replacement Parts Association (MARPA) conference (October 23-25, 2013, Las Vegas, NV). Seven companies responded to the survey request: six manufacturers and one FAA designee company. The purpose of the survey was to obtain industry cost-benefit estimates of the effect of three possible options being considered by the CBA WG for those small companies deemed "below the threshold" at which larger companies would be required to implement a Design Organization system as well as a mandatory implementation of SMS. (See section III.b.ii for more information on "below the threshold companies.") Adoption of one of the three options is intended to address the ARC tasking that any proposal for Design Organization and SMS be scalable to small businesses.

Survey Presentation

Members of the CBA WG, representing both industry and the FAA, offered a presentation to industry at the MARPA 2013 conference. The presentation was directed at small manufacturers, which make up a large segment of the Parts Manufacture Approval (PMA) industry. The presentation addressed the progress of the Part 21/SMS ARC and what recommendations could be expected from the ARC. The CBA WG further presented three options that could be applicable to those businesses deemed to be "below the threshold" at which mandatory implementation of a DO/SMS program recommended by the ARC would not be required or would became economically infeasible based on business size.

The presentation began with an introduction to the ARC and working groups. It further described the CBA WG and explained that the purpose of the presentation was to obtain data from industry to assist in the development of new methodologies for performing cost-benefit analyses in lieu of an aircraft accident-based approach.

The presentation discussed the current method by which projects are approved. This explanation, known and understood by the attendees, involves direct FAA involvement, uses designees, relies on a compliance-based process of one-for-one findings of compliance, and allows for voluntary implementation of SMS principles.

The presentation then offered a discussion of three possible options being considered by the ARC at the time of the presentation. The first option presented contemplated a mandatory DO/SMS program being necessary for all businesses regardless of size.

The second option, presented under the working title "Scaled DO," contemplated a systems-based oversight system. This option is referred to as the "Accredited Organization" approach under section III.b.ii on "below the threshold companies." After presenting this option at the Annual MARPA Conference, the name "Scaled DO" was changed to "Accredited Organization."

For the purpose of this section we will refer to this option as the Scaled DO, because this is the language used in the survey questions.

Under this approach, a business adopting the Scaled DO would be subject to reduced FAA oversight of individual showing of compliance. Instead, the business would be subject to oversight of systems to ensure compliance. The adopting business would exercise increased authority to initiate projects without FAA approval and operate under decreased design and production oversight. The adopting business would no longer be subject to the one-for-one show-find compliance model, but instead would be subject to systems oversight and reduced or periodic show-find by the FAA, depending on the complexity of a given project.

The third option described a modified version of the current model of oversight and approval. This model contemplated a reduction in Designated Engineering Representatives (DERs) as the FAA scales back the number of DER certifications it would renew or issue in an effort to conserve resources. The model also expects that project prioritization (known as sequencing) would be a factor in the processing of applications.

Survey Results

The survey was comprised of thirteen questions designed to gauge the effects of the three proposed options contemplated by the ARC. The respondents provided business names and points of contact for the purposes of follow up surveys if necessary. In order to maintain confidentiality, the respondent companies and contacts are not identified in this report.

The first three questions requested background information about each respondent:

1. *Select your company size range:*

	1-10 employees		*11-25 employees*		*26-50 employees*		*51-100 employees*
	101-500 employees		*501-1000 employees*		*1001-1499 employees*		*1500+ employees*

2. *In what State is your company primarily located?*

3. *Select all certificates that apply to your company:*

	TC		*PC*		*STC*
	PMA		*TSOA*		*MRA*

Five of the seven respondents reported a company size of 1-10 employees, one company reported 26-50 employees, and one company reported 51-100 employees.

Five companies reported PMA certificates as applicable to their company; two companies reported PC certificates as applicable to their company; two companies reported STC as applicable to their company; one company reported TC, TSOA, and MRA were also applicable.

A majority of the respondents were very small companies (1-10 employees) in the PMA business. This result was not surprising, as the MARPA conference is a conference for PMA companies and customers.

3. *What percentage of total average annual costs is attributable to FAA certification activities?*
   a. 0% *d. 30%*
   b. 10% *e. 50%*
   c. 20%

   ***If able, please provide the total average annual costs attributable to FAA certification activities in dollars. $______________*

In response to this question:

- two companies reported that 10% of costs were attributable to certification;
- two companies reported that 20% of costs were attributable to certification;
- two companies reported that 30% of costs were attributable to certification; and
- one company reported that 100% of costs were attributable to certification activities.

Two companies were able to provide cost estimates in dollars: one company reporting 30% of costs attributable to certification estimated the real cost to be approximately $1 million; the company reporting 100% of costs attributable to certification estimated the real cost to range between $400,000 and $1.5 million.

5. *Effect of each method on company costs:*

   i. *What percentage change in cost do you estimate would result from adopting a DO?*
      a. 30% or higher *e. -10%*
      b. 20% *f. -20%*
      c. 10% *g. -30% or lower*
      d. 0%

   ii. *What percentage change in cost do you estimate would result from adopting a Scaled DO?*

      a. 30% or higher e. -10%
      b. 20% *f. -20%*
      c. 10% *g. -30% or lower*
      d. 0%

   iii. *What percentage change in cost do you estimate would result from continuing in the Modified Current Model with fewer DERs?*

      a. 30% or higher *e. -10%*
      b. 20% *f. -20%*
      c. 10% *g. -30% or lower*
      d. 0%

These three questions asked respondents to estimate to what degree they estimated their costs would change based upon the three proposals being considered by the ARC, as explained in the presentation.

When considering a change to the proposed mandatory DO method,

- four companies estimated costs would increase at least 30%;
- one company estimated an increase of 20%;
- one company estimated an increase of 10%; and
- one company provided no response.

The resulting average estimated cost increase of a mandatory DO method was approximately 25%.

When considering a change to the proposed "Scaled DO" method:

- three companies estimated costs would increase at least 30%;
- three companies estimated costs would increase 10%; and
- one company provided no response.

The resulting average estimated cost increase of adoption of the Scaled DO method was approximately 20%.

When considering a change to the current model, designated a Modified Current Model,

- one company estimated costs would increase at least 30%;
- one company estimated costs would increase 20%;
- four companies estimated no change in costs; and
- one company provided no response.

The resulting average estimated cost increase of adoption of the Modified Current Model was approximately 8.3%.

6. ***If your company was able to initiate projects immediately (no sequencing queue) what do you estimate would be the effect on annual revenue?***

a. 30% or higher	*e. -10%*
b. 20%	*f. -20%*
c. 10%	*g. -30% or lower*
d. 0%	

This question asked respondents to estimate the effect on revenues if their company was not required to wait in the sequencing or project prioritization queue to initiate a project. The purpose of the question was to gauge the perceived benefit of privileges associated with both the Mandatory DO and Scaled DO models.

When considering the benefit of immediate project initiation:

- one company estimated at least a 30% increase in revenue;
- one company estimated a 20% increase in revenue;
- four companies estimated a 10% increase in revenue; and
- one company provided no response.

The resulting average estimated increase in revenue as a result of immediate project initiation (no sequencing queue delay) was approximately 15%.

7. If your company was able to initiate projects immediately (no sequencing queue) what do you estimate would be the effect on product time to market?

a. No Change
b. 3 months sooner
c. 6 months sooner
d. 9 months sooner
e. 12 months or more

This question asked respondents to estimate the effect on product time to market if their company was not required to wait in the sequencing or project prioritization queue to initiate a project. The purpose of the question was to gauge the perceived benefit of privileges associated with both the Mandatory DO and Scaled DO models.

When considering the benefit of immediate project initiation:

- one company estimated it could bring products to market 9 months sooner;
- five companies estimated they could bring products to market 3 months sooner; and
- one company provided no response.

The resulting average estimated time savings as a result of immediate project initiation (no sequencing queue) was approximately 4 months.

8. What do you estimate would be the effect on annual costs given a 50% reduction in DERs?

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

This question asked respondents to estimate the effect on annual costs if the number of certificated DERs was reduced by 50%. The purpose of this question was to gauge the perceived costs associated with a significant reduction in DERs associated with the Modified Current Model.

When considering the costs of a 50% reduction in DERs:

- four respondents estimated their costs would increase at least 30%;
- one company estimated its cost would increase approximately 10%;
- one company estimated 0% change in costs; and
- one company provided no response.

The resulting average estimated increase in costs as a result of a 50% reduction in DERs was approximately 21.6%.

9. *What do you estimate would be the effect on product time to market given a 50% reduction in DERs?*

   a. *No Change*
   b. *3 months sooner*
   c. *6 months sooner*
   d. *9 months sooner*
   e. *12 months or more*

This question asked respondents to estimate the effect on product time to market if the number of certificated DERs was reduced by 50%. The purpose of this question was to gauge the perceived costs associated with a significant reduction in DERs associated with the Modified Current Model.

When considering the effect on product time to market of a 50% reduction in DERs:

- three respondents estimated that such a reduction would result in an increase time to market of at least 12 months;
- one respondent estimated an increase of approximately six months;
- one respondent estimated an increase of approximately 3 months;
- one respondent estimated no change; and
- one company provided no response.

The resulting average estimated increase in time to market as a result in a 50% reduction of DERs was approximately 7.5 months.

10. *Please answer the following questions related to designees and ODA:*

    a. *Is your company an ODA? ____ Y______ N*

    b. *Does your company have DERs? ______ Y______ N*

    c. *Do you utilize consultant DERs? ______ Y______ N*

The purpose of this question was to solicit information from respondents with respect to the current source of their design data approval.

In response:

- one respondent reported holding an ODA,
- one company reported having its own DERs, and
- seven companies (all respondents) reporting utilizing consultant DERs.

Widespread use of consultant DERs may lend support to respondents' estimates of increased costs and times to market based on a 50% reduction in DERs, anticipated in questions 8 and 9.

11. For certification process requirements only, which of the following most closely approximates your average annual certification costs?

a. $10,000
b. $50,000
c. $100,000
d. $500,000
e. $1,000,000

This question asked respondents to estimate annual costs solely attributable to certification. The responses varied broadly:

- two respondents estimated annual certification costs of approximately $10,000;
- one respondent estimated annual costs of approximately $50,000;
- one respondent estimated costs of approximately $100,000;
- one respondent estimated costs of approximately $500,000;
- one respondent estimated costs of at least $1 million; and
- one respondent provided no response.

The resulting average annual certification costs under the current model are approximately $278,333.

12. Which option is most likely applicable to your business?

a. Design Organization
b. Scaled Design Organization (autonomy w/ 3rd party audits)
c. Current system (reduced DERs plus sequencing process)

This question asked respondents to anticipate which of the three proposed models would best fit their business. In response:

- one respondent stated that the DO model would be most applicable;
- two companies responded that the scaled DO or modified current model would be most applicable;
- three companies stated that the modified current model would be most applicable; and
- one company provided no response.

13. *For the purpose of better understanding the impact of any proposed changes, please provide FAA approved product/services annual sales (Optional)* ___________________________

Willingness to respond to this question was limited, with only two responses. One company reported annual sales of approximately $1.2 million, and one company reported annual sales of approximately $5 million.

V.d.ii. COST BENEFIT SURVEY OF LARGE ORGANIZATIONS

The large company survey was designed by the CBA WG and sent by the Part 21/SMS ARC to seven U.S. aerospace companies-- including airframe manufacturers, engine manufacturers, and an appliance manufacturer. All seven companies were represented on the ARC. Useful responses were promptly received from all seven companies.

Survey Preamble

In a preamble to the survey questions, the document discussed the potential benefits of DO with SMS as a systems approach. The DO (with SMS) would be an FAA-certificated organization that would have the privileges and responsibilities for finding compliance rather than just showing compliance as is currently required under the current designee system (ODA and/or individual designees). The current system requires, for each project, a highly redundant series of compliance "showings" by the manufacturer, followed by corresponding FAA "findings" of compliance. The FAA's level of project involvement (LOPI) is high.

Under the DO system, the FAA would concentrate its limited resources on performance-based auditing and oversight of the manufacturer's systems, rather than on individual projects. The FAA's LOPI would be greatly reduced or even eliminated by eliminating redundant findings by the FAA in areas such as flight testing, conformity, etc. The FAA's LOPI would depend on the degree of project risk or novelty. For projects of low risk or high standardization, the FAA's LOPI would be *low* and could even be reduced to zero for standardized products of sufficiently low risk, in which case the manufacturer could initiate and undertake the project on its own. The only direct involvement of the FAA in the project would be to issue the certificate or approval upon project completion. For projects of greater risk or novelty, the FAA would have a higher LOPI since the FAA would have to establish a certification basis, taking into account special conditions, exemptions, equivalent level of safety (ELOS) findings, etc. But with the FAA involved at just the beginning and at the end of the project level, the FAA's LOPI would still be greatly reduced compared to the current system.

Survey Results

The survey was comprised of fourteen questions designed to obtain industry cost-benefit estimates of a requirement being considered by the ARC that large firms be required to change from an ODA/Individual Designee System to a DO along with implementation of SMS.

The first three questions requested background information about each respondent:

1.Parent company name:
2. Aviation company name (e.g. subsidiary, division, business unit):
3.Aviation comp any contact person, telephone number, and email address:

It is important to distinguish between the parent company and the aviation company, which may be a subsidiary, division, business unit, etc. of the parent company. This was the case for all seven of the large aviation companies that were surveyed.

The respondents provided business names and points of contact for the purposes of follow up surveys if necessary. In order to maintain confidentiality, the respondent companies and contacts are not identified in this report.

> *4. Aviation company number of employees (recent years):*
>
> *5. Aviation company total revenues: $_________.*
>
> *6. Aviation company revenues from sales of FAA-approved products or articles (optional, but encouraged): $ _________*
>
> *7. Percentage of aviation company revenues derived from sales of FAA-approved products or articles: $_________.*

Questions 4 through 7 were intended to measure the aviation company size. Employment and total revenues are standard size metrics. Even though all seven companies are considered large, there is an order of magnitude difference between the smallest company in the sample compared to the largest company, with employment size ranging from 7,500 to 80,000 and total revenues ranging from $3 billion to $53 billion.

Questions 6 and 7 asked for aviation company revenues from sales of FAA-approved products or articles and for the same estimate as a percentage of aviation company revenues. Six of seven respondents answered one or both of these questions, so we either were given complete information for these questions or we could calculate it. Since the proposed rule applies only to aviation products that must be approved by the FAA, for our purposes this is a better value measure of size than total aviation company revenues. The percentage varied widely from 25% to 85%, with a median value of 68%, attesting to the importance of distinguishing between the two measures.

> *8. Your company uses which of the following? (Please check all that apply.) [ODA, Company Designees, Consultant Designees]*

Six of seven companies reported using ODAs. Half of these also used company and consultant designees. One company reported using company designees only.

9. Check all certificates/approvals that apply to your company:

________Type Certificate (TC)
________Amended Type Certificate (ATC)
________Supplemental Type Certificate (STC)
________Amended Supplemental Type Certificate (ASTC)
________Parts Manufacturer Approval (PMA)

Not surprisingly, large aviation companies generally apply for a wide range of certificate/approval types. The table below summarizes the responses received:

CERTIFICATES/APPROVALS	NO. OF COMPANIES
All	3
TC, ATC, STC, PMA	2
TC, ATC	2

10a. What percentage of total costs of FAA-approved products, in a typical year, is attributable to compliance with FAA regulations? (Put differently, what percentage of your costs of FAA-approved products would not occur if there were no FAA regulation of your products?) Please choose the answer closes to your estimate (0%, 10%, 20%, 30%, 50%, Other (explain)).

*10b. *If possible, please provide a dollar amount for the percentage indicated above: $ _______.*

We asked this question primarily as a percentage because we anticipated that companies would have difficulty in estimating a dollar amount. All companies answered the percentage question and three companies answered the dollar amount question. The purpose of this question was to get an objective, consistent measure of the burden of FAA regulation and, therefore, what scope there might be for regulatory changes, such as the proposed DO system that could reduce that burden.

Removing one outlier of 70% from the sample, the median response was 20%. Retaining the outlier, the median response was 30%.

11. The FAA anticipates that there may be <u>incremental non-recurring transition</u> costs in converting from an ODA (or individual designee system) to a DO with SMS. The FAA anticipates that large firms will have two years to convert from their current system to a DO with SMS.

Please provide your estimate of these transition costs, if any. (Unless you state otherwise, the FAA will assume these costs would be spread equally over the two-year conversion period.) $__

12. The FAA anticipates that there may be <u>incremental recurring</u> costs and benefits for a DO system with SMS, and there could be offsetting savings in recurring costs. As noted above, the FAA anticipates that cost savings could result from the DO privileges that eliminate redundant findings (conformity, testing, etc.).

In answering the following question please consider the current elements of SMS that your company has already implemented.

a. Please provide an estimate of your changes in recurring costs as a result of changing from an ODA (or individual designee system) to a DO with SMS. $ __________________.

b. Please provide an estimate of your changes in recurring benefits (cost savings) as a result of changing from an ODA (or individual designee system) to a DO with SMS. $______________.

These are the key questions of the survey, as they address the issue of whether or not the proposed DO system is cost-beneficial. Question 11 asked for estimates of the incremental non-recurring transition costs in moving from an ODA (or individual designee system to the DO system. Question 12 asked for estimates of incremental recurring costs and benefits of the DO system.

The WG was somewhat surprised to learn that the large companies considered the proposed DO system to be far from cost-beneficial. Two companies provided no cost-benefit estimates as they stated that estimates were "difficult to estimate at this time" or that estimates were "too premature to determine." One company's responses were large outliers, so just four of the responses were incorporated in the analysis.

For these companies the median response for question 11—non-recurring transition costs—was $2 million, but with one estimate at a very high $30 million.

For Question 12, the four responding companies found recurring costs to be much higher than recurring benefits. The ratio of costs/benefits for the four companies were:

- Company 2: 1-2/3
- Company 3: 1-3/4
- Company 4: 2
- Company 5: 5

This gave a median response of approximately 2 to 1, costs to benefit.

Discussion with ARC company representatives suggest that possible reasons for this result are that the large company representatives believe that:

- the DO system provides no additional benefits beyond what is provided by the ODA, or that will be provided when the ODA is fully matured; or
- the DO proposal is premature since the ODA has not fully matured; or
- the DO system is far from cost-beneficial now, but could be cost-beneficial after other companies have adopted it and worked out the implementation.

Additionally, informal discussions with company representatives after the survey was completed indicate that the companies did not sufficiently focus on their potential benefits in responding to the survey. This finding suggests that greater attention must be given to potential benefits in future surveys.

13. What are the most important privileges that you anticipate from becoming a DO? If possible please provide estimates of your anticipated cost savings from these privileges.

With the exception of the outlier company, all companies expected some benefits from the DO system. The CBA WG expected companies to answer this question with reference to the many possible redundancy eliminations discussed in the survey preamble. However, just two companies did so; both cited elimination of redundant conformity and one also cited elimination of redundant aircraft flight testing. The other four companies responded in generalities, citing *"Systemic/centralized oversight," "Work more efficiently,"* etc. One company stated that "*Over the years, we have adopted various delegation structures without prohibitive burdens to our business. In fact, many were accomplished with recognition of a benefit to business operators.*"

These results point again to the necessity, already noted, of focusing greater attention on potential benefits in future surveys.

14. Under the current regulatory framework, FAA sequencing may force a delay in applicant projects from several months to over a year. The FAA anticipates that sequencing would be eliminated for DOs.

Please choose the estimate closest to the average direct delay to your projects caused by current FAA sequencing:

_________ *0 months*
_________ *3 months*
_________ *6 months*
_________ *9 months*
_________ *12 months*
_________ *More than 12 months*

Four of the seven companies reported delays caused by FAA sequencing of 3 to 6 months. One company reported a recurring annual benefit of reduced delay under the DO system of $3 million. The cost of delay and the corresponding potential benefit of reduced delay under the DO system are important subjects for further analysis.

V.d.iii. COST BENEFIT ANALYSIS OF SMS

A cost benefit analysis of SMS was not specifically performed. The CBA WG chose not to perform an independent analysis of SMS for two primary reasons:

1. The ARC came to an agreement that SMS would be an integrated piece of a Design Organization. Therefore, breaking out SMS as an independent entity was not preferred by ARC members submitting cost and benefit data.

2. SMS is intended to be an integrated part of a company business process and not a standalone "layer" or tasking. Given the difficulties in costing out process-oriented requirements, SMS was not looked at independently.

However, even though follow on activity needs to be performed in this area, the CBA WG does perceive there to be a benefit in implementing SMS, with or without a DO. If SMS is not regulated by the FAA when required by other countries or ICAO, companies interested in doing business outside of the U.S. will need to meet SMS requirements for each country in which they choose to do business. This could create multiple and duplicative Safety Management Systems for companies doing international business. Please refer to section IV for additional details on International Harmonization.

VI. LESSONS LEARNED

VI.a. ROLE OF A CBA WG IN ARC ACTIVITIES

1. Establishing a Cost-Benefit Analysis Working Group was a beneficial step.

Cost benefit analyses (CBA) have traditionally been an afterthought in the course of previous FAA Aviation Rulemaking Committee (ARC) activities. The FAA normally takes the action to develop a regulatory analysis only during a formal rulemaking process, usually long after the ARC's final recommendations are submitted to the FAA.

The Part 21/SMS ARC took steps to break with tradition by making CBA a part of the ARC from the beginning and throughout its activity. For the first time under any FAA advisory committee a CBA WG was chartered and established to play a fundamental role in the development of the ARC's recommendations. As a result, the need for a CBA was recognized by the ARC from the time the ARC was initiated.

The CBA WG recommends that there should, in most cases, be a role for such a group in future ARCs.

2. CBA WG membership should be drawn from the full ARC.

In course of its work, the CBA WG was directed to stay connected to the other three Working Groups to facilitate inclusion of their thinking and recommended actions into a methodology for assessing costs and benefits.

Future ARCs would benefit if CBA is required not only to be considered early on, but to be required as part of the charter of each Working Group that is established under an ARC.

On the other hand, if a separate CBA WG must be established, its membership should be drawn from the full ARC. It is important that a CBA WG be significantly informed of the ARC's direction throughout the process in order to be fully informed in its final recommendations; an integrated and assimilated connection with the full ARC will ensure this.

3. CBA WG activity should be phased in.

The introduction of a separate CBA WG should be phased in over the course of the ARC. While CBA itself should be considered by the ARC from the beginning, a working group focused on CBA should be initiated when the full ARC recommendations reach a high level of maturity. At the onset, the CBA WG did not have a clear idea of the specific directional goals toward which the ARC was aiming. The CBA WG's first activities for several months were based on assumptions of what the ARC would eventually recommend, some of which turned out to be erroneous.

Even though the CBA WG stayed connected with the full ARC, two decisions made by the other WGs late in the ARC process served to preclude much of the initial work of the CBA WG, requiring a significant amount of rework:

- The decision not to address smaller ("below-the-threshold") entities under the ARC's work. *(This decision was made approximately half-way through the course of the ARC.)*

- The decisions to require SMS, but not to mandate DO, for the larger entities. *(This decision was made as part of the final recommendations of the Organizational WG, very late in the ARC process.)*

The cost surveys that the CBA WG originally designed and deployed to obtain necessary data based on our original assumptions, were intended to capture these very costs. While the data gathered from the two surveys are still valuable, the surveys may have been quite different (and more appropriate) had the two decisions been made early on in the course of the ARC and if the CBA WG had been more embedded in the decision-making.

In light of this experience, we recommend that future CBA WGs be initiated about a third or a half of the way into the course of the ARC, when the recommendations reach a high level of maturity. This is to ensure that that the CBA WG has a fairly certain idea of the directional goals of the ARC before attempting to target and capture costs. This approach simply recognizes the deliberative and developmental nature of the ARC process, where goals and directions evolve as the ARC members consider various approaches. Because CBA is so dependent upon analyzing the impact of specifically proposed requirements, waiting for some form of consensus on an ARC approach could save some wasted effort in the future.

4. An FAA economist must be a member of the WG.

It is essential to have an FAA economist participate as a regular member of the CBA WG. While the CBA WG was encouraged to think "out of the box" for new ways to perform quantitative and qualitative analyses, having an FAA economist on the team brought a level of discipline and reality to our analyses. In addition, an FAA economist also brings detailed knowledge regarding analytical methodologies that will be acceptable to the FAA and OMB. This is of immense value in developing CBA data that can actually be used by the FAA in the rulemaking process, hopefully shortening the time required to prepare a proposed rule for publication.

VII. CONCLUSION

In conclusion, the CBA WG found that overall change is needed for both the industry and for the FAA. Based on discussion and statistics, there is a uniform concern that the current certification system is not sustainable given industry growth and the FAA change in resources and budgetary constraints of recent years. The CBA WG cannot, within its limited scope, collectively conclude that a DO with the inclusion of SMS is the appropriate change; however, it is becoming more and more apparent that a major change to the current certification system is needed. This conclusion is a combination of statistical data, quantitative and qualitative analysis, and assumptions all gathered by the CBA WG.

The constraints and advantages of the CBA WG led to the following findings:

- A Design Organization that is recommended as voluntary does not require a cost benefit analysis. If the efforts for implementation are voluntary then the costs incurred are also voluntary.

- The cost vs. benefit of implementing SMS without a Design Organization must be further researched. Given the late decision by the Organization Working Group to recommend DO as optional, the CBA WG did not have sufficient time to gather data on SMS independent of a DO.

Of the data gathered from small organizations pertaining to implementing mandatory DO with SMS, a Scaled DO, or Modified Current Model, the following key findings were made:

- The 2013 MARPA Conference was extremely useful in the fact that small business does not always have the resources to participate full time on Aviation Rulemaking Committees. Holding a workshop and distributing a survey during the MARPA conference proved that small business does have a strong interest in proposed changes to certification. Additionally, there is a common feeling that change to the current system is needed.

- The resulting average estimated cost increase of adoption of:
    - DO with the inclusion of SMS was approximately 25%;
    - Scaled DO (Accredited Organization) was approximately 20%; and
    - Modified Current Model was approximately 8.3%.

- The data also revealed that the resulting average estimated increase in revenue as a result of immediate project initiation (no sequencing queue delay) was approximately 15%. This is a significant benefit that may compensate for cost of a DO with SMS or the Scaled DO (Accredited Organization).

- Respondents estimated the effect on revenues if their company was not required to wait in the sequencing or project prioritization queue to initiate a project. The purpose of the question was to gauge the perceived benefit of privileges associated with both the Mandatory DO and Scaled DO models. The resulting average estimated time savings as a result of immediate project initiation (no sequencing queue) was approximately 4 months.

Of the data gathered from <u>large organizations</u> pertaining to implementing mandatory DO with SMS, the following key findings were made:

- The large company survey responses considered a mandatory DO system to be far from cost-beneficial. Two companies provided no cost-benefit estimates, as they stated that estimates were "difficult to estimate at this time" or that estimates were "too premature to determine." One company's responses were large outliers, so just four useful responses were received. This gave a median response of approximately 2 to 1, costs to benefits.

- Discussion with ARC company representatives suggests that possible reasons for this result are that the large company representatives believe that:

  - the DO system provides no additional benefits beyond what is provided by the ODA, or that will be provided when ODA is "fully matured;" or

  - the DO proposal is premature since ODA has not fully matured; or

  - the DO system is far from cost-beneficial now, but could be cost-beneficial after other companies have adopted it and worked out issues with implementation.

- Additionally, informal discussions with company representatives after the survey was completed indicated that the companies did not sufficiently focus on their potential benefits in responding to the survey. This finding suggests that greater attention must be given to potential benefits in future surveys.

Additional key findings of the CBA WG include:

- Manufacturers had difficulty articulating baseline certification costs. Part 21 is a process oriented rule, therefore, this made for a very broad and difficult rule to cost out. The cost was calculated in a more general format and described mostly in percentages by the majority of participants.

- Large and small manufacturers had difficulty articulating benefits. Although the benefits were understood by participants from a conceptual level, most participants were unable to express benefits in monetary values. Therefore, a benefits survey is strongly encouraged as a follow-on activity to this ARC and to future rulemaking efforts.

Lastly, in the event a formal rulemaking project takes place the formal cost benefit analysis should consider the following recommendations to the traditional process.

- Consider a separate survey to gather benefit data. A key finding was that respondents had significant difficulty articulating benefits. Gathering data from multiple benefit questions can provide adequate data to calculate efficiencies. Relying on the industry to calculate this information is not a viable solution. In the case of SMS and changes to part 21, process oriented requirements are far too broad to calculate in one question.
- When benefits were described in a form of a question respondents were able to better estimate cost savings.
- Efficiencies can be calculated through a number of equations commonly used in industry and by other agencies. The most simple of these includes the following:

  Efficiency = Expense/Revenue

  This is one simple example of a possible solution to calculating efficiencies in typical business operations.
- Efficiencies must be broken out into tangible items whenever possible. In areas where this is not possible a qualitative assessment is acceptable to OMB according to OMB Circular A4.
- The CBA WG did not look at SMS independent of a DO, however, a common response by the industry was to consider the following:
  - Identify industry cost of maintaining and satisfying multiple SMSs

    compared with

    A single SMS accepted internationally.

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APPENDIX A

Part 21/SMS Cost-Benefit Working Group Cost Survey of Large Companies

Cost of Potential Rule Changes to Aircraft Certification Process

You are receiving this survey because your company is a large aviation design and manufacturing company (D&M) that may be affected by the FAA's planned rulemaking to streamline part 21 certification requirements. The intent of this rulemaking activity is to facilitate shifting DAHs to a systems approach similar to that used for production approval holder requirements. The FAA anticipates that this effort will most likely replace the current Organization Designation Authorization (ODA) program (or individual designee system) with a new Design Organization (DO) program, which includes implementation of a Safety Management System (SMS).

*We are reaching out to you to obtain information that will help us conduct a required analysis to determine the costs and benefits associated with potential regulatory changes. Please be aware that all information provided will be held as strictly **confidential** and will be **de-identified** when used in our analyses.*

Your cooperation in this activity is very much appreciated.

Background

In late 2012, the FAA chartered the Part 21/Safety Management System (SMS) Aviation Rulemaking Committee (ARC). This ARC was tasked with recommending improvements, to the effectiveness and efficiency of existing certification procedures, along with incorporating SMS into the design and manufacturing environments. The recommendations could likely be for rulemaking to integrate these improved certification procedures into Part 21, "Certification Procedures for Products and Parts." As with any rulemaking, the law requires the FAA to perform a cost-benefit analysis to determine the economic impact of the rule.

This cost survey has been developed by the Cost Benefit Analysis Working Group to solicit information from you to help us identify the changes in your certification costs. The proposed revision of Part 21 certification procedures would require your design and manufacturing (D&M) company to replace its current designee system (ODA and/or individual designees) with a new Design Organization (DO) and require the incorporation of a Safety Management System.

The DO Concept in Brief

Under this new concept, a DO (which includes SMS) would be an FAA-certificated organization that would have the privileges and responsibilities for finding compliance rather than just showing compliance as is currently required for an ODA. This authority would be based on the DO having adequate engineering, design and testing capabilities, standards, and safeguards to ensure that the product being certificated is properly designed and manufactured, performs properly, and meets the regulations.

Greatly reduced or even eliminated would be the redundant testing and evaluations in the current model under which a series of compliance "showings" by the manufacturer are followed by FAA "findings" verifying compliance. These redundancies may include:

1. Ground testing
2. Coupon/material testing
3. Component part testing
4. Flight testing
5. Noise testing
6. Conformity
7. Supplier qualification, evaluation, and use of test plans
8. Data change control

As a result, the FAA's level of project involvement (LOPI) would be greatly reduced. Projects with greater risk or novelty would have a higher--although still greatly reduced--LOPI since in establishing a certification basis the FAA would have to take into account special conditions, exemptions, and equivalent level of safety (ELOS) findings, etc. For less risky/less novel products the FAA's LOPI would be much lower and could even be reduced to zero for standardized products of sufficiently low risk. Reduced LOPI would allow the FAA to concentrate its limited resources on risk management and performance-based auditing and oversight.*(Continued on next page.)*

Part 21/SMS ARC
Large Business – Cost Survey

This survey requests your cost estimates of potential changes to the existing Part 21 regulation that would require the conversion of your company to a DO (as defined above) with full implementation of SMS.
For the following questions, please use current dollars for all dollar estimates. You may type your answers, creating space as necessary.

COMPANY DATA

1. Parent company name: ______________________________.
2. Aviation company name (e.g. subsidiary, division, business unit):

   ______________________________.

3. Aviation company contact person, telephone number, and email address:

   ______________________________.

4. Aviation company number of employees (recent years): ____________________.
5. Aviation company total revenues $ ____________________.
6. Aviation company revenues from sales of FAA-approved products or articles (optional, but encouraged):

   $____________________.

7. Percentage of aviation company revenues derived from sales of FAA-approved products or articles:

   $______________________________.

8. Your company uses which of the following? (Please check all that apply.)

Check	Designee System
	ODA
	Company Designees
	Consultant Designees

9. Check all certificates/approvals that apply to your company:

Check	Type of Certificate/Approval
	Type Certificate (TC)
	Amended Type Certificate (ATC)
	Supplemental Type Certificate (STC)
	Amended Supplemental Type Certificate (ASTC)
	Parts Manufacturer Approval (PMA)

COST ESTIMATES

10. What percentage of total costs of FAA-approved products, in a typical year, is attributable to compliance with FAA regulations? (Put differently, what percentage of your costs of FAA-approved products would not occur if there were no FAA regulation of your products?)

Please choose the answer closest to your estimate

Check	Percentage Cost
	0%
	10%
	20%
	30%
	50%
	Other (explain):

*If possible, please provide a dollar amount for the percentage indicated above.

$ ____________________

11. The FAA anticipates that there may be incremental non-recurring transition costs in converting from an ODA (or individual designee system) to a DO with SMS. The FAA

anticipates that large firms will have two years to convert from their current system to a DO with SMS.

Please provide your estimate of these transition costs, if any. (Unless you state otherwise, the FAA will assume these costs would be spread equally over the two-year conversion period.)

$ ____________________

12. The FAA anticipates that there may be incremental recurring costs and benefits for a DO system with SMS, and there could be offsetting savings in recurring costs. As noted above, the FAA anticipates that cost savings could result from the DO privileges that eliminate redundant findings (conformity, testing, etc.).

    In answering the following question please consider the current elements of SMS that your company has already implemented.

    a. Please provide an estimate of your changes in recurring costs as a result of changing from an ODA (or individual designee system) to a DO with SMS.

$ ____________________

    b. Please provide an estimate of your changes in recurring benefits (cost savings) as a result of changing from an ODA (or individual designee system) to a DO with SMS.

$ ____________________

13. What are the most important privileges that you anticipate from becoming a DO? If possible please provide estimates of your anticipated cost savings from these privileges

Privilege	Cost Savings
	$
Total Cost Savings	$

Note: Your figure for Total Cost Savings should be consistent with your calculation of recurring cost savings in question 12.

14. Under the current regulatory framework, FAA sequencing may force a delay in applicant projects from several months to over a year. The FAA anticipates that sequencing would be eliminated for DOs.

Please choose the estimate closest to the average direct delay to your projects caused by current FAA sequencing.

Check	Sequencing Delay
	0 months delay
	3 months delay
	6 months delay
	9 months delay
	12 months delay
	More than 12 months delay (Please specify length of delay.) ___________________

15. Please identify any additional significant cost-benefit impacts, other than already discussed in the preamble above or responded to in the survey.

For clarification of the survey questions, please contact Daniel Leach, Economist, FAA Office of Aviation Policy and Plans, Economic Analysis Division (APO-300), tel: 202-267-3335, e-mail: daniel.leach@faa.gov. For technical questions please contact Amy Garzaro, Aerospace Engineer, FAA Aircraft Certification Service, Safety Management Design and Analysis Branch (AIR-150), tel: 727-559-1387, e-mail: amy.garzaro@faa.gov.

APPENDIX B

Part 21/SMS Cost-Benefit Working Group Cost Survey of Small Companies

Part 21/SMS ARC Impact on Small Business – Questionnaire

October 23, 2013

Company Name (Optional) ____________________

Point of Contact Name/Phone Number if interested in participating further:

____

1. **Select your company size range:**

	1-10 employees		11-25 employees		26-50 employees		51-100 employees
	101-500 employees		501-1000 employees		1001-1499 employees		1500+ employees

2. **In what State is your company primarily located?** ____________________

3. **Select all certificates that apply to your company:**

	TC		PC		STC
	PMA		TSOA		MRA

4. **What percentage of total average annual costs is attributable to FAA certification activities?**

   a. 0% b. 10% c. 20% d. 30% e. 50%

   **If able, please provide the total average annual costs attributable to FAA certification activities in dollars. $____________

5. **Effect of each method on company costs:**

   I. **What percentage change in cost do you estimate would result from adopting a DO?**

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

II. **What percentage change in cost do you estimate would result from adopting a scaled DO?**

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

III. **What percentage change in cost do you estimate would result from continuing in the modified current model with fewer DERs?**

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

6. **If your company was able to initiate projects immediately (no sequencing queue) what do you estimate would be the effect on annual revenue?**

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

7. **If your company was able to initiate projects immediately (no sequencing queue) what do you estimate would be the effect on product time to market?**

a. No Change
b. 3 months sooner
c. 6 months sooner
d. 9 months sooner
e. 12 months or more

8. **What do you estimate would be the effect on annual costs given a 50% reduction in DERs?**

a. 30% or higher
b. 20%
c. 10%
d. 0%
e. -10%
f. -20%
g. -30% or lower

9. **What do you estimate would be the effect on product time to market given a 50% reduction in DERs?**

a. No Change
b. 3 months sooner
c. 6 months sooner
d. 9 months or sooner
e. 12 months or sooner

10. **Please answer the following questions related to designees and ODA:**

a. Is your company an ODA? ___Y___N

b. Does your company have DERs? ___Y___N

c. Do you utilize consultant DERs? ___Y___N

11. **For certification process requirements only, which of the following most closely approximates your average annual certification costs?**

a. $10,000
b. $50,000
c. $100,000
d. $500,000
e. $1,000,000

12. **Which option is most likely applicable to your business?**

a. Design Organization
b. Scaled Design Organization (autonomy w/ 3rd party audits)
c. Current system (reduced DERs plus sequencing process)

13. **For the purpose of better understanding the impact of any proposed changes, please provide FAA approved product/services annual sales (Optional)** ____________________

APPENDIX C

CBA Working Group Members

Segment	Organization	Name
Association - AIA	AIA	George Novak
Association - GAMA	GAMA	Jens Hennig
Association - MARPA	MARPA	Ryan Aggergaard
Transport	Boeing	Jill DeMarco
Systems	Honeywell	Joe Caldwell
FAA	AIR-100	Dave Hempe
FAA	**AIR-150**	**Amy Garzaro***
FAA	APO-300	Daniel Leach
EASA	EASA	Miklos Kedves
Observer	EASA	Jan Novak
Observer	EASA	Eric Sivel
Observer	ANAC	Maria Clara

***Working Group Lead**

APPENDIX K—SM ICG FINDINGS ON SMS EQUIVALENCE

SAFETY MANAGEMENT
INTERNATIONAL COLLABORATION GROUP

SM ICG Findings on SMS Equivalence

April 14, 2011

This paper was prepared by the Safety Management International Group (SM ICG). The purpose of the SM ICG is to promote a common understanding of Safety Management System (SMS)/State Safety Program (SSP) principles and requirements, facilitating their application across the international aviation community.

The current core membership of the SM ICG includes the National Civil Aviation Agency (ANAC) of Brazil, the Civil Aviation Authority of the Netherlands, the Civil Aviation Authority of New Zealand, the Civil Aviation Safety Authority (CASA) of Australia, the Direction Générale de l'Aviation Civile (DGAC) in France, the European Aviation Safety Agency (EASA), the Federal Office of Civil Aviation (FOCA) of Switzerland, Japan Civil Aviation Bureau (JCAB), the United States Federal Aviation Administration (FAA) Aviation Safety Organization, Transport Canada Civil Aviation (TCCA) and the Civil Aviation Authority of United Kingdom (UK CAA). Additionally, the International Civil Aviation Organization (ICAO) is an observer to this group.

Members of the SM ICG:

- Collaborate on common SMS/SSP topics of interest
- Share lessons learned
- Encourage the progression of a harmonized SMS
- Share products with the aviation community
- Collaborate with international organizations such as ICAO and civil aviation authorities that have implemented or are implementing SMS and SSP

For further information regarding the SM ICG please contact:

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International Civil Aviation Organization (ICAO) standards require each state to implement a State Safety Program (SSP). SSP requirements include mandates for States to require certain aviation product and service providers to implement Safety Management Systems (SMS). A number of Product and Service Providers (P/SPs) worldwide have expressed concern regarding implementation and acceptance processes for Safety Management Systems (SMSs). This is especially acute for P/SPs that are subject to certification, approval, or other authorizations of their products and services by multiple authorities.

In many cases, SMSs will be a prerequisite for issuance of an organizational certificate. This is the case for those organizations whose activities are controlled by certification of their operational processes, such as Air Operator Certificate (AOC) holders and Approved Maintenance Organizations (AMOs). State-P/SP relationships for type certificate holders and production certificate holders, however, are more varied between authorities. For example, some authorities certificate design organizations and some do not. In either case, the product itself is also subject to type design approval or certification.

For regulators, the problem becomes one of ensuring an equivalent level of safety when granting authorizations for other States' P/SPs without imposing excessive technical, legal, and administrative burdens on the companies. For P/SPs, the problem becomes one of not only being required to go through multiple authorities' acceptance and auditing processes, it also presents them with the possibility of conflicting requirements, a significant management problem.

While ICAO standards outline requirements for SMS, including a detailed SMS framework, the performance of any organizational system or process in practice depends not only on the requirements, but the way in which those requirements are implemented. For States to be confident in the equivalence of safety performance of product and service providers whose SMSs have been accepted by another State, the two states will need to agree on standards, expectations for final implementation, acceptance processes, performance measurement strategies, and processes for continued oversight.

The Safety Management International Collaboration Group (SMICG) a chartered group of technical representatives of several aviation safety authorities, was asked to analyze the issue of equivalence of SMS and the implications of SMS acceptance among authorities. The group found two major components to this issue.

The first component concerns the nature of mutual or reciprocal recognition of SMS by different authorities. It was recognized that there are existing precedents and current processes for dealing with this part of the issue including bi-lateral agreements that cover a broad range of aviation organizations, products, services, and activities. These involve a mixture of diplomatic, legal, and technical arrangements between States. Given the group's charter and core expertise, it was the consensus of the SMICG that the latter element should be the sole focus of the group's analysis. Given that, the SMICG members also felt that existing frameworks for interaction between states were adequate. However, in all cases of bi-lateral actions, an assessment of technical equivalence is necessary.

The second component further breaks down the subject of technical equivalence into five areas. SMICG members offered that there is more to technical equivalence than simply having a common set of standards. If the primary interest is in the "bottom line" performance of the products, services, or processes of the organizations whose SMS is being evaluated, additional elements must be evaluated. Having a commonly accepted framework for evaluating SMSs should make these evaluations more structured and efficient Those elements include:

1. Basic Process Requirements. While not sufficient to establish equivalence, use of a common set of basic core requirements is necessary. These have been established in the various ICAO Annexes (with the current exception Annex 8).
2. Implementation Expectations Each State will prepare specific expectations for processes, programs, methods, and tools related to implementing and demonstrating performance on the part of P/SPs. This is where the basic requirements are interpreted into operational definitions, documentation and record-keeping requirements, and procedures.
3. Acceptance Methodology. The methods that the State uses to evaluate the process design and management capability of the P/SP may vary between states. This is usually a function of the State's oversight system (Critical Element of Oversight number 6 – Licensing, Certification and Approval). The combination of specific requirements for implementation and the methodology for acceptance by the State is a large determinant of performance capability. The SMICG Documentation WG is developing an SMS evaluation tool that could be used to support this task.
4. Performance Measurement. States must measure performance of safety management practices in the SMS. Therefore, the methodology used by each State to measure safety performance of P/SPs is important in understanding the performance potential and status of P/SP/s certificated or otherwise approved/accepted by the State.
5. Continuing Oversight Policies and Methods. In order to assure the performance status of P/SPs and their SMSs, continuing oversight is essential. This is also part of a State's oversight responsibility (Critical Element of Oversight number 7 – Surveillance Obligations). Thus each State must have a good understanding and mutual confidence in the methods used to oversee P/SP's SMSs in order to establish equivalence. This will provide confidence that the P/SP is maintaining the same performance capability that was established at initial acceptance.

The SMICG's existing areas of study encompass most of these five critical elements. Therefore, the group offers to continue current projects and, where necessary, draw linkages to the above areas in order to contribute to mutual understanding of the elements of technical equivalence. Implementation of the products to be developed by the SMICG workgroups will provide a baseline for establishing technical equivalence of SMS performance.

The SMICG also recognizes that the issue of equivalence is most acute for design organizations, where differences in certification processes are most significant. The next most potentially problematic area would be in the case of AMOs, where organizational certification is nearly universal but where certification by multiple States' authorities is common. The special problems of these groups will be highlighted in SMICG products.

APPENDIX L—EASA DO APPROVAL CERTIFICATE

European Aviation Safety Agency

APPROVAL CERTIFICATE

EASA.21J.031

Pursuant to Regulations (EC) 1592/2002 and (EC) 1702/2003 and subject to the conditions specified below, the Agency hereby certifies

AIRBUS
1, Rond-Point Maurice Bellonte
31700 Blagnac Cedex
France

as a DESIGN ORGANISATION

approved according to Part 21, Section A, Subpart J

CONDITIONS :

1. The approval is limited to that specified in the enclosed Terms of Approval, and
2. This approval requires compliance with the procedures specified in the Design Organisation Handbook ref. DOM in the latest revision, and
3. This approval is valid whilst the approved Design Organisation remains in compliance with Part 21, Section A, Subpart J.
4. Subject to compliance with the foregoing conditions, this approval shall remain valid until surrendered or revoked.

For the European Aviation Safety Agency,

Date of issue: 28 September 2004

Norbert LOHL
Certification Director

APPENDIX M—RESPONSIBILITY OF EXPORTERS

ASA
AVIATION SUPPLIERS ASSOCIATION

Recommendation for the Removal of 14 C.F.R. § 21.335(b):
Responsibilities of Exporters-Duration of Effectiveness of Packaging

Submitted by the
Aviation Suppliers Association
2233 Wisconsin Ave, NW, Suite 503
Washington, DC 20007

For more information, please contact:
Jason Dickstein
General Counsel
(202) 347-6899

The only packaging metric related to packaging duration is found in ATA Spec 300. Spec 300 lists Category I, II, and III packagings to describe the effectiveness of reusable, multi-trip packaging containers. Category I packaging is usable for 100 round-trips, Category II for 10 round-trips, and Category III for 1 round-trip. Spec 300 does not describe or contemplate a duration requirement for a single-use packaging. More importantly, most packaging used for export of aircraft parts is not designed or certified to ATA Spec 300, so it is not identified by a Spec 300 round-trip limit.

In addition to an absence of single-use packing efficacy duration metrics from packing manufacturers, no guidance material has been produced by the FAA to explain either to industry or to FAA personnel the appropriate methods for determining and stating the duration and effectiveness of packaging. The enforcement of this provision has never been considered an enforcement priority for the FAA.

The provision appears to offer no safety benefits. It does not appear to serve any government interest. It is also a recordkeeping requirement that fails to meet the requirements of the Paperwork Reduction Act (and is therefore unenforceable according to 44 U.S.C. 3512).

Conclusion

Given that Part 21 is currently in the process of a significant re-write, now is an appropriate time to remove § 21.335(b). The paragraph adds needless confusion to the regulations, is impossible to comply with from a practical perspective, and has never been an FAA enforcement priority, making it an unnecessary waste of scare FAA resources. For these reasons ASA recommends that 14 C.F.R. § 21.335(b) be deleted from the Federal Aviation Regulations.

Issue

14 C.F.R. § 21.335(b) states that each exporter of aircraft parts must "[p]reserve and package products and articles as necessary to protect them against corrosion and damage during transit or storage and state the duration of effectiveness of such preservation and packaging." There is no available guidance for compliance with this requirement, nor is data generally available regarding duration of effectiveness of packing. It is not reasonably possible for exporters to comply with this requirement, nor does this requirement serve any government interest. We therefore recommend that Paragraph 21.335(b) of the Federal Aviation Regulations be removed.

Discussion

Part 21 of the Federal Aviation Regulations is currently undergoing significant revisions to incorporate SMS principles into the regulations as well as to make other changes. 14 C.F.R. § 21.335(b) is an unworkable provision based on industry practices, does not reflect the actual nature of packaging for shipments, and has never been an enforcement priority of the FAA.

14 C.F.R. § 21.335(b) reads as follows:

> Unless otherwise agreed to by the importing country or jurisdiction, each exporter must . . . [p]reserve and package products and articles as necessary to protect them against corrosion and damage during transit or storage and state the duration of effectiveness of such preservation and packaging

The duration and effectiveness of single-use packaging is not a metric that is typically available from packaging manufacturers. This is likely because the shipping industry has generally not faced an issue with packaging of such ephemeral effectiveness that its duration has been an issue during the course of a single-use shipment. The practical result of the reliable durability of single-use packaging is that no reliable metrics are produced by or available from packaging manufacturers, making the requirements of § 21.335(b) nearly impossible to satisfy.

APPENDIX N—APPLICANT DECLARATION AND HOLDER OBLIGATION

[DATE]

Gilles Morin
Chief Projects (AARDE)
National Aircraft Certification Branch
Transport Canada Civil Aviation
330 Sparks Street
Tower C, 3rd Floor
Ottawa, Ontario K1A 0N8

SUBJECT: **ENGINE** TYPE CERTIFICATION / APPLICANT DECLARATION AND UNDERTAKING TO CARRY OUT RESPONSIBILITIES PER CAR 521.33 AND 521.57

REFERENCES:
1/ Application For Transport Canada Type Certification Of The **ENGINE**
2/ Transport Canada **ENGINE** Issue Paper G-01, Edition 6 [CLOSED]

Dear Sir:

Type Certificate Applicant / Holder Corp. initially made Application for Transport Canada Type Certification of the **ENGINE** on [**date]** (Reference 1).

On behalf of **Type Certificate Applicant / Holder Corp.** and as required by CAR 521.33 and 521.57, I the undersigned, **[Program - Vice President or Director or Manager]** , declare that:

- **Type Certificate Applicant / Holder Corp** has demonstrated that the **ENGINE,** as defined by Top Engine Assembly Drawing XXXX, complies with the Type Certification Basis defined by Transport Canada **ENGINE** Issue Paper G-01 (Reference 4) and that the **ENGINE** incorporates no unsafe features;
- Findings of compliance have been made by the cognizant [organizational Delegates] and are recorded in the **ENGINE** Compliance Program, XXX, attached.
- As recorded in TCCA **"ENGINE** – TCCA LOI Completion Statement" [RDIMS #XXXX], Transport Canada specialists' Level of Involvement has been completed for the **ENGINE** program.

Further, **Type Certificate Applicant / Holder Corp.** will undertake the responsibilities of a design approval document holder as specified in Canadian Aviation Regulations Part V, Subpart 21, Division VIII.

Yours truly
Type Certificate Applicant / Holder Corp.

Program - Vice President or Director or Manager

TCCA

CAR 521.57 Applicant Declaration / Holder Obligations

1

CAR 521.57 - Type Certificate Issued:

The design approval applicant has demonstrated compliance with the requirements in the cert. basis;

All compliance tests completed and reports reviewed / submitted / accepted or approved

The design approval applicant has made required Declarations

TCCA LOI is complete and no unresolved issues remain

The Minister (company delegates + TCCA specialists) has made findings of compliance with requirements of the Certification Basis;

The compliance program is completed for all requirements and completed / signed off (Finding of Compliance) by delegates

All required documents (e.g. Installation Manual, ICDs, AWL Limitations, ICAs) are approved

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CAR 521 Required APPLICANT Declarations

(PRIOR TO ISSUE OF TYPE CERTIFICATE)

CAR 521.33(b)

APPLICANT Declaration attesting to the demonstration of compliance of the type design of the aeronautical product with its certification basis

CAR 521.57(b)

Signed undertaking by APPLICANT to carry out the responsibilities of the HOLDER specified in Division VIII

3

Conformity with Certification Basis

521.33 An applicant for a type certificate in respect of an aeronautical product shall

(*a*) demonstrate to the Minister that the aeronautical product conforms to the certification basis established by the Minister under section 521.30;

(*b*) submit to the Minister a declaration attesting to the demonstration of conformity of the aeronautical product with its certification basis;

(*c*) make available to the Minister the means by which conformity is established;

(*d*) in the case of an aircraft, record the noise levels in its flight manual or in a supplement to that manual using the *Guidelines for the Administration of Noise Certification Documentation* set out in Attachment G of Annex 16, Volume I to the Convention; and

(*e*) submit to the Minister for approval any manuals, instructions and limitations that are required by the certification basis established in respect of the aeronautical product.

Issuance of a Type Certificate

521.57 (1) Subject to section 6.71 of the Act, the Minister shall issue a type certificate in respect of an aeronautical product if the applicant

(*a*) submits the declaration required under paragraph 521.33(*b*);

(*b*) submits a signed undertaking to carry out the responsibilities specified in Division VIII; and

(*c*) meets the requirements set out in subsection (2) or (3) in respect of the category of the aeronautical product.

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CAR 521.57(b)

Declaration –Type Certificate Holder Obligations

APPLICANT undertakes to carry out the responsibilities of a design approval document HOLDER, as set out in Division VIII of Part V Subpart 21 of the CARs, regarding:

- ✓ technical capability,
- ✓ service difficulty reporting,
- ✓ establishing a service difficulty reporting system,
- ✓ investigation of service difficulty reports,
- ✓ mandatory changes,
- ✓ transfers,
- ✓ record keeping and loss or disposal of records,
- ✓ manuals,
- ✓ instructions for continued airworthiness
- ✓ supplemental integrity instructions [Part 25 Only]

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CAR 521 – Division VIII

Design Approval Holder Responsibilities

- 521.351 - Division VIII — Responsibilities of a Design Approval Document Holder
  - 521.351 - Application
  - 521.352 - Technical Capability
  - 521.353 - Service Difficulty Reporting
  - 521.354 - Establishing a Service Difficulty Reporting System
  - 521.355 - Investigation of Service Difficulty Reports
  - 521.356 - Mandatory Changes
  - 521.357 - Transfer
  - 521.365 - Record Keeping
  - 521.366 - Loss or Disposal of Records
  - 521.367 - Manuals
  - 521.368 - Instructions for Continued Airworthiness
  - 521.369 - Supplemental Integrity Instructions

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APPENDIX O—ACCOUNTABILITY FRAMEWORK

Accountability Framework -- Applicant Statement of Compliance and FAA Discretionary Function

2013 ODA Seminar
Seattle, WA
September 11, 2013

What do we mean by Accountability Framework?

- **Any process involving more than one entity requires dividing up responsibility for portions of the entire process**
- **Accountability Framework simply means holding all stakeholders accountable for their portion**
- **It's a philosophy substantiated in Title 49 of US Code and reflected in regulations and policy**

Accountability Framework – Applicant SofC and Discretionary Function
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The Underlying Premise Is …

Applicants & Approval Holders →	Are legally responsible for fully complying with all applicable regulations (ref. 14CFR 21)
The FAA Administrator →	Has the authority under the statutes to exercise discretion in: Promulgating airworthiness regulations and standards in the interest of safety, and Defining, by regulations and directives, how the FAA will oversee compliance by those who we regulate.

Governmental Discretionary Function is Not New

Federal Aviation Administration 2

Accountability Framework

<u>Applicants</u> for a design approval have a regulatory obligation to:

- Use means of compliance acceptable to the FAA
- Submit data that "Shows" that their designs are compliant

Design Approval <u>Holders</u> have an ongoing regulatory obligation to:

- Maintain compliant designs with no unsafe features
- Report product failures, malfunctions, and defects

<u>FAA</u> promotes (not ensures) Aviation Safety by…

- Issuing regulations
- <u>Specifying the certification basis</u>
- Providing guidance regarding acceptable means of compliance
- <u>Overseeing compliance</u>
- Taking enforcement actions as necessary
- <u>Issuing certificates and approvals</u>; and
- Mandating corrective action as necessary

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Accountability Framework in Part 21

- **An Applicant is required to…**
  - Conduct all inspections and tests to show compliance of design and product (14 CFR 21.33(b)).
  - Make all flight tests that the Administrator finds necessary (14 CFR 21.35(b)).
  - Submit all data showing compliance (14 CFR 21.21(b)).
  - Provide a statement certifying compliance (14 CFR 21.20(b))
- **The Administrator…**
  - Finds upon examination of the type design that applicable requirements have been met (14 CFR 21.21(b)1)
  - Makes any inspections and tests necessary to determine compliance of applicant's design and product (14 CFR 21.33(a)).

Applicant's Certifying Statement of Compliance

- **New 14 CFR Part 21 Effective April 16, 2011**
- **"an applicant … must provide a statement certifying that the applicant has complied with the [applicable] requirements"**
  - § 21.20(b) for TC/STC and amended TC/STC applicants
  - § 21.97(a)(3) for major change to type design applicants
  - § 21.303(a)(5) PMA applicants
- **"Compliance Listing" required**
  - § 21.20(a) and § 21.97(a)(2)

Applicant's Certifying Statement of Compliance

- **Applicant submits statement to ODA Administrator at end of project**
  - Signed by individual "having authority over the certification, and legally representing the applicant…"
- **Guidance**
  - Advisory Circular, AC 21-51, Published 9/27/2011
  - Will be addressed in Order 8110.4D

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Accountability Framework & Applicants Certifying Statement of Compliance

- **Accountability Framework – holds each stakeholder responsible for their part**
- **Statement of Compliance – requires applicant to legally state compliance has been shown**
- **FAA required to make a finding – evidence of which is a certificate**
  - This does not mean that the FAA makes a discrete finding of compliance to every rule
  - Rather FAA determines how much involvement is required. We call this our Discretionary Function

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FAA Discretionary Function is…

… the ability to make decisions by applying <u>judgment and making reasonable choices</u> as we perform our work <u>within the bounds</u> of the statutes, regulations, and directives (i.e.; Orders & Notices) that prescribe how the FAA will perform its work

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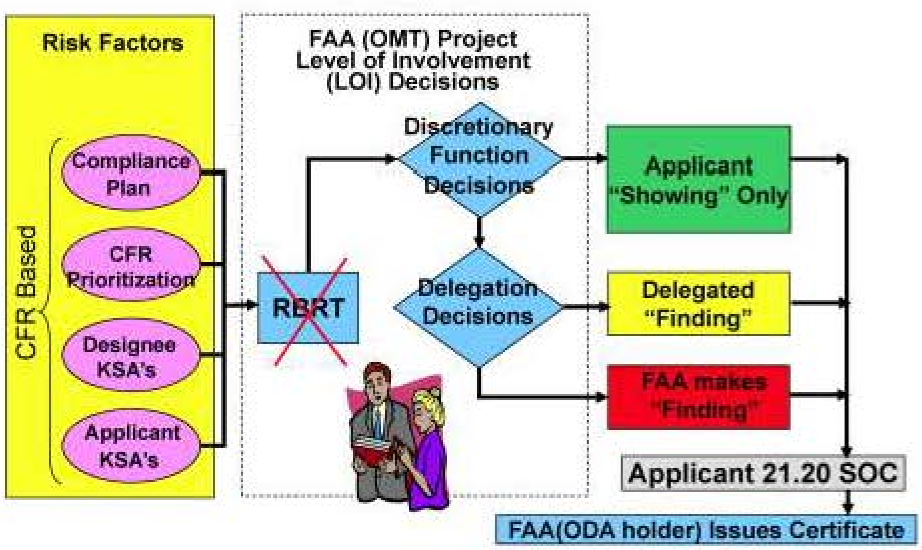
FAA Level of Involvement Decisions



APPENDIX P—USE OF APPLICANT SHOWINGS ON ODA PROJECTS

Use of Applicant Showings on ODA Projects

2013 ODA Seminar

Seattle, WA

September 11, 2013

Overview

– Evolution/Background

– Today/Tomorrow

– 8110.4D Approach

– ODA Approach

Use of Applicant Showings

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"Applicant Showings"

- **A means to implement FAA discretion in ODA projects**
- **Align ODA processes with**
  - Accountability framework
  - 8110.4D Approach
- **Recognition of applicant substantiation activities rather than "ODA unit" involvement**
  - E.g. test, inspection, analysis, etc.

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Evolution of FAA Certification Paths

Without Organizational Delegation	With Organizational Delegation (ODA)	Certified Design and Prod Organization (CDPO)

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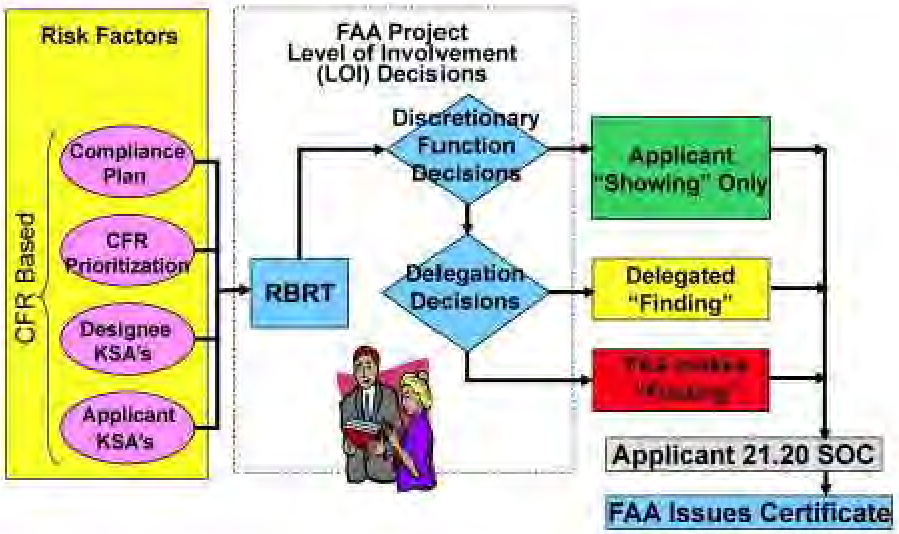
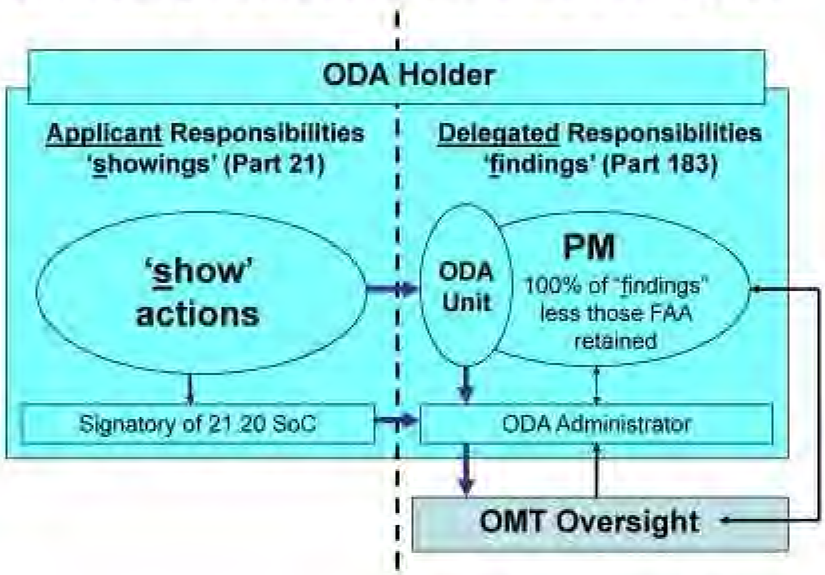
FAA Level of Involvement Decisions



ODA Today without RBRT/SMS Principles



Attributes Today Without RBRT/SMS Principles

- **Mainly product focused**
- **Typically every action by applicant requires action by ODA -- No FAA discretionary function decision making**
- **No Risk Management or reliance on applicant showings**
- **Many applicants still "throw compliance over the fence"**
  - **21.20(a) Statement of Compliance attempts to change that**

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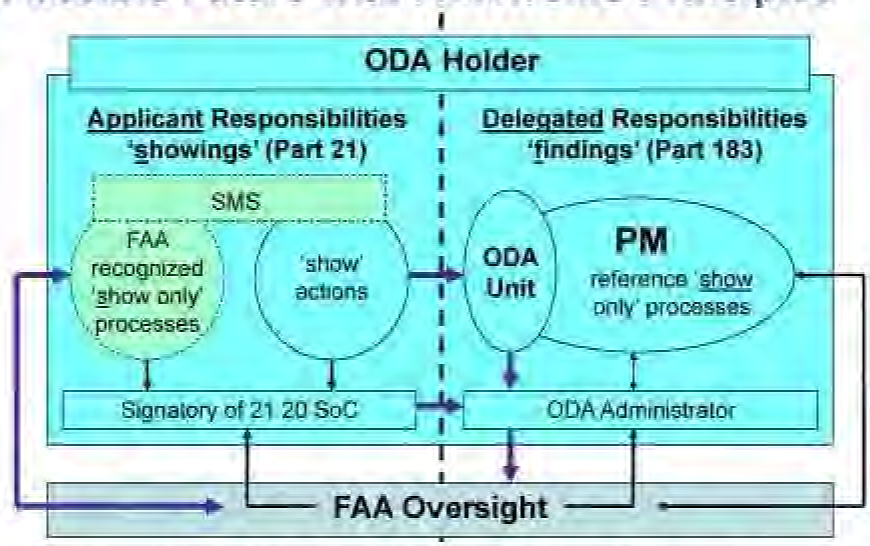
Possible Future with RBRT/SMS Principles



- Not required by Part 21, but supports FAA recognition of 'show only' processes

Attributes with RBRT/SMS Principles

- Greater system focus
- Every action by applicant does not require action by ODA
- Incorporates risk management and reliance on applicant showings
- Compliance built in throughout design phase

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Summary of Key Principles

- Compliance should be the goal from the beginning of the process and not something inspected in at the end
- Compliance by process can mitigate higher risk areas
- Discretionary Function is only exercised by FAA (not designees)
- ODA holder can propose and OMT can recognize "applicant showing" processes

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8110.4D Approach

- **Goes back to these basic part 21 principles (Accountability Framework) and incorporates FAA discretion.**
  - The **applicant is responsible** to make sure the substantiation data is correct (show compliance).
  - FAA makes a ***decision*** what inspections and tests it will witness or conduct and what data it will review.
- **FAA involvement is not required for the applicant to show compliance and fulfill their regulatory obligations.**

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8110.4D Approach

- **The FAA "finds" by "spot checking" (Discretion) using FAA authority to:**
  - Witness applicant tests or inspections.
  - Conduct FAA tests and inspections.
  - Review substantiating data submitted by the applicant.
  - Review the type design data submitted by the applicant.
- **FAA may choose to rely on applicant showing and statement of compliance.**

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Rev D – FAA "Level of Involvement"

- **Implementation via:**
  - direct FAA involvement
  - use of designees allocated based on risk
- **FAA may choose to rely on applicant showing and statement of compliance.**

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"Standard" vs. "ODA" Approaches

Standard

- **Applicant "shows"**
- **FAA LOI Decisions**
- **Starting place – none on the table**
- **FAA manages project resources**
- **FAA decides what to look at, or not look at**
- **Risk tools defined-in use**

ODA

- **Applicant "shows"**
- **OMT LOI decisions**
- **Starting place – ODA Procedures Manual**
- **ODA manages project resources**
- **ODA holder may propose what ODA unit not look at**
- **Risk tools not yet available**

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ODA Approach

- **Available under TC, STC, and PMA**
- **Reliance on applicant showing activity may be established for individual activities:**
  - Compliance data review
  - Test witnessing
  - Conformity inspections
  - Flight Test

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ODA Approach

- **FAA discretion - use of applicant showings is determined by the OMT**
  - ODA holder may propose FAA recognition of applicant showings in certification plan/PNL
  - Procedures manual may address applicant showings activity agreed to by the OMT
- **Recognition of applicant showings based on risk**
  - Airworthiness Standard risk
  - Complexity of substantiation activity
  - Established/robust procedures for higher risk activity documented in ODA manual

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ODA Approach

- **Risk tools not yet established for ODA projects**
  - Use of RBRT being looked at in 2013
- **OMT judgment/discretion to accept**
- **SMS/QMS not required to implement applicant showings**

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ODA Approach

- **Use of applicant showings does not change "applicant" responsibilities**
  - Inspection, tests
  - Establish compliance
  - Data review
- **Can result in compliance findings with less UM involvement**
  - Engineering UM approval without requiring UM conformity or test-witnessing

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ODA Approach-Data Review

- **OMT requires UMs to review and determine compliance unless safety risk is acceptable based on**
  - Criticality of risk to the product
  - Applicant experience and history
  - Maturity of compliance assurance processes

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ODA Approach-Test Witnessing and Inspection

- **OMT requires UM test witnessing/inspection unless safety risk is acceptable based on:**
  - Associated airworthiness standard
  - Risk of non-conformity
  - Proven processes
    - EASA DOA/POA for conformity

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Oversight of Applicant Showings

- **Oversight of applicant showings**
  - Not addressed in ODA or any other order
  - Will be addressed in future FAA policy

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Summary

- **The Applicant is always responsible for "showing" compliance**
- **Recognition of applicant showings determined by OMT**
- **Test witnessing & conformity might be good starting points**
- **Higher risk areas will require effective processes**
- **Risk tools being considered for the future**

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