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U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
National Policy

ORDER 1110.XX

Effective Date:
May 22, 2006

SUBJ: CERTIFIED DESIGN ORGANIZATION (CDO) AVIATION RULEMAKING COMMITTEE

1. PURPOSE. This order constitutes the charter for the Certified Design Organization (CDO) Aviation Rulemaking Committee (ARC) that is designated and established pursuant to the Administrator's authority under Title 49 of the United States Code, Section 106(p)(5).

2. DISTRIBUTION. This order is distributed to the Associate Administrator for Aviation Safety; the Office of the Chief Counsel; the director and division level in the Aircraft Certification and Flight Standards Services; and the director level of the Offices of Rulemaking, Budget, and Financial Management.

3. BACKGROUND. Congress included in the *Vision 100-Century of Aviation Reauthorization Act* of 2003 the requirement for development and oversight of a system for certification of design organizations. These certified design organizations (CDOs) will be authorized to certify compliance with the requirements and minimum standards prescribed under Title 49 USC 44701(a). The Act also allows the Administrator to rely on certifications of compliance by a design organization when making a finding to issue a type certificate.

The FAA has determined that the language under the current legislative intent is limited. The FAA is currently submitting a Congressional Report addressing broader statutory authority for other design approval holders, including production approval holders, as well as a revised schedule.

4. OBJECTIVES AND SCOPE OF ACTIVITIES. An ARC will enable the FAA to respond effectively in developing a CDO program. The committee will make its recommendations, which may include proposals for rulemaking, suggested processes, policies and guidance that will serve as the foundation of the program, and further action the agency may need to take in support of the program. As part of its task, the ARC may also review existing regulations and make recommendations to amend or delete them as consistent with its mission. The ARC will function solely in an advisory capacity, but is expected to present and discuss whatever input, guidance and recommendations the members of the committee consider relevant to the ultimate disposition of the development of CDO.

A CDO Working Group Report, dated August 9, 2005, addressing the CDO concept has been submitted for consideration. This report should be used as additional reference material during ARC deliberations.

Although the current statutory language for certification of design organizations is limited to type certificates, amended type certificates, supplemental type certificates, and amended supplemental type certificates, the committee may make recommendations to include any organization seeking or holding any design and/or production approval, e.g., Parts Manufacturer Approval, which the FAA will consider consistent with its legislative authority at that time.

5. DELIVERABLES. By September 30, 2006, the ARC will submit an initial report detailing its recommendations. The report should identify significant areas of agreement as well as areas where consensus could not be reached. The report should contain recommendations detailing the guiding principles necessary to propose regulatory language for drafting an NPRM. The ARC will continue to work on guidance and policy related issues through September 30, 2007, and will submit a final report by that date. The Associate Administrator for Aviation Safety may extend these deadlines for up to 6 months if it is in the interest of the FAA to do so. The Associate Administrator for Aviation Safety may amend the tasking to ensure that the objectives and the scope of the activities are met.

6. ORGANIZATION AND ADMINISTRATION.

a. The Associate Administrator for Aviation Safety shall have the sole discretion to appoint members or organizations to the committee. The committee shall consist of members of the aviation community, including the public and/or other federal government entity representatives of various viewpoints. The FAA shall provide participation and support from all affected lines of business.

b. The Associate Administrator for Aviation Safety shall receive all committee recommendations and reports. The Associate Administrator, through the Aircraft Certification Service, shall be responsible for providing administrative support for the committee.

c. The Associate Administrator for Aviation Safety is the sponsor of the committee, and shall select FAA and industry co-chairs for the committee. The co-chairs shall:

(1) Determine, in conjunction with the other members of the committee, when a meeting is required.

(2) Arrange notification of all committee members of the time and place for each meeting.

(3) Formulate an agenda for each meeting and conduct the meeting.

(4) Form working groups as necessary to conduct its business in the most efficient manner possible.

7. MEMBERSHIP.

a. The membership of the committee may include the following public and government organizations:

(1) Industry representatives; including representatives from air carriers, manufacturers, repair stations, and other private sector aviation industry associations.

(2) The Federal Aviation Administration Aviation Safety line of business

(3) Other Federal Aviation Administration lines of business as required to meet committee objectives.

(4) Foreign authorities (Note: Representatives will be encouraged to fully participate in committee discussions, but foreign authorities will not vote on committee issues.)

b. The membership shall be balanced in points of view, interests, and knowledge of the objectives and scope of the committee. While representatives of their employers and/or associations, committee members will be expected to contribute fully in all areas of the committees' work.

8. COSTS AND COMPENSATION. The estimated operating cost (including pro rata share of salaries of FAA employees) is $274,000. Non-government representatives serve without government compensation and bear all costs related to their participation on the committee.

9. PUBLIC PARTICIPATION. Interested persons or organizations who are not members of this committee, but wish to attend a meeting, must request and receive approval in advance of the meeting from both co-chairs.

10. AVAILABILITY OF RECORDS. Subject to the conditions of the Freedom of Information Act, 5 U.S. Code, Section 522, records, reports, agendas, working papers and other documents that are made available to or prepared for or by the Committee shall be available for public inspection and copying at the Aircraft Certification Service, 800 Independence Avenue SW, Washington, DC 20591. Fees shall be charged for information furnished to the public in accordance with the fee schedule published in Part 7 of Title 49, Code of Federal Regulations.

11. PUBLIC INTEREST. The formation of the CDO ARC is determined to be in the public interest in connection with the performance of duties imposed on FAA by law.

12. EFFECTIVE DATE AND DURATION. This committee is effective May 22, 2006. The committee shall remain in existence until May 22, 2008, unless sooner terminated or extended by the Administrator.

Marion C. Blakey

Marion C. Blakey
Administrator

Certified Design Organization
Aviation Rulemaking Committee

Report to the Federal Aviation Administration

May 2008

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I. INTRODUCTION

This report provides a discussion of the concepts developed by the Certified Design Organization (CDO) Aviation Rulemaking Committee (ARC) to build the foundation for the CDO program.

CDO builds on the years of experience that the FAA and Industry have had working together under delegation concepts, while at the same time the public has experienced an unprecedented increase in safety. Yet CDO is a step beyond current delegation programs. For the first time, it provides requirements and forms the basis for formal FAA recognition of a design organization's capabilities within the Code of Federal Regulations.

As a privilege of its certificate, the CDO holder will make statements of compliance that the FAA may accept without any further showing in granting the CDO holder a type certificate or other design approval. As envisioned by the ARC, this privilege is facilitated by CDO determinations of compliance resulting in FAA approved data, with no direct compliance decisions made by the FAA. To gain this privilege, the applicant for a CDO certificate must demonstrate to the FAA that they have systems in place that have safety and compliance by process as embedded business practices. Under CDO, compliance is not something that will need to be declared or inspected-in by the FAA or its designees at the end of the engineering process.

FAA oversight of the CDO's compliance system will position the FAA to have a greater impact on an applicant's compliance processes than ever before. Under CDO, the FAA will retain all the oversight responsibility and accessibility that it presently has. The FAA will have unhindered access to compliance activities within the CDO should it wish to observe or audit any ongoing or completed CDO activity. In addition, through the CDO systems approach to achieving compliance, the FAA will approve all CDO processes necessary to demonstrate regulatory compliance rather than placing the majority of its focus on examining the resulting product to determine if those processes produced a compliant outcome.

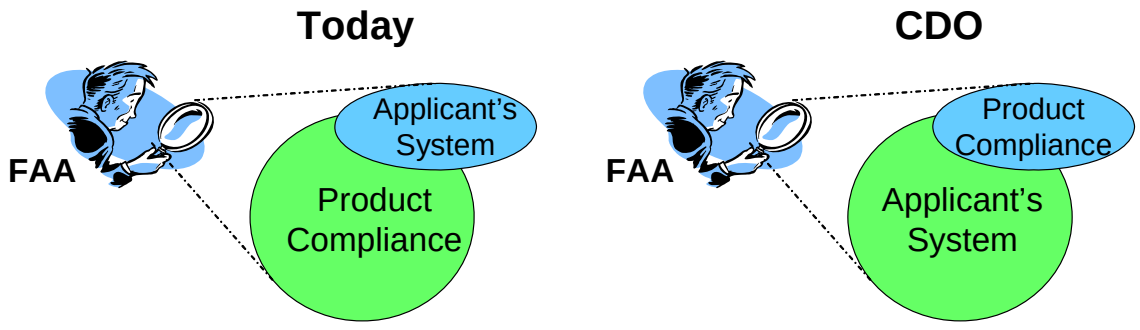

Figure 1 – Focus of FAA Oversight

This report contains all the goals, objectives, principles, and compliance, quality, and safety system attributes that the ARC believes a company must possess to obtain a CDO certificate. These elements are all intertwined and this report must be read in its entirety for the reader to fully comprehend how it all fits together. For this reason, the ARC has chosen not to try and summarize the concept in an executive summary.

II. BACKGROUND

In the *Vision 100-Century of Aviation Reauthorization Act of 2003*, Congress authorized the Federal Aviation Administration (FAA) to develop and oversee a system for the certification of certain design organizations. This report refers to a design organization receiving this certification as a "Certified Design Organization," or CDO. Appendix A of this report contains Section 227 of the Reauthorization Act, which provides the statutory basis for the concept.

In accordance with Section 227, a CDO will be authorized to

> *" … certify compliance with the requirements and minimum standards prescribed under Title 49 USC (Title 49) 44701(a)."*

The FAA then, at its discretion, may --

> *" … rely on certifications of compliance by a design organization when making a finding"* --

for the issuance of a certificate.

For decades, applicants have been required to show compliance with those minimum safety standards in order to obtain a type or supplemental type certificate or other design approval. Under this new CDO concept, the FAA may issue a design organization certificate, referred to as a CDO certificate, when the FAA determines that --

> *" … the design organization has adequate engineering, design, and testing capabilities, standards, and safeguards to ensure that the product being certified is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under section 44701(a)."*

When the CDO certificate holder applies for a design approval, it will be authorized to submit to the Administrator a statement of compliance indicating that the design complies with the applicable certification requirements. This statement of compliance is the "certification of compliance" referred to in the authorizing statute.

Historically, the FAA determines the amount and extent of the compliance data it chooses to review before issuing a design approval. That program-by-program decision is based on an assessment of which data are critical to establishing the airworthiness of the design. The FAA's goal has been to tailor its review to maximize the safety benefits of its oversight, which is consistent with the statutory discretionary authority it has when performing its oversight of the Industry it regulates.

By setting specific and rigorous standards for the issuance of a CDO certificate, the FAA will be able to place more reliance on the design approval holder or applicant to demonstrate compliance with applicable FAA requirements. The more the FAA can rely on the CDO certificate holders, the more it can focus its resources on significant safety issues. This process is enabled by the Vision 100 – Century of Aviation Reauthorization Act.

II. A. The Enabling Legislation

Section 44704 of Title 49 authorizes the issuance of design organization certificates by the year 2010. That regulation specifies that the FAA --

> " … *Administrator may issue a design organization certificate to a design organization to authorize the organization to certify compliance with the requirements and minimum standards prescribed under section 44701(a) for the type certification of aircraft, aircraft engines, propellers, or appliances.*"

Intent and Interpretation of Legislative Language. Most members of the ARC believe the intent of this language is that the FAA may issue a CDO certificate to any qualified design organization that can certify compliance with the requirements and minimum standards prescribed in Title 14 of the Code of Federal Regulations (14 CFR) Parts 21, 23, 25, 27, 29, 31, 33, and 35.

However, some have interpreted this language to restrict the CDO certificate to organizations that are holders of, or are seeking, type certificates, supplemental type certificates, or amendments to those certificates which would prohibit FAA from issuing a CDO certificate to other qualified organizations performing design approval functions, such as TSO manufacturers of systems and components like avionics and landing gear.

Production Activities under CDO. In addition, the ARC believes that the legislation would allow a CDO to produce conforming articles, products, parts and appliances in support of its certification projects. However, the legislation has been interpreted by some as <u>not</u> including provisions that would allow the production activities after design approval (e.g., Production Certificate) to be managed under the CDO certificate. The ARC maintains that this would not achieve the intended safety and efficiency benefits of CDO desired by Industry and the FAA.

II.A.(1) Industry-Desired Legislative Changes

The Industry believes there is a strong need for <u>all</u> FAA-recognized design organizations to have the ability to receive a design organization certificate for the activities they perform. CDO provides an opportunity for the FAA and Industry to

leverage the experience and expertise of aviation design organizations to streamline the certification process and focus FAA's resources on safety critical items and overall system safety management.

The statutory language establishing CDO in the 2003 Reauthorization Act is founded on the recommendations made by the National Resource Council in a 1998 report on "*Improving the Continued Airworthiness of Civil Aircraft – A Strategy for the FAA's Aircraft Certification Service.*" Industry's intent in promoting the language contained in the 2003 Reauthorization Act was to allow FAA to certify the competency of any design organization to make discrete determinations of compliance with the requirements and minimum standards prescribed in 14 CFR Parts 21, 23, 25, 27, 29, 31, 33, 34, 35, and 36 for the type certification of aircraft, aircraft engines, propellers, or appliances.

Clarifying the Scope of CDO. Industry supports clarification of the statutory language to specify that a CDO may be issued to any appropriately qualified design organization that certifies compliance with the requirements and minimum aviation safety standards. This would ensure that the CDO system safety approach to FAA oversight is available for all qualified design organizations, including Parts Manufacture Approval (PMA) and Technical Standard Order (TSO) design approval holders.

In addition, the scope of the current statutory language does not expressly include the ability to allow the CDO to manage its post-design approval production and airworthiness activities under its CDO certificate.

Efforts to Change Statutory Language. The Industry has been working with the Congress to clarify the applicability and scope of the CDO statutory language in section 44704 to include all design organizations and all post-design approval production and airworthiness activities. No changes have been made, however, at the time of the release of this report.

II.A.(2) FAA Report to Congress

As required by the previous Reauthorization Act, the FAA sent a plan to Congress for the development and oversight of a system for certification of design organizations (see Appendix B). While the FAA plan to Congress proposed an extension of two years, subsequent discussions between FAA and congressional staff resulted in a revised request for three years, extending the implementation date to 2013.

In addition, the plan recommends increasing the benefit to FAA from CDO, by means of:

(1) inclusion of post-design approval production activity under CDO; and

(2) clarifying the scope of CDO to include all design approval holders (including TSOs and PMAs).

The inclusion of production activity is discussed in greater detail later in this report.

II. B. Chartered CDO ARC

On May 22, 2006, the FAA Administrator chartered an Aviation Rulemaking Committee (ARC) to assist the FAA in developing the CDO program. The committee consisted of a cross-section of members of the civil aviation community and appropriate FAA personnel. The ARC membership is listed in Appendix C. The ARC Charter is contained in Appendix D.

The ARC was tasked with making recommendations, including proposals for rulemaking, suggested processes, policies, and guidance that will serve as the foundation of the program, and further actions the agency should take in support of the program.

In accomplishing its task, the ARC reviewed existing regulations and policy, as well as other related materials. The ARC presented and discussed in-depth principles, guidance, and recommendations that the members of the committee considered relevant to the implementation of the CDO concept.

In its advisory capacity, the ARC submits this report and its associated recommendations.

II. C. The ARC Report

Report Contents. This report summarizes the activities of the committee and its recommendations for the development, scope, and operation of a CDO program from Industry and FAA perspectives. This report reflects the deliberations of the committee on these issues, and provides the reasons for including some concepts and procedures for a CDO and for not including some others.

The concepts developed within this report are based on the assumption that the legislation will be changed to allow CDO principles to be applied to all design

organizations, including those which hold TSOA or PMA, and those authorized to perform post-design approval production and airworthiness functions.

Clarification of Terms Used. Where this report uses terms such as "the ARC agrees," "the ARC believes," or "the ARC recommends," those represent full agreement by all members of the ARC. When the word "consensus" is used with respect to the ARC, it means that, while some members may not have fully agreed with a concept, they accepted the majority position of the ARC.

Intent of Report. This report is intended to be a thorough presentation of background material to be used by the FAA in developing a notice of proposed rulemaking (NPRM). Taken in its entirety, it constitutes the ARC's recommendations detailing the guiding principles and attributes necessary to prepare regulatory language for the drafting of an NPRM. Therefore, it is recommended that this report be referenced in the NPRM.

A glossary or terms and a list of acronyms used in this report are contained in Appendix E and Appendix F, respectively.

II. D. FAA and Industry Share the Responsibility for Safety Success

Today the flying public enjoys an unprecedented level of safety as a direct result of the certification, maintenance, and operational approaches used today by Industry and the FAA.

Because of work done collectively by government and Industry, the airplane accident rate resulting in fatalities to airline passengers has been reduced to about one in every 14 million commercial flights. This has been accomplished, in part, with advances in technology, and improved processes for the design certification, production, maintenance, and operation of aviation products.

The Delegation System. The FAA has also increasingly recognized Industry's expertise and resources in creating its system of individual and organizational delegations. Expansion of civil aviation has far outpaced FAA's growth in resources. Reliance on designees or delegated organizations to make a statement of compliance with regulatory requirements has become a common tool used to leverage FAA's resources.

A chronological outline showing the history of the FAA's delegation system is given below:

- 1940's - DER, DMIR, DPE, etc. individual designees
- 1950's - DOA organizational delegations for small airplanes, propellers, and engines
- 1958 – Federal Aviation Act reaffirms delegation
- 1960's - DAS organizational delegation for repair stations
- 1970's - SFAR 36 authorizations for operators
- 1980's - DAR individual designees
- 1990's – ODAR organizational delegations
- 2006 – ODA organizational delegations for all products and organizations; replaces DOA, DAS, ODAR, and SFAR 36

DER (Designated Engineering Representative)
DMIR (Designated Manufacturing Inspection Representative)
DPE (Designated Pilot Examiner)
DOA (Delegation Option Authorization)
DAS (Designated Alteration Station),
SFAR (Special Federal Aviation Regulation) 36
DAR (Designated Airworthiness Representative
ODAR (Organizational Designated Airworthiness Representative)
ODA (Organization Designation Authorization)

The last decade in particular has brought about a substantial increase in safety – almost a 5-fold reduction in air carrier accidents. FAA and Industry co-operation, the use of structured data and analysis, and the shared commitment to safety have all contributed to this success.

It is notable to mention that many of the actions to achieve this record safety level were developed and implemented as a result of voluntary actions by Industry.

CDO Builds on Legacy of Cooperation. The CDO concept is intended to build on this legacy of cooperation between Industry and the FAA. This is a natural step toward more FAA reliance on Industry compliance expertise for those companies within the Industry that can demonstrate they have the competency, capability, and organizational maturity. This will allow FAA resources to focus more intensely on critical safety issues, technology development, and identification of important precursors necessary to prevent safety mishaps.

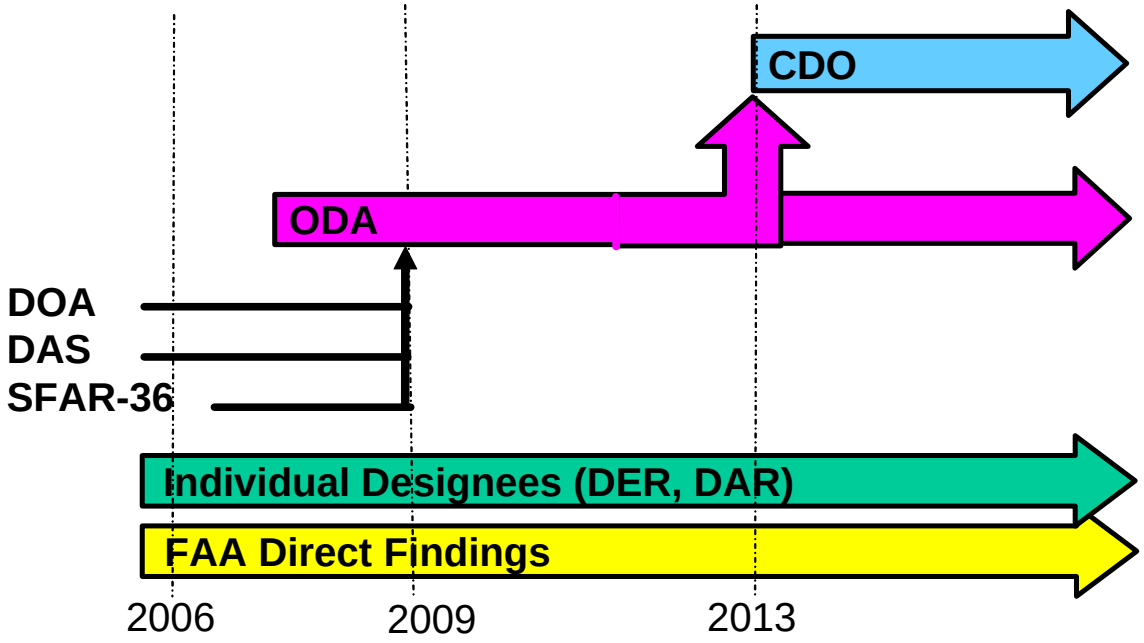

Figure 2 -- Evolution of Certification Paths

II. E. Our Commitment to Safety

While aviation technology has been maturing since the Wright Brothers first flew their airplane, the relationship between the FAA (including its predecessor the CAA) and Industry has also been maturing.

Industry's Role in Delegation. The Industry has assumed more of a role in facilitating FAA's finding of compliance (e.g., via organizational delegation), in addition to its responsibility of having to comply with the regulations. The aviation statutes and regulations for decades have contained the provisions for delegation to both individuals and companies, and have allowed FAA to rely on Industry resources and expertise through concepts other than delegation. Primary category aircraft certification is one concept where the Industry has assumed an enhanced role that permits reduced FAA involvement prior to the issuance of a type certificate.

In this respect, CDO parallels delegation (especially organizational delegation), where the Industry resources acting under FAA-delegated authority have determined compliance with FAA requirements. As with current delegation programs, the implementation of CDO should be deliberate and only permitted when the Industry has demonstrated that it meets the requirements necessary to provide the FAA with confidence that it can properly carry out the responsibilities associated with its authorized functions.

FAA Oversight Continues. In the delegation model, FAA has the ultimate responsibility for the oversight of its designees' performance. Similarly, the FAA will retain ultimate responsibility for the oversight of the CDO's performance to its approved system, with the authority to participate, assess, review, audit, or in other ways determine the health of that system, and the products and processes that result.

Future Challenges. FAA and Industry's joint challenge for the future is to continue the unprecedented safety improvements of the last decade, given the anticipated growth in aviation for the foreseeable future. The FAA predicts a threefold increase in demand for air travel within the US by the year 2025. The level of safety the public has come to expect will be challenged not only by this growth, but by the effects of new technology, acute global competition, and global engineering and manufacturing as well. These challenges will also affect the FAA. 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.

One way of achieving higher levels of safety is by developing the means to systematically measure the compliance capabilities of the Industry and, where competency is demonstrated, give Industry the authority to make a "certifying statement" of compliance. This enables the FAA to rely, through CDO, on the demonstrated competencies of the Industry and its compliance systems, rather than place its focus on the individual certification activities at these companies.

Availability of FAA Regulatory and Guidance Materials. The FAA has a website containing its regulations, policy, guidance material, and documents that describe the basis for its policies. Those materials were not available as recently as 10 years ago, and their availability has enabled the Industry to now be more aware of FAA safety objectives, practices, and procedures. This enables the Industry to ascertain that they comply with the regulations with more speed and certainty than before.

The website also enables FAA to readily provide guidance on its compliance expectations, so it can better focus its resources on emerging technologies and critical safety issues. It enables FAA to gear more of its activities to identifying and eliminating the precursors of safety mishaps.

Confidence is Hallmark of CDO Concept. The CDO concept, then, takes advantage of the experience gained from the use of FAA delegation systems and interactions with Industry, so that, with FAA oversight, greater confidence can be placed on Industry systems and procedures that ensure compliance.

This strengthened confidence in documented Industry systems and procedures to show compliance with safety regulations and standards enables the FAA to propose this new CDO concept. This confidence is the hallmark of the CDO concept that is defined within this report.

II. F. What is CDO?

The management of regulatory responsibilities through the issuance and oversight of certificates (i.e., pilot, airworthiness, air carrier, repair station, production) has existed and been successful for decades. The concept of a design organization certificate has existed for at least two decades.

Given (1) recent statutory changes authorizing CDO, (2) the increased availability of FAA information concerning regulatory compliance, (3) the rapid pace of technological change, and (4) growth in aviation, globalization, and increasing Industry capabilities, the FAA believes, and the ARC agrees, that it is time to further develop the CDO concepts into a workable program.

As validation of this conclusion, the CDO concept developed in this report is very similar to systems of this type in use or being developed by other competent aviation authorities.

As a means to formally recognize a design organization's capabilities, CDO encompasses the processes by which the certificate holder will manage its certification projects as well as the continued airworthiness of its legacy products consistent with the scope of its certificate.

II.F.(1) CDO Enhances Compliance by the Industry

Improving the Delegation System. 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.

This system has produced an excellent product safety record; but it can be improved, and the ARC believes CDO is a significant step that enables further improvement.

The current process of obtaining a design approval places no requirement on the applicant to establish a system of documented process and procedures to show compliance. This makes the certification process highly resource-intensive for the FAA to deal effectively with the variety of applicant capabilities that exist.

With CDO, the design organization operates in accordance with their FAA-approved processes and compliance assurance system. If a non-compliance is found by the CDO or by the FAA, the CDO's compliance assurance system is subject to review and change, as required by its FAA-approved procedures manual. The design organization 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 Enhances Compliance. Under CDO, the establishment and determination of compliant designs will be made through a compliance assurance system (CAS) that is embedded within the company, with appropriate internal checks and balances to ensure it is functioning properly.

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. Then, 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 CDO 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 CDO is subject to requirements for a safety management system (SMS) and quality management system (QMS). The systematic approach to the engineering certification process, coupled with CAS and QMS enhances the organization's overall ability to consistently perform the compliance assurance function, and to identify and correct problems that may arise. These three system requirements will be addressed in later sections of this report.

II.F.(2) CDO is Not "Self–Certification"

Under CDO, all determinations of compliance within the certificate holder's authority will be made by the CDO organization. This does <u>not</u> mean that CDO is self-certification by Industry.

The FAA will retain the right to review, audit, and otherwise oversee the operation of the CDO while it makes compliance determinations, as well as after the FAA has issued design and airworthiness certificates.

Approval by the FAA of CDO processes, certification bases, methods of compliance, and continued oversight during certification activities differentiate CDO from any self-certification process. This contrasts with self-certification, where, 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.F.(3) CDO is Further Recognition of Industry Maturity

The ARC recognizes that not all design organizations will choose to pursue CDO.

CDO is for those that demonstrate to the FAA they have established a system that is fully capable of reliably determining compliance. That demonstration must be by way of actual certification program experience -- it cannot be just a paperwork exercise.

In its initial stage of implementation, a CDO certificate may be sought and obtained by only some companies that meet the qualification requirements. As the Industry further matures, CDO may become more commonplace.

II. G. The Role of the FAA

Historically, there has been a shared safety responsibility between the FAA and the Industry it regulates.

The sole responsibility for complying with FAA regulations has always resided with the Industry, and will remain so under CDO. This responsibility is described in a Supreme Court ruling [United States v. Varig Airlines, 467 U.S. 797 (1984)] which noted:

> *"The FAA certification process is founded upon a relatively simple notion: the duty to ensure that an aircraft conforms to FAA safety regulations lies with the manufacturer and operator, while the FAA retains the responsibility for policing compliance. Thus, the manufacturer is required to develop the plans and specifications and perform the inspections and tests necessary to establish that an aircraft design comports with the applicable regulations; the FAA then reviews the data for conformity purposes by conducting a "spot check" of the manufacturer's work."*

In this case, the Court ruled that the FAA does not ensure or insure safety; it only promotes safety through its high safety standards.

It further ruled that the FAA has discretion to review Industry compliance to the degree it deems necessary in the public interest. Except where statutes direct otherwise, the FAA is free to choose what it wishes to review and how it wishes to do so.

FAA Role in Delegation. Over the years the FAA has augmented its resources through the use of designees. Private individuals and organizations have been delegated the responsibility to "find" compliance on behalf of the FAA. The FAA has the authority to decide in what aspects of a project it wants to be involved, whether to delegate its involvement, and, if so, to whom. The FAA has tailored its delegation programs to ensure that direct oversight of safety critical areas remains the sole responsibility of the FAA.

FAA Role in CDO. CDO is a logical step beyond delegation in that it allows the FAA to rely upon demonstrated Industry competencies and processes -- rather than FAA designees -- to determine compliance with FAA requirements. The ability of the CDO to make compliance determinations is a privilege of the CDO certificate; it is not a delegation.

The FAA approves the design organization's systems and processes that ensure regulatory compliance, and oversees the organization in its adherence to these systems and processes. The FAA's process for certifying the design organization, coupled with a strong oversight system, gives the FAA the assurance that it can rely on the compliance determinations made by the design organization.

While CDO does change the FAA's involvement in the certification process, key aspects remain the same.

- FAA retains sole responsibility for the issuance of safety regulations, establishing the certification basis for aeronautical products, and development of special conditions necessary during certification programs to ensure that novel or unusual design features of a product meet a level of safety equivalent to that established in the regulations.

- The FAA also retains sole responsibility for the issuance of equivalent safety findings and exemptions, and the approval of acceptable means of compliance for products in accordance with issued safety regulations.

- The FAA retains authority to conduct audits of the CDO, including compliance with safety regulations, and the processes contained or referenced in the CDO's procedures manual.

- In accordance with existing statutes, the FAA will continue to issue all type certificates.

II. H. Benefits of CDO

Systematic Approach to Compliance. The principal benefit of CDO is a *systematic approach* to compliance and safety, accomplished using standardized company processes that are reviewed and approved by the FAA. The system and its processes are continually analyzed for compliance, quality, and safety effectiveness throughout the regulated areas of each CDO.

Proactive Approach to Safety. Today, changes to certification programs within the FAA and Industry frequently emerge as a result of an in-service event (such as a product failure), and are applied using a "forensic" approach to safety. The ARC believes that design organizations and their relationships with the FAA have evolved to a point where a more "proactive" approach can be used to better meet aviation safety goals. The ARC developed the CDO concept with that goal in mind.

Greater Level of Applicant Compliance. The CDO concept requires certificate holders to develop and conform to its own processes, which integrate compliance into its design activity. The ARC believes a systematic review and assessment of those processes by the CDO will enable a greater level of applicant compliance assurance. The FAA will focus on ensuring each CDO's compliance with its own processes, and will conduct product and process audits as necessary. This approach integrates regulatory and process compliance directly into the CDO processes, and does not require FAA review of each discrete compliance showing.

Better Leveraging of both FAA and Industry Resources. Design organizations will benefit from CDO because it empowers companies to develop and market products more quickly than current FAA organizational delegation models allow. Further, design organizations will be able to more quickly scale and apply resources for regulatory compliance activities, rather than relying on FAA oversight resources to drive the schedule for finding compliance. Currently, certification projects are sometimes delayed for months because of FAA resource limitations, and the ARC expects demand for aviation products to increase in the next 5 -10 years. Some ARC members predict that FAA will not have sufficient resources for certification activities, considering this projected rise in demand.

A design organization holding a CDO certificate will be empowered to generate data developed under an FAA-approved system that is "eligible" for use in future certification projects. The FAA generally discourages this under the current delegation system, because a company would be unilaterally allocating FAA resources (either directly or indirectly) to carry out FAA approvals not associated with a specific certification project.

The FAA will benefit from CDO by allowing it to fulfill its safety mission using a more risk based approach and by optimally leveraging its resources as demand for its services increases. The CDO concept follows an established regulatory philosophy that Industry is responsible for ***showing*** compliance with regulations and FAA is responsible for

finding that the Industry has complied. The "culture of compliance" required of design organizations under CDO is integral to this philosophy and will be discussed in Section IV.D.(4) of this report.

More Consistency in Compliance. CDO will provide more consistency in:

- certification,
- the application of acceptable methods of compliance, and
- the application of policy interpretation.

The focus on structured processes that provide compliant products will minimize the need for repeated FAA interpretations, and the resulting certificate entitlement provides a more stable platform to conduct business than relying on repeated delegations from the FAA.

The FAA will have a new role in the certification process under CDO. Currently, the FAA is involved with every discrete finding of compliance; under CDO, the FAA will direct its oversight to organizational compliance systems. This places a greater responsibility on the design organization to develop strong processes that clearly demonstrate compliance. Routine FAA oversight will focus on these compliance systems and processes.

Early Prevention of Organizational or Process Barriers to Compliance. While the FAA still has a role in affirming the compliance of the end product, a CDO's focus on compliance by process will allow the FAA to focus on organizational and process barriers to compliance. Unlike today's system, where FAA typically does not detect organizational breakdowns unless they are discovered as part of an investigation into service problems or an accident, this type of oversight by the FAA of a CDO's systems and processes will make it better suited to proactively identify and prevent organizational breakdowns.

The organizational delegation system in use today requires that the FAA dedicate resources to overseeing organizations that are charged with making "findings" on behalf of the FAA. This focus may result in organizational cultures that place elements of the design organization in conflict with the organizational delegation, or cultivates a culture that recognizes compliance as "whatever the delegation will accept." The CDO concept redefines this approach by eliminating the organizational delegation's role as a "safety net" for catching mistakes made by the design organization. The result is the design organization taking full responsibility for compliance by embedding within itself a risk-based approach to ensuring compliance. While the FAA will maintain its own "safety net" function, its purpose will not be to check every discrete compliance activity performed by the CDO, but rather to oversee those systems that the CDO has put in place to ensure compliance. FAA oversight will facilitate a stronger focus on compliance by the entire design organization, using the systems and processes for design compliance throughout the product's life cycle.

Opportunity for More Effective FAA Guidance, Technical Oversight. Under CDO, FAA expects that certificate holders will use processes that result in consistent compliance activity, whether or not the FAA is providing direct oversight. Ideally, then, the FAA will be able to focus resources on producing more concise guidance, transmitted efficiently and effectively to regulated entities.

Further, FAA inspectors overseeing CDO activity will be better able to concentrate on specific technical areas. This technical oversight and reduction in administrative detail will allow FAA inspectors and engineers to more easily maintain their technical capabilities.

FAA participation with the CDO during the early phases of a design project will allow the FAA to identify areas requiring an improvement in its technical knowledge and allow the FAA to evaluate methods the CDO is applying to the design project.

III. A NEW APPROACH FOR THE 21ST CENTURY

The Certified Design Organization --CDO --enhances the concept of government / Industry shared responsibility for the design approval of aviation products. It is not a delegation in any sense of the concept as defined in section 44702(d) of Title 49 and FAA regulations that have implemented that statutory authority. Instead, CDO is a certificate, as defined in section 44704 ("Type certificates, production certificates, and airworthiness certificates"), and is subject to the full oversight of the Administrator under sections 44709 ("Amendments, modifications, suspensions, and revocations of certificates") and 44711 ("Prohibitions and exemption").

A key feature of the CDO concept is the authority of the CDO to perform authorized functions, such as making statements of compliance to the Administrator, as well as determinations of compliance that result in FAA approved data. These are privileges of the certificate and are the result of actions by numerous individuals within the CDO carrying out the processes established to ensure compliance with the requirements, rather than through specified company individuals acting on behalf of the FAA.

Simply stated, CDO is not a separate entity within the certificate holding organization; it is the entire organization.

The CDO concept necessitates a highly structured "culture of compliance" within the organization such that compliance is a result of every task of design, production, and airworthiness certification. It is a result of committed executive leadership and oversight and, at the same time, individual commitment to doing the assigned task in accordance with the strong corporate value placed on compliance and safety.

With compliance established through adherence to process, the CDO system may also include supplier processes that result in determinations of compliance, as long as those processes have been found to be consistent with CDO internal company processes and their oversight. This will support the globalization of aviation design, production, and airworthiness certification.

This globalization trend is expected to continue as aviation makes use of global talents and capabilities to keep up with its anticipated growth.

III. A. Accountability Framework

The foundation for development of the CDO 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 of 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 CDO is an accountability framework that clearly distinguishes the roles and responsibilities of both Industry and FAA. Applicants lacking certification experience, as well as the use of numerous FAA designees by many companies, 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 is 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** • **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 a fabrication inspection system or a quality control system** • **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. B. Safety Management System (SMS)

CDO will require the certificate holder to have and maintain an acceptable safety management system (SMS). The SMS must be a robust, proactive approach to initial and continued safety of the products and processes of the CDO. It is not just the resolution of in-service safety issues, but a proactive process to discover issues before they exhibit safety consequences. It is also a proactive process to discover breakdowns or needed improvements within the CDO system and its processes, and to correct them before they lead to non-compliances or unsafe conditions.

SMS Standards Developing Internationally. The ARC is aware of the worldwide effort to apply the principles of Safety Management to various aviation activities. The International Civil Aviation Organization (ICAO), FAA, Transport Canada, the European Aviation Safety Agency (EASA), and others have strategic goals to incorporate Safety Management principles into their aviation systems to varying degrees.

The FAA's Safety Management goals (described in the FAA Aviation Safety Organization (AVS) SMS doctrine in FAA Order VS 8000.1) include:

- establishment of a formal Safety Management System within its organization, and
- fostering similar Safety Management Systems within aviation product manufacturers and commercial operators.

SMS Standards Developed by the JPDO. To proactively address continued technological innovation and the forecasted growth in air traffic, several US government agencies have formed the Joint Planning and Development Office (JPDO). As a part of its actions, the JPDO plans to propose Safety Management concepts that are applicable to elements of the US National Airspace System (NAS).

The JPDO is currently working on standards that will define attributes of an SMS for service provider organizations (including manufacturers, operators, and maintenance facilities), and federal authorities that oversee the SMS. Because the JPDO effort is still ongoing, it is not possible for the ARC to ensure that the CDO SMS requirements it has proposed will be fully aligned with the final JPDO principles and requirements. However, this report accepts the foundational concepts provided in the JPDO draft documents and proposes specific SMS principles and processes as minimum requirements for a design organization's SMS.

Should the FAA propose to regulate SMS through broader rulemaking that would include CDO certificate holders, the ARC believes that rulemaking should be consistent with what it is recommending, and contain the minimum requirements presented in this report and the ARC's proposed NPRM (notice of proposed rulemaking).

SMS under CDO. To receive a CDO certificate, a design organization must demonstrate that it has established, and is able to maintain, an SMS that complies with attributes defined by the ARC in this report.

An SMS includes:

- safety policy,
- safety risk management,
- safety assurance, and
- safety promotion.

When combined with the requirements for a compliance assurance system (CAS) and a quality management system (QMS), the SMS will provide a systematic approach to the design, certification, and ongoing support of aviation products.

The ARC debated whether the SMS management principles should be applied by regulation to all certificates held by the CDO certificate holder. While there may be benefits in doing so, the ARC concluded that its charter is limited to proposing only those requirements directly applicable to CDO, and should not be used as the medium to propose SMS requirements on other certificates the CDO certificate holder might also hold (e.g., Repair Station, Production Certificate).

However, consensus was reached among ARC members that the SMS should encompass the lifecycle of the design organization's products, and the SMS must seek input from all information sources. This would include other elements of the CDO certificate holder's organization, including those elements holding other FAA certificates as well as the maintainers and operators of its products.

A Culture of Safety and Compliance. A principal tenet of CDO and its SMS is that an effective "safety culture" exists within the company. In the context of CDO, an effective safety culture must encompass all the company's operations involving engineering, manufacturing, and safety processes. It must embody a persistent dedication to reducing safety hazards involving the organization's processes and products.

A "culture of compliance" is a subset of a safety culture, in that it focuses on regulatory compliance.

Together, these cultures are evident when:

- people who recognize and act on their individual responsibility for safety and compliance are supported by the organization's safety and compliance assurance processes, and
- management takes an active role in leading and measuring the safety and compliance activities within the organization.

By their nature, these cultures are difficult to measure. Although they cannot be directly seen, these cultures can be observed through the presence or absence of certain organizational procedures, enablers, and desired behaviors. The CDO requirements throughout this document identify processes and desired behaviors that should develop and reinforce the cultures of safety and compliance at the organization. Within the SMS requirements are specific elements for safety promotion, the main goal of which is the development of the safety culture. Cultures of compliance and safety are discussed further in Section IV.D.(4) of this report.

Compliance by Process. A further objective of the CDO concept is the development and enabling of "compliance by process." This is the development of a process to show compliance that is:

- documented,
- repeatable,
- auditable, and
- capable of resulting in the same or higher level of confidence as a compliance showing with a skilled independent check.

Compliance by process, as defined by the ARC, leads to processes that result in compliance rather than the efforts of individual persons to demonstrate compliance, and requires that skilled individuals or other means be used to verify that compliance.

In a system using compliance by process, if the verification step results in compliance deficiencies being identified, the compliance process must be corrected so the verification is indeed an additional safeguard rather than a single-thread compliance process. Consistent with the concept that failures of validation should result in correction of the process leading to the compliance finding, any failures during certification compliance testing should be recorded and assessed for process improvements within the compliance assurance system, and for evaluation by the safety management system. The records of these test failures should be available to the FAA oversight team for review.

It is this equivalence of a skilled independent check that allows the FAA to:

- accept CDO determinations of compliance as a means by which FAA-approved data can be created, and
- rely on the statement of compliance made by the CDO in making its finding of compliance.

The criteria for determining that a verification process is equivalent to a skilled independent check will be included in guidance material related to the implementation of CDO.

Another feature of compliance by process is the recognition of the capabilities of the entire organization as the design certificate holder, rather than the capabilities of a subset of the organization, as is the case with delegation today. This means that the entire organization must be acting in unison under defined processes, with appropriate executive guidance and leadership.

IV. CDO GUIDING PRINCIPLES AND ATTRIBUTES

This section defines the guiding principles and system attributes that form the foundation of the CDO concept that are the framework for the ARC's proposed NPRM and for which the ARC recommends use by the FAA in developing CDO 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 determining compliance.
- Leveraging the capability of design organizations, allowing more efficient use of FAA oversight resources.
- Consistency with the accountability framework.
- Continuous improvement in safety processes and compliance.

IV. A. Overview

The CDO principles and attributes are defined in terms of overall objectives, not specific implementations. 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 small organization seeking approvals for a limited set of design modifications (defined by STC), or an organization with a full line of products, including aircraft. This range of organizational sizes and responsibilities demands that the CDO be scaled appropriately to the organization. It is obvious that a "one size fits all" principle is not appropriate for CDO. The ARC has approached this task by creating a single set of requirements, with the expectation that each requirement would be assessed for effective implementation in the organization.

Section-by-Section Overview. The sections that follow elaborate on the principles and attributes that make up the overarching program objectives that the ARC believes the FAA rulemaking effort should address (Appendix G contains a concise bulleted list).

- **Section IV.B** addresses the statutory or regulatory framework that has details on the regulatory requirements, details of the certificate, requirements for the certificate holder, privileges of a CDO, and requirements for the organization of the CDO.

- **Section IV.C** addresses the CDO certificate and its scope. This section discusses the concept of how a CDO must be functionally complete and how production may be incorporated within a CDO.

- **Section IV.D** contains the requirements for a systematic approach to compliance and safety, which include a compliance assurance system, safety management system, and quality management system.

- **Section IV.E** discusses supplier control requirements, including offshore suppliers.

- **Section IV.F** addresses items relating to the approval of data. This includes:
    - when data can be approved,
    - what it can be approved for,
    - how the approval should be communicated,
    - the use of previously approved data,
    - the use of the FAA delegation system, and
    - the need for outside organizations to be allowed to approve data within their technical specialty.

- **Section IV.G** addresses the other part 21requirements applicable and not applicable to CDO.

- **Section IV.H** addresses international considerations, including:
    - effects on bilateral agreements,
    - the need for international recognition,
    - the use of CDO compliance determinations internationally,
    - CDO use of data previously approved by another CAA,
    - use of technical assistance from a CAA,
    - type certificate validation, and
    - continued operational safety.

- **Section IV.I** discusses CDO implementation issues, including:
    - transition to CDO,
    - CDO self assessment,

- CDO appointment,
- FAA/CDO communication, and
- issue resolution between the FAA and a CDO.

- **Section IV.J** addresses FAA evaluation of a CDO, including:
  - evaluation of qualifications
  - a description of the FAA oversight envisioned,
  - the FAA guidance role,
  - what FAA involvement there would be in a typical project, and
  - ARC proposals for the development of appraisal standards for CDOs.
- **Section IV.K** addresses records retention requirements.
- **Section IV.L** addresses Technical Standard Order Authorization (TSOA) under CDO.
- **Section IV.M** discusses the applicability of FAA Orders to CDO procedures.
- **Section IV.N** the last section of this part of the document addresses the need for an FAA Order and Advisory Circular on CDO.

IV. B. Statutory Authority and Regulatory Considerations

IV.B.(1) A CDO Certificate is Not a Delegation

A CDO 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 CDO's ability to perform these functions is a privilege of its CDO certificate and not a delegation.

While CDO is a significant regulatory change, it is only an evolutionary step 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 CDO and the integrity of its determinations of compliance, to monitor and audit those determinations, and to issue certificates. In addition, the ability of the Administrator to amend, modify, suspend, revoke, or otherwise alter the CDO

certificate, as specified in sections 44709 and 44711 of Title 49, is not affected in any way.

IV.B.(2) Eligibility

a. CDO Must Be an Experienced Design Organization

One of the essential attributes of every CDO is that the certificate holder has completed certification activities leading to an FAA design approval, prior to receiving their CDO certificate.

Any legal "person" -- except an individual -- may apply for a CDO certificate. The ARC considers that an individual cannot provide process-based regulatory compliance with the necessary assurances.

In addition, the person must have been an applicant for, and be a holder of, a US type certificate, supplemental type certificate, parts manufacture approval (PMA), or technical standard order (TSO) authorization, consistent with the scope of the CDO certificate being sought. This is to ensure that the applicant has already been through a non-CDO design approval process for the type of CDO certificate for which it is applying. For instance, a person holding only TSO authorizations may apply for a CDO encompassing the type of articles for which it holds an authorization, and not a CDO covering any other design areas.

Purchase of Rights to a Certificate. The purchase of the rights to a Type Certificate (TC), Supplemental Type Certificate (STC), PMA, or TSO does not, in itself, make the purchaser eligible to apply for a CDO certificate. In this situation, the applicant for a CDO certificate, or for a change in scope of an existing CDO certificate, must demonstrate its ability to make all determinations of compliance and meet all regulatory requirements for the scope of certificate being sought through a non-CDO process.

Consortiums under CDO. The forming of consortiums to share the development costs of new products is becoming more common. The ARC considered how consortiums could function under the CDO principles, and agreed to the following basic tenets:

- To be eligible for a CDO certificate, a consortium must meet the definition of a "person" contained in 14 CFR Part 1.
- As an applicant, the consortium must also demonstrate that the consortium "acts" as one company with regard to its CDO responsibilities, within the scope of its certificate.
- If one or more of the consortium members is a CDO certificate holder, they may act in support of the consortium CDO certificate by making

determinations of compliance or approving data for the consortium under their own certificate privileges. It would be impractical for that member to operate under two different CDO certificates -- one for its own activities and one for those activities it accomplishes under the consortium CDO.

- In their simplest form, the consortium processes and procedures could be comprised of individual member processes and procedures approved under their individual certificates.

- In all cases, the consortium would be responsible for demonstrating that the individual company processes and procedures, taken as a whole, are in compliance with CDO requirements and are properly integrated.

To qualify for a CDO certificate, the applicant must have previously applied for, received, and presently hold a design approval for the scope of activities for which it desires a CDO certificate. If taken literally, this could be an impediment to consortiums obtaining a CDO certificate, as a consortium is usually created for one product, or a limited number of products. The ARC believes that, in the case of consortiums, this qualifying criterion should be assessed using the collective experience of the member companies. For instance, if the members of a consortium meet the qualifying criteria because of their own unique certification activities for large turbofan engines, then a consortium addressing the full scope for a new engine would be able to apply for a CDO certificate.

The ARC also believes that, if a foreign company is a member of a consortium and its experience in past programs is being used to help justify the scope of the consortium certificate, then such credit is only possible if the FAA has issued a type certificate, or other appropriate design approval, to that company for the scope of CDO certificate being sought by the consortium

The ARC also considered the situation where the consortium may not meet the requirements necessary to qualify for a CDO certificate, or may not desire to hold a CDO certificate, yet one or more members of the consortium may hold a CDO certificate that covers compliance activities that will be undertaken by the consortium. The ARC concludes there should be a prohibition against a CDO acting as a third-party in making determinations of compliance for someone holding or seeking an FAA approval, but, in this example, that conclusion might unnecessarily hinder the rightful activities of consortiums. If one or more consortium members hold a CDO certificate, to not allow determinations of compliance made under their certificate to be used by the consortium, would force the CDO certificate holder to have a second compliance system within the company and lead to unnecessary complication.

For this and other reasons, the ARC agreed that an exception should be made to the third-party use of CDO determinations of compliance specifically to allow

for the situation where the consortium is not a CDO certificate holder yet one or more members wishes to make determinations of compliance for its portion of the consortium activities.

In all cases the CDO certificate-holding member must operate within the limitations of its certificate and in accordance with its CDO Procedures Manual. The consortium must establish the validity of those CDO determinations of compliance for the program/project on which they are to be used.

In certain circumstances, a company or consortium may hold more than one CDO certificate. One example is where the company has more than one division, each of which is designing different types of products, parts, or appliances. This is considered to be an acceptable deviation from the basic principle of a CDO having integrated processes throughout the company and single-point oversight by the FAA; however, the ARC recommends that the approval for holding more than one certificate be reserved for the Director, Aircraft Certification Service.

Production Certificate Activities. The ARC recommends the FAA not issue a CDO certificate for production certificate activities only. Any CDO certificate under which the holder includes post-design approval production activity may only be issued to the holder of the design approval with which that production is associated.

b. Must be a US State of Design Organization

CDO will be limited to:

- applicants located in the United States, and
- only products, parts, and appliances where the US is the State of Design under ICAO Annex 8 for the design approval being sought.

The CDO process is not intended for foreign applicants who are seeking a TC or STC under §21.29, or a TSO article design approval under §21.607. Those companies should continue to seek approvals from their State authority and validation by the FAA under existing bilateral agreements.

IV.B.(3) Requirements and Obligations of the Holder

The CDO holder has certain requirements and obligations that must be met to qualify for the privileges of a CDO certificate.

a. Operate in Accordance with a Procedures Manual

A key aspect of the CDO concept is that it has a Procedures Manual that defines the procedures it will use to meet the regulatory requirements. It must have procedures in place to ensure that it is operating in accordance with the Procedures Manual, and there must be a process for taking action when changes or deviations occur.

b. Keep Procedures Manual Up to Date with FAA Regulatory Requirements and Policy

A CDO must maintain its Procedures Manual to ensure it is current with all regulatory requirements and FAA implementing policy. The CDO must have a process for continually researching changes to FAA regulations, policy, ACs, or other information to insure that is following the latest requirements or guidance as appropriate.

c. Maintain a Systematic Approach to Compliance and Safety

Further details on the system requirements are in a later section of this report.

d. Use Means of Compliance Acceptable to the FAA

A CDO must use means of compliance acceptable to the FAA when making compliance determinations. The means of compliance should take into consideration FAA policy, advisory circulars, and previously used means of compliance for similar applications that have been acceptable to the FAA. Any deviations from these must be discussed with the FAA.

Any new technology for which acceptable means of compliance have not been established must be reviewed with the FAA so that the CDO has a defined and acceptable path to compliance determination. These discussions should be held early in the program to ensure that problems don't arise late and necessitate significant redesign.

e. Provide a Statement to the Administrator

A CDO must provide a statement to the Administrator certifying that the CDO has complied with the applicable requirements for the design approval sought in accordance with its FAA-approved Procedures Manual. This statement of compliance must be based on documented evidence of a determination of compliance with all of the applicable requirements and minimum standards.

f. Manage All Certification and Post Certification Activity within its Scope of Authority

A CDO must manage all certification activity included within the scope of the CDO's authority.

The CDO must have documented processes for managing all testing and conformity.

In addition, a CDO must manage all post-certification activity included within the scope of the CDO's authority.

The CDO must have processes to address any quality escapes or in-service issues. These processes must include a risk assessment process for addressing any safety issues.

g. Maintain a Record of All Project Activity

A CDO is responsible for maintaining a record of all projects and their status, and for making that information available to the FAA in a manner acceptable to the Administrator. This might be a database where the CDO provides FAA access to specific portions of it to accomplish the intent of the requirement. This requirement is necessary to allow the FAA to perform oversight of the CDO.

h. Notify the FAA if Circumstances Prevent it from Meeting its Obligations

A CDO must also notify the FAA if there are any circumstances that prevent the CDO from meeting the obligations of its CDO certificate. The CDO must identify the issue and notify the FAA in a timely manner.

i. Allow the FAA to Make Any Inspection Necessary

The CDO certificate holder must allow the FAA to make any inspection necessary to determine compliance with the regulations.

The CDO certificate holder is also required to provide access for the FAA to perform on-site evaluations as the FAA considers necessary, and to access to the facilities and records of all its peripheral organizations, including suppliers that function under the CDO.

j. Maintain a Qualified Staff

Once the scope of the CDO certificate has been established, the certificate holder must always have a qualified management and technical staff with the appropriate mix of knowledge, skills, and abilities necessary to allow the organization to make a statement of compliance and perform other functions authorized under its certificate.

The qualified staff must be able at all times to determine that all the work performed by the CDO, including that accomplished by any temporary resources described in the next paragraph, is compliant with the requirements of their compliance assurance system.

A CDO certificate holder may augment its qualified staff with other skilled personnel or resources, as directed by the project or certification issue. These provisions include two specific situations that a typical CDO will encounter.

- One case is supplier resources that augment the CDO capability and operate under the CDO authority.
- The second case is technical specialists hired by the organization to enhance its technical capability in specific areas.

In both cases, the qualified management and technical staff must have the skills necessary to manage those activities and to determine that the work performed by any temporary resources utilized by the CDO is compliant with their certificate responsibilities.

The CDO must include a process for determining what constitutes the qualified staff needed to maintain the authorized scope of the CDO organization. If the qualified staff identified above is not maintained, this must be reported to the FAA and the CDO Procedures Manual must include provisions to ensure that no determinations of compliance are made within the CDO and that no statements of compliance are made to the Administrator in the affected areas.

IV.B.(4) The Rights and Privileges of a CDO

Like any other FAA certificate, a CDO certificate comes with defined rights, privileges, and responsibilities. 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 CDO certificate, including the types of covered products and services, would constitute a part of the CDO certificate.

The ARC has used the following conventions within this report:

- A "right" is something that is granted by the statute.
- A "privilege" is granted by the FAA under its regulations. These may be a "privilege of the certificate" that comes with a CDO certificate or it may be a privilege that is granted on other conditions.
- "Responsibilities" accompany rights and privileges. Throughout this report, we have typically referred to responsibilities that accompany the CDO certificate.

Not all CDO certificate holders will have the same scope of authority, but each should have all of the privileges necessary and sufficient to gain the approvals they are seeking, and maintain the approvals they already possess.

Entitlement to a CDO Certificate. One right associated with CDO is that *all persons who are found by the FAA to meet the published requirements are entitled to a CDO certificate.* Unlike the FAA's current system of delegation, CDO does not require an FAA determination of need. The FAA does not intend at this time to require design approval holders to become CDOs, but it does want to encourage the Industry to make full use of this new process if they can demonstrate the level of corporate maturity and certification expertise that is necessary.

The CDO certificate holder also has the right to retain the certificate unless the FAA takes certificate action in accordance with the procedures found in 14 CFR Part 13.

This report identifies the important criteria that must be met to qualify for a CDO. The granting of a CDO certificate should be a process that matches the applicant's skills, processes, and procedures to known regulatory requirements. Given the potential variety of business sizes and structures that may apply for a CDO, and the numerous FAA field offices at which a CDO application may be filed, consistency and standardization will be a challenge -- and a goal -- for the FAA. The ARC's proposed NPRM for CDO contains all necessary criteria to qualify for a CDO, and those criteria can be tailored to the scope of the design approval certificate being sought.

FAA Reliance on Compliance Statements. Section 44702(e)(3) of Title 49 states:

> *"The Administrator may rely on certifications of compliance by a design organization when making a finding."*

Compliance documents produced by the CDO holder include those created for the purpose of obtaining or amending a type or supplemental type certificate, approval of a change to type design, obtaining a TSO authorization, PMA, or a repair design approval. In order for FAA to rely on these compliance statements, a CDO is

required to have extensive processes to ensure compliance, which will be very costly and complicated to implement. Having expended the considerable time and money to develop the CDO processes, Industry will want assurance that the local FAA office does not arbitrarily decide to not rely on the determinations of compliance made by the CDO certificate holder, and make its own findings. Such actions would defeat the purpose of having a CDO.

The Industry members of the ARC argued that Title 49 is enabling language and that the FAA regulation should state that the FAA will rely on the compliance statement by the CDO certificate holder, unless the FAA has reason to believe that statement is not backed up by appropriate determinations of compliance, or is otherwise flawed. Industry cited a couple of examples where enabling legislation using the word "may" was promulgated into regulatory language using the word "shall' or "will."

This issue was discussed with the FAA members of the ARC and also with FAA management outside of the ARC's deliberative process. In the end, the FAA did not agree with the Industry's position and believes that it must maintain its right to make the final decision on all matters involving the issuance of certificates. The FAA made it clear that not accepting a CDO statement of compliance should be a very rare event and should only occur with the concurrence of FAA management.

The Industry members of the ARC understand the FAA position and agree that FAA has the right to make the final decision on all matters involving the issuance of certificates. However, these members also cite the need for a commitment to ensure that any non-reliance on the CDO statement of compliance has appropriate management oversight. This could be accomplished by using the word "will" rather than "may" in the FAA Order implementing CDO. The Order would clearly define the conditions under which further investigation into the CDO certification may be appropriate. The Industry believes that diligent oversight at the Director level within the FAA will minimize this occurrence. Therefore, having the final decision made at the Director level within the FAA should not be a burden to FAA management.

Privileges of CDO Certificate. Within the scope and limitations of its certificate, privileges of the CDO certificate will include:

- **Determining compliance and submittal of a statement of compliance** to the FAA for the purpose of obtaining a design approval (TC, STC, PMA, TSO);

- **Classifying changes to type design** as "major" or "minor;"

- **Creating FAA-approved changes** to a type or supplemental type design, TSO authorization, or PMA;

- **Creating FAA-approved data in support of major or minor repairs**, or major or minor alterations, to products for which it holds the TC or STC;

- **Creating FAA-approved data in support of the design approvals** it holds and is seeking;

- **Generating eligible data**;

- **Issuing information or instructions** approved under the authority of the CDO, including the Instructions for Continued Airworthiness or Aircraft Flight Manual;

- **Creating FAA-approved documentation changes** to the Instructions for Continued Airworthiness or Aircraft Flight Manual; and

- **Marking or identifying data** as FAA-approved.

Those CDO activities not associated with the issuance of a certificate, TSO authorization, or PMA approval would not require a “statement of compliance” to be submitted to the Administrator. Therefore, major and minor design changes, as well as technical data created by the CDO to support the continued airworthiness of an existing type design, would not require a statement to be submitted.

These privileges may be revised or revoked with certificate action if the CDO fails to meet its obligations under the authorizing regulations.

IV.B.(5) Issuance of Certificates

The ARC discussed whether or not a CDO should be able to issue type or airworthiness certificates. The ARC recognized that the existing statutes authorize only the FAA to issue these certificates, but did discuss whether or not the FAA should be given the statutory authority to allow certificates to be issued by a CDO. To do so would require additional Congressional action, and any FAA authorization to issue certificates, outside of delegation, would set precedence among international airworthiness authorities.

For these and other reasons, the ARC concluded that it would not recommend a statutory change authorizing a CDO to issue certificates under its CDO authorization.

Issuance of PMA and TSO Approvals. Similarly, the ARC recommends that the FAA issue all PMA and TSOA approvals to those CDOs authorized to make statements of compliance in these areas. While these types of approvals have both a design and production component, they are not "certificates" as defined in Section 44704 of Title 49, but rather "approvals" created by the Administrator under the authority of Section 44701 to issue safety regulations.

While the ARC has not identified a specific limitation in the statutes that would prohibit the direct issuance of these approvals by a CDO, the ARC agrees to having all design approvals issued by the FAA. This would serve to enhance public and international confidence in the system. Industry members of the ARC concur with this position, but believe that a CDO could be entrusted to issue PMA and TSOA approvals as one of the privileges of the certificate.

Issuance of Initial Type Certificates. The ARC believes the FAA should continue to issue all initial type certificates without the use of its designees, but it concluded that a form of delegation should be available to support CDO's in the issuance of amended type certificates, supplemental type certificates, airworthiness certificates, and initial design approvals.

Issuance of Certificates by Designees or Delegated Organizations. A CDO certificate holder could have individual company designees or an organizational delegation, with their responsibilities defined in separate FAA guidance and orders. The ARC concludes that, in most cases an organizational delegation would be more appropriate since the CDO concept is based on sound organizational principles. The purpose for the delegation is strictly for supporting the issuance of certificates and should embody the following principles:

- Assurance that all CDO and FAA-defined activities associated with the certificate to be issued have been completed according to the program plan.

- The statement by the CDO holder will not be re-evaluated to ensure that all determinations of compliance were properly accomplished. If the designee or delegated organization has data or an otherwise substantiated belief that might lead it to question the validity or completeness of the determinations of compliance, or believes the product contains an unsafe design feature, it must inform the FAA of those matters. The responsibility of resolving those matters rests with the FAA.

- Confirmation that any pre-defined FAA activities associated with certificate issuance have been completed.

NOTE: The FAA is responsible for notifying its designee or delegated organization of any ongoing FAA oversight that has detected a condition such that certificate issuance is not appropriate.

The ARC proposes that no additional rulemaking under 14 CFR Part 183 ("Representatives of the Administrator") is necessary to accomplish the above delegation objectives. The ARC has determined that delegation under §183.33 is broad enough to encompass any delegation activities necessary under the CDO concept. (See Appendix H of this report for further elaboration of this position.)

There was general consensus among the ARC members on the approach described above. Some ARC members still believe that, if the FAA finds the CDO to be fully competent, there should be no reason that the issuance of supplemental type certificates and airworthiness certificates could not be a privilege entrusted to the CDO.

IV.B.(6) The Generation of "Eligible Data"

Under a CDO certificate, compliance is an intended by-product of an FAA-approved CDO 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 type certification basis be established by the FAA for the product on which it is to be installed. Another essential element is that a type 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 commonplace for a company, within its normal engineering and production system, to develop products, parts, components, and processes for future use in type certification programs. In the case of a CDO certificate holder, if that development is accomplished under the approved CDO 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 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 CDO. The ARC refers to this as "eligible data."

"Eligible" data are data developed under the processes of an approved CDO system, given a specified, but not necessarily final, certification basis and product type design.

To use "eligible" data, the CDO holder must assess its compliance against the final type certification basis of the product and final type design 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 and its type certification basis.

The creation of "eligible" data is a concept that is intended for use internal to the CDO. No approval or compliance determination can be conferred upon the data if the data are provided for use outside the CDO.

IV.B.(7) Voluntary Disclosure Privileges

The FAA has several active voluntary disclosure programs for air carrier and production approval holders, among others. Those 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 those 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 CDO is a new type of certificate, the ARC concludes that the information presented above remains equally applicable for CDO, and the FAA voluntary disclosure policy should be extended to CDO certificate holders. Activities under a production approval are already covered by FAA voluntary disclosure policy. If the CDO certificate encompasses both design and production activities, as discussed later in this report, there should be one, all-encompassing voluntary disclosure program within the CDO.

The FAA voluntary disclosure reporting program is presented in Advisory Circular (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 CDO certificate holder under the same defined situation.

IV.B.(8) CDO Organization

The ARC does not recommend that any particular organizational structure be required; however, there are certain functional roles that must be defined. These include the

- CDO executive,
- CDO point(s) of contact, and
- those individuals authorized to make statements of compliance on behalf of the CDO.

The CDO Executive has the responsibility for all the functions covered by the scope of the CDO certificate. This executive must be identified by name and position within the company, and may also act as the point of contact for the CDO. The CDO Procedures Manual must contain an explanation of the reporting relationship of the executive to senior company management, and the relationship to the management structure within the CDO.

The CDO point(s) of contact is the person(s) within the CDO with whom the FAA will communicate on all CDO matters. A list of formal points of contact (POC) must be maintained by the CDO. The POC(s) for the CDO must have the collective experience commensurate with the scope of authority granted to the CDO. The CDO POC must have the knowledge of CDO processes and the applicable FAA regulations consistent with the scope of the CDO certificate. The CDO POC must also have unencumbered, but not necessarily direct, access to the CDO Executive.

The CDO must identify all individuals who have been directly authorized by the CDO Executive to make statements of compliance to the FAA for design and production activities, including statements leading to the issuance of certificates of airworthiness. The Procedures Manual must show the accountability relationship between these individuals and the CDO Executive.

IV.B.(9) Internal Audit and FAA Oversight Findings

Integral to the CDO processes are company internal audits. In addition, the FAA will be conducting its own independent oversight. A natural outcome of both company audits and FAA oversight activities are findings.

- **Internal audit findings** that are related to process non-conformances or regulatory non-compliances should be disclosed to the FAA oversight team.
- **FAA oversight findings** will be formally communicated to the CDO.

Findings in either of these categories should be placed into the CDO corrective action system for disposition.

Each corrective action resulting from FAA oversight findings will be reviewed by the FAA oversight team to assure that corrective action has been completed. The FAA oversight team may review the details of any internal CDO corrective actions, as well, as part of the oversight of the CDO systems.

There may be other internal audit findings that would not meet the criteria above for disclosure to the FAA; these can be worked by the CDO corrective action process without disclosure to the FAA oversight team. The CDO should maintain the status of such corrective actions and the FAA oversight team may review them as part of its CDO oversight.

IV.B.(10) Compliance and Enforcement

Enforcement action is one of many tools available to the FAA to ensure compliance. Under CDO, the design organization would be a certificate holder with an obligation to follow its approved procedures manual and processes. Therefore, failure of a CDO to adhere to its Procedures Manual processes or other regulatory requirements could result in appropriate enforcement actions.

While enforcement actions may be mitigated if communicated through a FAA recognized formal self-disclosure process, CDO certificate holders will be subject to a more rigorous compliance and enforcement atmosphere than most design and production organizations have been accustomed to under current FAA delegation programs.

Existing enforcement regulations contained in 14 CFR Part 13 should apply to CDO certificate holders. This includes everything from financial and administrative penalties to certificate action such as suspension, partial suspension, or revocation of the CDO certificate.

Since a CDO certificate is new, 14 CFR §13.19(b) must be revised to specifically include reference to CDO certificates.

IV.C. Scope and Limitation of CDO 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 SFAR 36, DAS, or ODA authorizations or their own company designees, or may contract with consultant designees to perform design approval functions. This describes but a few of the organizations that make a business of engaging in design and production certification activities.

Many of these aviation companies can benefit from the CDO concept of operation. In turn, the safety benefits of a more complete corporate focus on compliance and safety can further permeate the Industry if these organizations are afforded the opportunity to obtain CDO certificates. For this reason, the criteria for obtaining and holding a CDO certificate must be such that they can be tailored to the size and functions of the specific CDO certificate holder.

As has always been the case, Industry is responsible for compliance with the regulations; this will not change under the CDO concept of operation. The rigor associated with that compliance is contained within the FAA-approved CDO Procedures Manual, and it must be tailored to the size of the organization and the complexity of the items that the certificate holder designs or produces.

A total "culture of compliance" must exist within each CDO company, but how that culture is established will likely differ for each CDO certificate holder.

The key is to define criteria against which all potential CDO certificate holders will be measured, but recognizing that there will be variables specific to different types and sizes of companies.

IV.C.(1) FAA Limitations on the Certificate

A CDO certificate may cover type certification activities, supplemental type certification activities, and activities leading to the issuance of TSO authorizations or PMAs, as well as activities associated with a production approval. For a particular CDO, the FAA may limit the scope of activities that might be accomplished by that CDO.

Type Certificates. For instance, for type certification activities, it would be rare that a certificate holder would be able to perform <u>all</u> the responsibilities necessary

for demonstrating compliance for all products that are eligible to receive a type certificate. For this reason, the FAA may restrict a CDO certificate to only products covered by a specific subpart 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 CDO certificate activities within a given regulatory subpart. For instance, a manufacturer might only have the experience necessary to properly comply with CDO 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 CDO 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 supplemental type certificates, 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.

TSO and PMA. In the case of TSO authorization holders, the scope will likely be further limited based upon the technical capabilities of the applicant. For instance some companies have broad technical capabilities across many avionics products, while others might have expertise in just one TSO area yet possess several different TSO authorizations. In the case of PMA the scope would likely be tailored to each certificate holder.

Determining the Appropriate Scope of a CDO. When determining an appropriate scope for a CDO 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 CDO 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 collocated design and production facilities, and the use of common processes and procedures.

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

IV.C.(2) Scope of CDO Certificate Rights and Privileges Must Be "Functionally Complete"

The CDO certificate rights and privileges must be functionally complete, which means they must cover all activities that an applicant would have to undertake in order to fully complete a design approval project within its scope of authority. The CDO 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 approva**l, 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; instructions for continued airworthiness, 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, repair data, and amended type and supplemental type certificates.

- **Manufacturing and airworthiness activities**, such as the prototype 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 CDO certificate, the FAA may wish to grant the CDO holder the additional privilege of making compliance determinations to CAA requirements.)

IV.C.(3) Manufacturing and Production Functions Under CDO

There are two types of manufacturing and production functions that need to be addressed with respect to CDO:

- Those prototype manufacturing functions associated with obtaining a design approval, and
- Those associated with a production certificate (PC) or production approval (i.e., post-design approval production).

Within its scope of authority, every CDO will be allowed to perform the prototype manufacturing functions related to its design activities. This includes such things as:

- Conformity inspection
- Determine conformity of parts and test articles
- Determine conformity of test setup
- Determine conformity of installations

The CDO 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.

The ARC also addressed the issue of including post-design approval production activities under the CDO program. However, the current legislation does not contain provisions for the inclusion of production approvals within a CDO certificate. Both Industry and the FAA have indicated a desire to have the CDO concept result in an integrated approach to both design and production activities, maintaining that it will enhance safety and result in more efficient use of both Industry and FAA resources.

The ARC discussed whether the CDO holder for the design of aircraft, aircraft engines, and propellers could combine its CDO certificate with an existing production certificate, or whether the certificates should remain separate. The ARC concluded that most of the benefits of a combined certificate can be achieved with separate certificates, as long as its production activities can be accomplished in accordance with CDO procedures, with all its responsibilities and privileges.

One benefit that would be achieved by having a production approval managed under a CDO certificate is the resulting requirement for a single SMS governing both the design organization certificate and the production activities. Although the CDO rule would not require a SMS to cover the post-design approval production aspects as a requirement of the CDO certificate, the ARC finds it difficult to envision an SMS bounded by the organizational division between design and production. The ARC believes that an effective SMS will seek information and identify hazards wherever

directed by the data it gathers. This includes seeking as well as providing safety information to those in the field, or within the company itself, who are responsible for the production, maintenance, and operation of its designs.

The ARC believes that both FAA and Industry would benefit from a more efficient certificate management approach that would result from combining the operation of the design and production activities under the CDO certificate. The ARC also believes that combined activities would be more effective in promoting a common safety culture and integration between functions. Furthermore, the ARC envisions that the production activities should continue to meet all of the requirements of Part 21, subpart G, as well as the requirements established for the CDO subpart, unless otherwise specified. The result would be a single SMS, QMS and CAS governing both the design and production activities.

The ARC agrees that a CDO would not be appropriate for production activities only, as the current production approvals, such as production certificate (PC), PMA, and TSO authorization, are sufficient to cover those activities. Additionally, the continued operational safety responsibilities embodied in a CDO are the responsibility of the design approval holder, a concept that stems from ICAO Annex 8 and 14 CFR Part 21. It is difficult to see how a production-only activity, such as production under a license agreement, could comply with the CDO regulatory requirements. Having the design approval holder and a separate production certificate holder both responsible for continued operational safety activities would be confusing with regard to who is responsible.

In considering what additional responsibilities and privileges a production approval holder (PAH) might be afforded when operating under a CDO certificate, the ARC recognized the robust nature of the CDO systems based approach to compliance, as addressed in other sections of this report. With the exception of issuing standard airworthiness certificates, the ARC recommends that the PAH have the same privileges that are currently delegated to an ODA. In addition, the ARC recommends that additional privileges be granted with respect to the management of the production quality system based on the CDO requirement to have a systematic approach to compliance.

Below are the additional privileges the ARC believes are appropriate under CDO for a PAH for the management of its production activities:

- **Approve substantive changes to the quality control manual/procedures --** In Section V of this report, the ARC describes a tiered approach to the CDO procedures manual that seeks to create a top level document that is FAA approved, but that also references sub-tier processes that are controlled by the CDO and can be modified without requiring FAA approval. The ARC envisions a similar approach with respect to the production quality manual except some substantive changes would require FAA approval. These would include, for example: quality

control systems associated with new materials and their associated processes; the use of new inspection tools or the application of old tools to new situations; and the use of substantially new processes and procedures in the performance of quality assurance functions.

- **Perform airworthiness inspections associated with its production approval, and issue airworthiness approvals for both export and domestic use.**

In specifying what production privileges would be afforded the CDO certificate holder, the ARC considered the same two options that were addressed for design approvals under CDO. Rather than change several existing production requirements in Part 21 to recognize that the CDO had additional privileges, the ARC agreed that these additional privileges should be listed in the rule together with all other CDO requirements.

IV.C.(4) Flight Standards Functions

Section 21.17(a)(1) requires an applicant for a type certificate 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 type certificate 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.

- Instructions for Continued Airworthiness (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 CDO certificate holder, with appropriate FAA oversight. Since compliance with the instructions for continued airworthiness requirement in §XX.1529, §31.82, §33.4, and §35.4 are to be determined by the CDO certificate holder, the ARC recommends that the maintenance aspects of those requirements also be determined by the CDO. The CDO 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 ARC believes that the formulation and execution of the FOEB, FSB, and MRB should continue as Flight Standards AEG functions, with support from the CDO certificate holder. All findings of compliance to airworthiness standards associated with those boards would be made by the CDO certificate holder consistent with its Procedures Manual. Some additional responsibilities associated with the operation of those boards might be assigned to a CDO certificate holder, under Flight Standards policy, after experience is gained. This would necessitate a revision to the CDO 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 type certificates and amended type certificates 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 CDO procedures and would not require board review. This is because the type boards are identified in an FAA order and the CDO certificate holder is free to propose its own procedures in lieu of those identified in existing FAA orders.

For a CDO, there would not be a flight manual review board as the sole responsibility for determining compliance for the flight manual would reside with the CDO 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 CDO Procedures Manual.

IV.C.(5) 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 ARC recognizes the distinction between the airworthiness requirements of 14 CFR and the noise, fuel venting, and emissions requirements, the ARC believes that a CDO 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 CDO compliance, safety, and quality systems to ensure proper compliance determinations. This is in keeping with the ARC's principle of a CDO making 100% of the compliance determinations.

The ARC recommends that the FAA propose to the EPA that the process-based approach to compliance, as established by CDO 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.

IV. D. Requirement to Have a Systematic Approach to Compliance and Safety

As previously discussed, a CDO must have systems in place that assure any and all determinations 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 an FAA-approved Compliance Assurance System (CAS). As previously discussed, an established and maintainable Safety Management System (SMS) is a prerequisite to issuance of a CDO certificate. There are common elements of process assurance, internal audits, corrective action, and others that also reside within the framework of a Quality Management System (QMS).

A systematic approach to compliance and safety therefore encompasses several elements, including a CAS, SMS, and QMS. The goal of these systems is to provide systematic approaches to compliance and safety, and ensure that their execution supports the continued growth of cultures of compliance and safety. While each of the objectives of the systems discussed below need to be satisfied by the CDO, they may be arranged or grouped differently or encompassed within organizational systems with different names.

The QMS requirements and the SMS requirements identify system objectives that must be met. Compliance with the CDO rule for these systems is accomplished by having and using these systems in managing company activities. The ARC proposes that the rule establishing CDO does not need to require that the outcomes from these systems achieve alignment with FAA decisions on the same items. It is foreseen that, with similar goals, most outcomes will be aligned, but that alignment should not be the criteria for compliance.

While agreeing that specific outcomes cannot be regulated, FAA members of the ARC recognized that these systems form the basis on which the FAA's confidence in the CDO is placed and that there must be a means by which the FAA can require changes to these systems when appropriate. Industry members of the ARC expressed concerns that such a means could also result in additional requirements being placed on the CDO. The ARC did not come to an agreement on how this issue could be resolved, but recommends that this issue be specifically addressed by the FAA as it looks at developing SMS requirements as part of the broader SMS rulemaking activity by the Office of Aviation Safety (AVS).

Unlike the QMS and SMS, the CAS must produce outcomes that are found compliant by the FAA. It is not a system to generate alternative criteria for the showing of compliance; instead, it is designed to allow alternative methods for the showing of compliance that result in concurrence with the showings as a "finding of compliance." The compliance assurance system should also result in showings with sufficient reliability that the finding of compliance can be made on the basis of the statement of compliance from the CDO. This is in line with the authorizing statute. Any FAA review of compliance showings of the CDO will be done as part of the oversight of the organization.

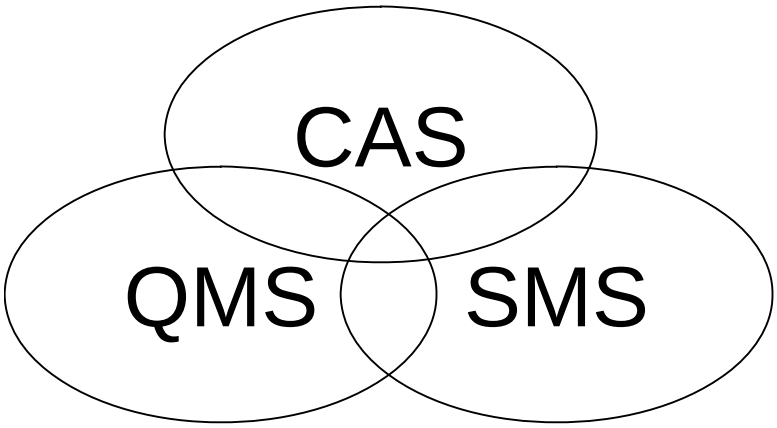

Figure 3 – System Components of a CDO

IV.D.(1) Compliance Assurance System

The CDO applicant must demonstrate that it has established and is able to maintain a regulatory compliance assurance system (CAS) for:

(1) the control and management of the design;

(2) design changes of products, parts, and appliances covered by the scope of the application; and

(3) any production activities associated with those design approvals.

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

The applicant's regulatory CAS must contain means to provide a high degree of assurance that the design and design changes of the applicant's products, parts, and appliances, comply with the applicable airworthiness requirements.

As appropriate to compliance and safety, the compliance assurance process for the various aspects of the type design must include safeguards and/or a checking function of the determinations 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 CDO as compliant with the regulatory requirements.

The CAS should include the processes and methods used to:

- Acquire current regulations and policy related to the scope of its certificate;
- Perform compliance planning;
- Execute compliance plans;
- Verify compliance;
- Identify and define criteria for the transitions between the compliance planning phase, the compliance determination phase, and the compliance verification phase of projects as defined by the items above;
- Develop and document product, component, part, article, and compliance data configuration management;
- Coordinate with the FAA in the establishment of certification requirements and acceptable methods of compliance, and in the performance of FAA surveillance and audits; and
- Ensure the statement of compliance is properly executed.

Individuals used for performing compliance activities. Where the system is dependent on the qualifications of individuals performing some of these processes and methods, means must be provided to ensure:

- The initial and continuing qualifications of the individual are appropriate to the tasks being performed;
- A periodic review of the work performed to ensure it is consistent with the compliance assurance system objectives; and
- A record is kept of the individual's accomplishment of the compliance activity.

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.

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

Assurance of compliance with the regulatory requirements, including the performance of suppliers, is of critical importance to the success of CDO. As discussed previously, there are no FAA designees used by the CDO. Therefore, the quality of the CDO'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 CDO's statement of compliance when making its finding.

IV.D.(2) Safety Management System (SMS)

An effective SMS must evaluate the safety impacts of decisions being made throughout the lifecycle of the product. It provides a formal framework for collecting information, analyzing information, making informative decisions based on the information, implementing change, and monitoring the effectiveness of change. In order to accomplish these objectives, the safety management system within a CDO organization should have the following elements:

- safety policy,
- safety risk management,
- safety assurance, and
- safety promotion.

Safety policy is the clear identification of the organization's safety goals and objectives, including the methods and process that will be used to achieve them. It communicates a management commitment and expectation that the organization will incorporate and continually improve safety compliance in all aspects of their business and business practices.

Safety risk management is used to assess product, component, part, or article system design and verify that it adequately controls safety risk. Safety risk management should identify the system of interest, identify the hazards confronted or created by that system, analyze the risk of those hazards, assess the risk to determine if it requires additional controls or mitigation, and control the risk by incorporating or implementing additional controls or mitigation.

Safety assurance is the process used to continually assess activity to identify new hazards and to ensure risk controls for those hazards already identified are effective. The safety assurance process should include information acquisition, analysis,

system assessment, and development of preventive or corrective actions. These processes should apply to all activities in the lifecycle of the product whether internal or external to the organization.

Safety promotion includes the actions taken to create an environment where safety objectives can be achieved. The key objective of safety promotion is the development and support of a positive safety culture. A safety culture is the product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to, and the style and proficiency of, an organization's safety programs.

Safety Culture. In the desired safety culture, people acknowledge their accountability and act on their individual responsibility for safety. They trust and rely on the organization's processes for managing safety. The environment is characterized by good communication between management and personnel, and people continue to learn and develop through training and coaching.

Attributes of a positive safety culture are —

- Staffing by competent personnel who
  - understand hazards and associated safety risk,
  - are properly trained,
  - have the skill and experience to define safe work practices, and
  - ensure safe products/services are produced.
- An environment where people are encouraged to develop and apply their skill and knowledge to enhance safety.
- Individual opinion is valued within the organization and personnel are encouraged to identify threats to safety and to seek the changes necessary to overcome them.
- Effective communications, including a non-punitive environment for reporting safety concerns.
- A "just culture" that recognizes where disciplinary action may be warranted and there is a commonly understood difference between acceptable and unacceptable actions.
- Adequate resources to support the commitment to safety.
- A process for sharing safety information to develop and apply lessons learned with regard to hazard identification, safety risk analysis and assessment, safety risk controls, and other safety risk management

responses. Sharing of information related to corrective actions, and results of management reviews is encouraged.

- Safety is a core value of the organization that endures over time, even in the face of significant personnel changes at any level.

- Willingness to recognize when basic assumptions should be challenged and changes are warranted – an adaptive and agile organization.

The ARC supports the requirements and the attributes of an SMS as described in the preceding paragraphs.

Protection of SMS Data. Some members of the ARC, however, expressed concern about the additional liability exposure resulting from SMS data generated with respect to hazard identification, the associated risks, and the mitigating actions taken with respect to those risks, especially as they relate to internal company policies and procedures. Such data might be used to later "second guess" the manufacturer's decisions, should the data be made available.

While actions associated with civil lawsuits are beyond the scope of the ARC, many Industry ARC members are concerned that the requirement for a well-run and well-documented SMS will result in corporate decisions not to seek CDO.

The issue is further compounded if SMS data is required to be submitted to the FAA rather than just made available. Such data might be sought through the Freedom of Information Act (FOIA) by any interested party. The ARC believes data cannot be protected under the provisions of 14 CFR Part 193 ("Protection of voluntarily submitted information") unless the data is provided to the FAA voluntarily and the data aid in fulfilling the FAA's safety responsibility. As such, the rulemaking proposed by the ARC does not require the SMS data to be submitted to the FAA. The FAA would have access to the data, as necessary, to perform its statutory responsibility for certificate oversight.

There has been discussion of liability under SMS in the international arena as well. According to the ICAO Journal, Volume 61, November/December 2006, ICAO has developed legal guidelines recommending enactment of national laws and regulations to safeguard data collected for safety purposes. The ARC supports this ICAO recommendation and encourages that it be further studied to support efforts that would reduce barriers to the acceptance of SMS within the US aviation system.

The ARC also notes that the collection of safety data and its future use as described with safety management has been hampered in the past by ineffective systems of data filing or classification. This has resulted not only in specific data being difficult to find, but failure to effectively use the data that are accessible. The ARC supports the work of the Commercial Aviation Safety Team (CAST)/ICAO Common Taxonomy Team (CICTT) to develop common taxonomies. The ARC recommends that any organization creating or revising a data classification method

for use with its SMS should review the work of this team and consider the use of these taxonomies in their data system.

IV.D.(3) Quality Management System (QMS)

A design organization must have a QMS in place to be entitled to a CDO certificate. A QMS provides a means for the organization to:

- assure systematic performance of its duties,
- receive employee and customer feedback,
- continuously improve its performance,
- measure its performance,
- assure that it has appropriate configuration management,
- verify that personnel are qualified for their tasks, and
- maintain management awareness of organizational performance.

Each of these features has an important role in the ability of the CDO to fulfill its obligations under the CDO certificate.

The systematic performance of the duties of the organization, or process assurance, allows reliance on the use of approved procedures. It provides a mechanism to identify when the organization is drifting away from its defined procedures, and allows corrective action to improve the performance or revise the procedures as necessary. Measuring the performance of the organization allows for this process assurance, as well as providing data to be used in assessing changes under its continuous improvement programs.

Receiving employee and customer feedback through a formal process supports continuous improvement programs. Employee feedback provides a mechanism to correct processes that are difficult to follow and may result in deviations from procedures. Without a mechanism to identify and correct these items, process deviations can become an accepted behavior. Customer feedback provides information on how the product or services are being received and may identify areas within formal processes that should be changed. This feedback may range from customer satisfaction issues to airworthiness or safety concerns as the product is fielded.

Continuous improvement is an important feature of a QMS, as it is the mechanism that supports the correction of issues found in the performance of the organization by the activities above. Without continuous improvement (corrective action) the

activities described in the previous paragraphs do not effectively contribute to the overall performance of the organization.

The CDO will need to measure its performance to assure itself and the FAA that it is fulfilling its obligations under the CDO certificate. The measurement tools that it uses will vary but should include internal audits of methods and processes used. This supports the above mentioned goals of process assurance and enables early identification of problems.

An appropriate configuration management system must be in place to cover the processes and methods used by the CDO, as well as the data produced by the CDO, in order to support the goals of using system oversight to manage the CDO rather than specific project oversight. The methods used and the data produced must be reliably available and readily retrievable to allow post certification oversight.

Personnel qualification must be verified periodically to assure that people are assigned tasks within their respective skill sets. All of the activities of the CDO are dependent on people doing the right things at the right times. The verification of personnel qualification serves as another check to support reliable performance of the CDO's systems to assure safety and compliance.

Management review and involvement is an important aspect of a QMS. It allows the company leadership to establish priorities in line with the duties and obligations of the CDO certificate and to assure that the performance is not placing the company at risk of non-compliance. It also provides other valuable management oversight information that is useful, but may not be directly relevant to the CDO certificate.

Common Elements with CAS. The elements of a QMS as described above overlap and parallel many of the elements of the CAS. These systems may have common elements, but the focus is somewhat different: the QMS is oriented toward assuring that the organization does what it has committed to without undetected omissions or errors; whereas, the CAS is focused specifically on the issues of compliance with the regulations.

IV.D.(4) Cultures of Compliance and Safety

The ARC discussed the importance of a corporate culture to an organization’s ability to properly function as a CDO. There was general agreement that a culture of compliance and a safety culture are important to the proper operation of a CDO and are goals for successful CDO implementation. However, it is difficult to mandate or measure a specific culture or a specific level of a cultural attribute. As a result, the ARC recommends there be specific system processes or objectives for the CDO to demonstrate how they have been implemented. The ARC maintains that

the implementation of the identified processes and objectives will lead to enhanced cultures of compliance and safety.

The material in this section provides useful cultural indicators for organizations to use when evaluating their readiness to become a CDO, or when measuring their ongoing development as a CDO.

Culture of Compliance. Attributes of a safety culture were included in the previous section of this report that covered SMS. Most of this following section discusses items related to a culture of compliance, although there is overlap in a number of areas. A well-established culture of compliance facilitates the organization's ability to manage safety and to continually improve, because leadership and decision-makers at all levels work together to learn and adapt, thus improving the system's ability to determine and support safety outcomes.

A culture of compliance, in its simplest form, is the product of individual and group values and commitments, attributes and norms, competencies, patterns and systems of behavior, and consistencies -- all working together to create a commitment to regulatory compliance. Compliance is an attribute of the system, not just a result of it; it is "the way things are done" within the CDO.

A culture of compliance may not be measured directly, but it may be observed and measured in accordance with the following indicators:

Examples of POSITIVE Indicators

+ There is strong executive leadership and understanding of compliance matters.
+ Compliance is actively managed at every level.
+ People acknowledge and act on their individual responsibility for compliance.
+ People trust and rely on the organization's process for managing compliance.
+ There is unimpeded communication between management and employees, in both directions.
+ The need for improvement is communicated without retribution.
+ There is collaboration with all customers and suppliers.
+ People continue to learn and develop through training and coaching.
+ Everyone is held accountable for their contribution to the system.
+ There are documented executive declarations of corporate commitment
+ There is an uncompromising corporate code of conduct.
+ There are compliance training programs.
+ Internal compliance surveys are regularly conducted.
+ Compliance self-assessments and audits are regularly conducted.
+ The company exhibits behavior that demonstrates that regulatory compliance is of equal or greater importance than the contractual requirements made to customers.
+ Compliance is embedded in the company's design processes.
+ Regulatory compliance is recognized and rewarded.
+ Subordinate managers have performance measures related to a culture of compliance.

Examples of NEGATIVE Indicators

- The organization's management is unresponsive to FAA requirements and oversight activities.
- The organization has not been forthcoming with the FAA on its CDO program or regulatory compliance deficiencies.
- The organization considers compliance as an afterthought of design, and not integral to it.
- The organization does not value regulatory requirements as essential to safety (i.e., some regulations are important, others are discretionary).

The CDO must maintain a proper balance between compliance and safety assurances and production pressures. Some observations from the ARC that may be useful to CDO applicants or holders are:

- People act in accordance with the way they are rewarded.
- People within the system will experience dilemmas. The system must have means to ensure that, when people with responsibility feel conflicting pressure, they are protected from undue pressure.
- There should be a type of Safety Ombudsman within a CDO organization – an independent entity where internal CDO issues can be surfaced.

As noted in the introductory paragraphs of this section, certain aspects of a strong culture of compliance or safety culture are measurable; cultures of compliance and safety are not something that can be easily regulated under 14 CFR Part 21. As a result, the CDO ARC has chosen to recommend instead requirements for processes and qualities that have historically led to highly effective organizational cultures.

IV. E. Supplier Control

IV.E.(1) General Requirements

An applicant for, or holder of, a design approval has sole responsibility for proper control of all its suppliers, be they suppliers of engineering services, manufacturing of 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 FAA-approved data, products, parts or appliances, the FAA holds the applicant or holder of the design certificate responsible to correct the matter. This long-standing principle remains for the design approval holder even if the holder is also the holder of a CDO certificate.

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

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

- the criticality of the design,
- its experience with the supplier,
- the supplier's standing 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 factors appropriate in determining the degree of supplier oversight necessary.

The ARC recommends that CDO certificate holders be able to cooperate with other companies to pool supplier oversight responsibilities, 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 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 CDO 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 CDO oversight.

IV.E.(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 CDO may authorize foreign suppliers to make determinations of compliance only after the CDO has evaluated the suppliers' systems and determined that they are qualified to act in that capacity under the CDO processes.

To fulfill its supplier management responsibilities, a CDO may also propose as part of its quality system, a reduced 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 CDO, for example, a contract with an 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 CDO to make compliance determinations, those determinations must be documented in accordance with the CDO's processes.

The CDO 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 CDO may take credit for the surveillance of the supplier by its CAA. That credit would result in a reduced need for oversight by the CDO, and the process for defining that reduced oversight should be defined within the supplier surveillance portion of the CDO Procedures Manual. The CDO, for example, could review periodic reports from audits performed by the supplier CAA or establish some other means of tracking supplier performance. The CDO 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 CDO oversight methodology applied to foreign suppliers having capabilities recognized by their respective CAA would be evaluated as part of the FAA's oversight function.

Another option would be for the foreign supplier to contract with their authority to perform surveillance over CDO activities performed by that supplier. For any CDO oversight credit to come from such an agreement, the CAA oversight must be consistent with activities that are covered under a bilateral airworthiness agreement between the US and the State in which the CAA resides. Such activity would not be accomplished under the bilateral agreement, though, and the FAA involvement would only be to review how that arrangement impacts the approved CDO supplier oversight process.

Similarly, if a CDO were to hire a qualified third-party organization (such as Bureau Veritas) or another CAA to perform some of its oversight, the CDO would need to be able to show how such services are being used to offset the frequency or type of surveillance visits, etc., conducted directly by the CDO. The third party organization would have to be treated as a supplier to the CDO.

The FAA's CDO guidance materials should further define how much credit/relief can be granted in these various international situations, and the criteria by which it is to decide if that credit should be allowed.

IV. F. CDO Approval of Data

The ARC deliberated extensively over the issue of how data are approved within the CDO concept. Some FAA members of the ARC questioned the need for CDO generation of FAA-approved compliance and design data prior to FAA issuance of a certificate or design approval. The Industry members of the ARC suggested that this ability was critical to the CDO concept and is consistent with FAA's current practice under delegation; suggesting that anything less would be viewed as a step backwards. These deliberations ultimately resulted in the ARC seeking guidance from FAA management. The resulting decision was that the ARC should base is recommendations on the following:

- A CDO should be able to approve data for both the designs it holds and the designs it is seeking; and

- CDO compliance determinations should result in data that "are" FAA-approved.

The paragraphs below are based on this guidance and address the ARC's proposal for how data becomes approved through CDO processes.

Traditional Concept of "FAA-Approved" Data. In the FAA's current system, all compliance and type design data that have received approval by the FAA for use in the global aviation system have been referred to as "FAA-approved." This includes data approved by the FAA through the issuance of a certificate or design approval, as well as discrete approvals made by the FAA or its designees.

The ARC recommends that a key principle of CDO include the ability for the certificate holder to create FAA-approved data as a privilege of its certificate through the proper execution of its processes, without the direct involvement of the FAA or its designees. In granting this privilege to each CDO, it is essential that the FAA affirm to its international airworthiness partners that such CDO data is FAA-approved.

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 type certificate holder executes the "method acceptable to the Administrator." In this case, the FAA is exercising its discretionary authority not to review the data prior to it being FAA-approved. While section 21.95 applies only to minor changes to a type certificate, FAA's discretionary authority is not limited to only minor changes.

Applying Existing Concept to CDO. The ARC recommends that this existing concept be applied to compliance and type design data determined to be compliant by a CDO certificate holder (i.e., CDO creation of FAA-approved data before any substantiating or descriptive data are submitted to the FAA). The CDO regulatory requirements, along with the processes and procedures contained in an FAA-approved CDO Procedures Manual, will 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 found to be compliant by the CDO.

Under this concept a CDO is not approving data on behalf of the FAA, because a CDO is not a delegation. Rather, the FAA is using its discretionary authority to approve the data through a method it has determined to be acceptable. Once the FAA-approved CDO process for making a compliance determination has been properly executed, the data used in that determination of compliance and any associated type design data are FAA-approved.

The ARC's proposed NPRM, discussed later in this report, contains language that authorizes the creation of FAA-approved data under the CDO concept, for all situations for which "FAA-approved" data are currently being generated. As such, there is no need to revise any other regulations, policy, guidance, or orders that refer to "approved" or "FAA-approved" data. Data approved under the CDO concept are FAA-approved and are acceptable for use in all these situations.

Approved Data Versus Accepted Data. It should be noted that there are situations in which a determination of compliance does not result in approved data. That situation exists whenever a rule, for which the CDO is making a determination of compliance, indicates the FAA will only make a determination that something is acceptable, and not approved. In those cases the determination by the CDO that the rule has been complied with only results in the creation of acceptable data. An example of this situation is the airworthiness standards related to instructions for continued airworthiness (ICA). In the case of the ICA, only the limitations section is approved by the FAA, and the rest of the manual is found to be acceptable to the FAA. In this case, the CDO certificate holder's determination of compliance would result in the limitations section of the ICA being approved data and the rest of the ICA being data acceptable to the FAA. Another example is the Aircraft Flight Manual for which the regulatory requirements result in both approved and acceptable data.

IV.F.(1) CDO Creation of FAA-Approved Data

A CDO holder has the authority to make determinations of compliance that result in the creation of FAA-approved data. This authority applies to design approvals it holds, as well as those approvals that it is seeking. This includes both compliance and type design data. This means that, at its discretion and without any action by the FAA, the CDO may create FAA-approved data to support design changes not

requiring a new application or certification basis, as well as FAA-approved data to support repairs and alterations by third parties for design approvals held by the CDO certificate holder. This gives the CDO certificate holder the authority to identify, as FAA-approved, those data needed to support the design, maintenance, and continued airworthiness activities associated with its type design or TSO authorization.

A CDO does not have the authority to approve data to support certification or maintenance activities in support of products, parts, or appliances other than those for which the design approval is held, or is being sought, by the CDO certificate holder. This is because the FAA-approved CDO processes used to create FAA-approved data are only applicable to products, parts, and appliances identified within the scope of the CDO certificate.

IV.F.(2) Standardized form for CDO Transmittal of FAA-Approved Data

A new or revised form is needed for domestic and international recognition of FAA-approved data created under the CDO concept. The ARC 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 could be entitled "CDO FAA-approved Data," as opposed to "Statement of Compliance," to recognize the source of the data approval and because there are no provisions within the CDO concept for recommending approval of data. Thus, "approved" is the only statement that can be made about the data. The portion of the form related to recommending approval would not be applicable to CDO.

The new 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.

IV.F.(3) Use of Previously Approved Data

The CDO may use data that have been previously approved as part of another FAA-authorized project that it, a supplier, or a partner has conducted. These data must have been FAA-approved, or determined to be compliant by another CAA consistent with a bilateral airworthiness agreement existing at the time of the determination. Previously approved data may be used whether or not the project for which it was approved is completed. The CDO must determine that the data are valid and applicable to the project on which it is to be used. For any data that has been determined by the CDO to be deficient or in any way questionable as to its compliance or approval, the CDO has the responsibility to correct those deficiencies with respect to its use of the data, and notify the FAA of its determination. The

CDO must record the use of previously approved data in its compliance determination documents.

While the CDO may use data that has been approved by the FAA or determined to be compliant by a CAA, the CDO cannot contract with FAA designees or suppliers for new data approvals solely for the use of the CDO in simplifying its responsibilities for determining compliance. If a supplier is actively working on a design or process for which it is seeking FAA approval under another FAA-authorized project, the CDO may use that data for an ongoing project once the data has been approved, as long as it makes a determination that it is valid and applicable to its project. In making its determination of compliance, a CDO may rely on the fact that the data was approved by the FAA or found to be compliant by a CAA, but it must assess the compliance and safety risk associated with its degree of reliance under its CAS and SMS programs.

CDO use of existing certificates and design approvals are treated as discussed above for previously approved data because they are "stand-alone design approvals" made by the FAA or recognized CAA. A CDO may use existing certificates or design approvals obtained by third parties as part of its compliance process for new designs, provided that the CDO has determined the data are applicable and valid for integration into a CDO design.

IV.F.(4) Use of FAA's Delegation System

One of the basic principles developed for CDO is that the FAA makes no discrete findings of compliance. Design organizations are issued a CDO 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 CDO's statement of compliance in making its overall compliance finding when issuing a type certificate or other design approval.

Since the FAA is making no discrete compliance findings, there is no basis for allowing the use of engineering designees, either at the design organization 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 CDO concept, there is nothing to delegate. Thus, the advantage to Industry of being able to make all determinations of compliance is that the CDO is not dependent upon the existing delegation system. For CDO, the FAA delegation system is only used to support issuance of certificates and design approvals.

This does not mean that CDO's cannot use individuals and companies that also hold FAA delegations, but those designees would be acting solely as a supplier to the CDO and any compliance determinations made by such suppliers must be

conducted under a system determined acceptable by the CDO. They are not acting as representatives of the FAA Administrator.

A CDO may take the FAA-designee status into consideration when determining the appropriate method and level of supplier oversight. That oversight must be defined within the CDO supplier procedures and must include both the qualification of that supplier and periodic oversight. In conducting its oversight of the supplier, the CDO 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. The CDO must assess and find acceptable the compliance and safety risk associated with its degree of reliance on this type of supplier, under its CAS and SMS processes. The CDO must also be satisfied that these organizations or individuals are performing as expected, and are aware of any FAA corrective action related to designee performance. The CDO could achieve this awareness by contractually requiring the designee to provide records of any FAA corrective action, such as designee counseling letters or ODA audit records.

While the Industry members of the ARC understand the FAA's position, they would still prefer that suppliers holding FAA delegations be allowed to supply data to CDO's through their FAA delegation using existing approval forms. This issue was discussed at length within the ARC and it was clear the FAA was not inclined to change its position on the matter. The Industry agreed not to pursue a further FAA review of the matter and the ARC agreed as a whole to the position as discussed above. However, should the FAA in any way change its position in the future, the Industry asks that a CDO be allowed to use the FAA delegation system to the degree that is afforded any other applicant under any current FAA certification processes.

IV.F.(5) 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 design approval certificates. The CDO 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, parts, and appliances rely on these specialty services to supplement their capabilities. The ARC recognizes a need to create a new process wherein these specialty companies are recognized for their capability, and that capability can be used to supplement CDO (and ODA) compliance activities, as

well as those of other applicants. The ARC has chosen to call these companies "Specialty Service Providers."

The ARC recommends that the FAA give priority to developing a means for recognizing these specialty service providers. This concept could encompass technical specialties ranging from the more complicated [such as flammability, dynamic seats, icing, electromagnetic interference (EMI), and high-intensity radiated fields (HIRF)] to the more routine specialties [such as materials testing, non-destructive inspection (NDI) 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 ARC's 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 ARC offers the following initial principles and details for the FAA's consideration. The ARC recommends that this concept be developed through the direct participation of the Industry in an advisory capacity because of the variety of issues that must be addressed and the need to create Industry consensus standards.

- The data developed by these organizations must be directly useable by all applicants without further approval of the service provider's data.

- The data must be recognized and accepted internationally.

- The data should be generated through compliance with Industry consensus standards acceptable to the FAA as evidence of compliance with specific airworthiness standards.

- The possibility of third party approval and oversight of these service providers should be considered.

- These service providers need not be designees of the Administrator, provided that the resultant compliance data they create can be used by applicants when the applicant determines it to be applicable for their particular project.

- Persons using these service providers 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 FAA-recognized expertise of these service providers.

- The continued compliance responsibility of applicants who use these service providers is not reduced by the fact that these companies are recognized by the FAA for their expertise. The type certificate, PMA approval, 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 continued operational safety issues.

The ARC recognizes that there are different methods that may be used to implement the specialty service provider concept. The ARC believes that specialty service providers should be available for CDO use, even if the FAA uses a form of delegation to facilitate data approvals by a specialty service provider.

IV. G. Other Part 21 Requirements

It is important to recognize that the holder of a CDO certificate, like any other applicant or certificate holder, must comply with the other requirements of 14 CFR Part 21, unless otherwise stated.

IV.G.(1) Some Part 21 Requirements not Applicable

There are several places within 14 CFR, chapter 1, subchapter C, most of them being in Part 21, where the principles embodied within the CDO concept conflict with existing regulations.

The ARC saw two possible avenues available to resolve those conflicts: One was to change each rule wherein a conflict occurred; the other was to place a single section within the CDO requirements that contained the means of compliance by which the CDO would comply with the conflicted rules. In no case would the compliance objective of the conflicted rule be changed. The ARC chose the latter approach, as it results in all the CDO requirements residing in one place within Part 21.

In most cases, the exception results from the fact that, under the CDO concept, all determinations of compliance are made by the certificate holder, in lieu of detailed findings of compliance being made by the FAA. The alternative means is to have appropriate procedures in the CDO Procedures Manual that implement the alternative means of compliance. The CDO regulation must contain a paragraph that specifically requires those alternative means of compliance to be placed in the Procedures Manual. Both the procedures for complying with the requirements (the "what") and the operational procedures (the "how") in this case must be FAA approved.

IV.G.(2) CDO Project Applications and Activity Reporting

The ARC believes there are many projects that the CDO certificate holder may complete without having to notify the FAA, since the CDO 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. The ARC considered trying to define a subset of projects for which the CDO certificate holder would be required to notify the FAA when initiating the project, but was unsuccessful.

Part 21 already specifies when an application must be made to the FAA. This includes applications for TC, STC, PMA and TSOA. The ARC 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 design approval, amended type certificates requiring a new model designation, new supplemental type certificates, and any project that might reasonably be expected to have a revised type certification basis under section 21.101.

The ARC discussed other CDO activities that would not require an application. The ARC concluded that in all cases the FAA must be provided access to a record of all compliance activities being performed by the CDO. That could be a hand 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 ARC 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 involvement. This complete project listing would provide the FAA with information regarding the CDO's activities and would help guide FAA oversight of the CDO.

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.G.(3) Changed Product Rule

The derivative type certification requirements, which apply to type and supplemental type certificates, 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 require FAA involvement, and it is expected that a CDO would notify the FAA when it undertakes such projects.

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

IV. H. International Considerations

IV.H.(1) Bilateral Agreements and International Recognition of CDO

One privilege of a CDO certificate is the authority to make determinations of compliance, and present the Administrator with a statement of compliance that may be relied upon by the FAA for issuance of a certificate.

Principle of Reciprocal Acceptance. Current US 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 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 CDO. Since CDO 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 make a determination whether the CDO program meets the intent of the bilateral agreement and can be accepted. Since CDO is not a delegation, there is a possibility it may not be recognized by all bilateral partners as being equivalent to a FAA delegation system under current and future bilateral agreements.

It is likely that current bilateral airworthiness agreements will need to be revised to amend the definition of the term "compliance finding" to include determinations of compliance made as a result of review, investigation, inspection, test, and/or

analysis by either a CDO or the FAA and its designees. It is expected that this system will be internationally recognized as being consistent with that used by EASA for its design organization approval (DOA) program under its part 21 regulations.

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

IV.H.(2) International use of CDO Compliance Determinations

Current regulations and policy recognize the FAA as making all determinations of compliance. Since this will no longer be the case with CDO, the regulations and policy must be revised and the significance of these changes must be explained to the CAAs.

Use of the terminology "certification determinations" or "approved data" when referring to FAA and CAA activities, and "determinations of compliance" and "approved data" for CDO, could be confusing to other authorities and will need to be explained by the FAA.

Current FAA guidance related to type validations (Order 8110.52, "Type Validation and Post-Type Validation Procedures") seeks to distinguish between (1) the FAA's statutory "finding" function that it executes when it issues a type certificate and individual findings of compliance made by the FAA or its designees, and (2) determinations of compliance made by a CAA, leading to the issuance of an FAA certificate. Even another CAA only makes a "statement of compliance" to the FAA.

Today's bilateral agreements assume that all certification tasks (e.g., witnessing tests) are conducted either by the FAA directly or by one of its designees. Current bilateral agreements may need to be revised to amend the definition of the term "compliance finding" to include determinations of compliance made as a result of review, investigation, inspection, test, and/or analysis by either the FAA or a CDO.

IV.H.(3) CDO Use of Data Previously Approved By a Foreign CAA

A CDO may use technical data in its compliance package that has been previously approved for another purpose under the system of another CAA, provided that there is a bilateral agreement between the FAA and that aviation authority that recognizes such data approvals, and the data is within the scope of the agreement. It is also

necessary for the data approved by the partner CAA to be applicable to the CDO's new or existing design.

The requirements for accepting previously approved data from foreign sources is described in FAA Order 8110.51 and would apply equally to a CDO as they apply today to the FAA.

To accept such data the CDO must ensure that these two conditions are met:

- The data must be applicable for the new FAA certification project, and
- The data must be valid. The compliance determination must have been made under the provisions of a bilateral agreement with the FAA, and have had direct CAA involvement in that determination. Direct involvement also means that the determination could have been made under a delegation or other authorization from the CAA.

If the CAA's recognized compliance system was not involved in approval of the specific data or there is no US bilateral with that CAA, then the data are not considered to be valid as "previously approved" data. In that case, the CDO would need to perform all tests and analyses necessary to support its determination of compliance.

IV.H.(4) Use of Technical Assistance from a CAA

Since the FAA would not be making discrete regulatory compliance findings in support of CDO projects, the FAA has no need to seek technical assistance from a partner CAA requesting them to conduct conformity, witness tests, approve reports, etc., on behalf of the FAA for CDO programs. The FAA may, however, request CAA assistance to review CDO-initiated conformity, testing, or compliance documentation as part of its CDO oversight function. This oversight assistance by the CAA requires a bilateral agreement, and FAA's continued confidence in the CAA competency to perform under the provisions of the bilateral agreement. This assistance is no different than what FAA currently uses during its oversight of foreign suppliers to type certificate applicants or production approval holders.

Technical Assistance Between Governments. Current bilateral agreements provide for technical assistance when significant activities are conducted in the territory of the partner aviation authority, for example, conformity inspection of prototype parts, production oversight, investigations of service problems, etc. Such assistance is provided upon request and by mutual agreement, and as resources permit. These technical assistance activities are always government-to-government and are intended to help the aviation authorities reduce their workload (i.e., avoid the undue burden imposed on the exporting authority in the undertaking of its certification and oversight functions at locations outside the country of export). The technical assistance activity performed by a foreign CAA in no way relieves the

FAA of its responsibilities for regulatory oversight and airworthiness certification of US designs. Moreover, the provisions for technical assistance in bilateral agreements are provided solely to assist the authorities in performing their respective regulatory functions.

Technical Assistance and the CDO. Although technical assistance may secondarily assist the Industry, requests for technical assistance cannot be made directly by a CDO to a bilateral partner authority, nor would the FAA be able to forward a request for technical assistance on behalf of a CDO to another authority. As proposed, the CDO is responsible for all of its compliance declarations without FAA support. The FAA, however, may request technical assistance from a bilateral partner CAA as part of its own oversight of the CDO's performance.

ARC Concerns. Industry members of the ARC remain concerned that, if a foreign CAA were not involved in work performed at overseas suppliers, it could negatively impact a CAA's viability in terms of technical competence and funding due to fee-for-service arrangements. This may lead to CAA resistance to the CDO concept. Mitigating this concern is the likelihood that CAAs will simply change their fee structure to accommodate any reduced involvement, as well as the recognition that many certification programs are part of a joint FAA/CAA validation program, providing an avenue for CAA involvement. The FAA believes there will not be an impact on fees because fees have never been linked to the technical comparability of regulatory systems, and because fees for technical assistance are minimal.

There also was some concern within the ARC that reducing the frequency of these agreements would lessen international partnerships. However, several members of the ARC concluded that the CAA level of involvement needed to support validation programs, as well as the continued CDO-oversight assistance to the FAA, will continue to foster good relations with other airworthiness authorities,

Use of CAA on CDO Projects. The ARC discussed use of a CAA on CDO projects (as it streamlines the certification process from Industry's perspective). However, the FAA believes that this effectively transfers responsibility from the CDO to the FAA for maintenance and oversight of this activity, and this is not consistent with the principles of CDO or the accountability framework. The FAA believes this would also likely require significant FAA resources to essentially conduct supplier oversight on behalf of the CDO.

If There are Future Changes. The Industry believes that international relationships among authorities is likely to change in the future as the certification of products, parts, and appliances becomes more international in scope, and the major manufacturers rely more on suppliers for design and production activities. The major manufacturers then become integrators of highly complex systems and structures into a certificated design. This trend is likely to cause some CAA organizations to create delegations or certificates for suppliers of components that

eventually will be integrated into complete products. EASA has chartered a regulatory team to consider this matter.

The Industry understands and accepts the FAA position with respect to the use of CAA technical assistance in making determinations of compliance. The Industry requests that if working arrangements and procedures change within bilateral agreements a CDO should be able to avail itself of any new arrangements for the mutual acceptance of determinations of compliance, to the same degree that non-CDO certificate holders are able to. The Industry believes there may still be improvements that can be made in the use of determinations of compliance made by a CAA in the international development of products.

IV.H.(5) Type Certificate (TC) Validation

Current processes for another authority to certify a product designed in the United States are based on giving maximum recognition to the findings made by the FAA as the authority of the State of Design. The process of checking or verifying these findings, as a basis of a type certificate issued by another CAA, is generally referred to as "type validation". When the FAA and another CAA are operating under a bilateral agreement, the procedures for type validation are spelled out either in the bilateral agreement or related documents (e.g., the FAA/EASA type validation principles).

Validations are based upon a reliance on each other's certification systems and a high degree of mutual confidence in each other's technical competence for a particular type of product. Essentially all compliance findings can be made by the State of Design authority (Certificating Authority) under a validation project. Any specific findings that are retained by the importing authority (Validating Authority) are mutually agreed to between the authorities. It is becoming a common practice for the validating authority to allow the certificating authority to make essentially all of the compliance determinations to the validating authority's airworthiness requirements.

CDO presents some challenges for the FAA to carry out its traditional obligations during a validation project. The FAA will be expected to have had enough involvement in CDO activities (via approval of the certification basis, issue papers, CDO oversight, etc.) to be able to support the Validating Authority with questions regarding decisions made during certification. The FAA will retain the responsibility for leading all discussions with the Validating Authority, but may need greater CDO involvement in order to minimize any regression in the progress FAA and Industry have made to date in minimizing a Validating Authority's level of involvement. Otherwise, there may be an increase in the volume of retained findings by a Validating Authority.

The ARC has concluded that the FAA should be able to support its role in the validation efforts of products developed by a CDO. In a validation process, the CAA is validating the FAA-issued (or in-process) type certificate with respect to compliance with its own standards. Thus, the validation process is between two aviation authorities, with the CDO providing technical expertise when necessary on how it determined compliance. The manner by which the FAA acquires the familiarity with the product and the determinations of compliance is different in that it is through the CDO oversight and management role rather than through individual project activity. The FAA and Industry will have to evaluate validations conducted under the CDO process to ensure the bilateral recognition of the ability of the FAA to make compliance determinations on behalf of the CAA has not been diminished.

Compliance determinations to foreign airworthiness standards will still be required under the bilateral agreements when products are validated. That means a CDO must demonstrate competency in applying foreign airworthiness requirements, such as EASA certification specifications, if another CAA is going to accept those compliance determinations. CDO certificate privileges do not include compliance with CAA regulations; however, this may be an additional privilege the Administrator is likely to grant to a CDO holder. This privilege is at the Administrator's discretion, but when granted, should specifically identify those foreign regulations for which the CDO is considered qualified to make compliance determinations. These determinations may also need to be audited during FAA's oversight. If for any reason, a bilateral partner is unwilling to accept determinations to its standards other than FAA determinations, then that limit would also need to be clearly identified in the bilateral and to the CDO community.

IV.H.(6) Continued Operational Safety

ICAO Annex 6 requirements and existing bilateral agreements require the FAA and partner CAA to inform each other of airworthiness issues surrounding products that are under their State of Design responsibility. Annex 6 and bilateral agreements also require the authorities to notify each other of any Mandatory Continued Airworthiness Information that they have issued on their own or on the bilateral partner's State of Design products, parts, or appliances.

FAA's requirement for notification under existing bilateral agreements will remain in effect for products, parts, and appliances certified under a CDO in the United States. Existing 14 CFR Part 21 regulations and SMS principles ensure that the FAA is fully cognizant of the airworthiness issues identified by a CDO, or involving a design developed by a CDO, so that the FAA may take appropriate Airworthiness Directive actions. This will also ensure that the United States continues to conform to the Standards and Recommended Practices (SARP) identified by ICAO for continued operational safety in aviation.

IV. I. CDO Implementation

This section addresses a number of issues related to the implementation of CDO. First, it addresses transitions that need to be considered in the initial implementation of CDO and in the continuing support of CDO. It also addresses the self evaluation that the ARC believes that each applicant for CDO or expansion of a CDO should make. Lastly, this section discusses issues related to the CDO appointment and the assignment of evaluation teams to determine that an organization is ready to perform as a CDO.

IV.I.(1) CDO Transitions

There are three significant transition issues to be addressed by the FAA and Industry in the transition to CDO. These are:

(1) assuring that the requirements defined within this report and required by the proposed NPRM are practical to implement and achieve their effectiveness;

(2) identifying how an organization could establish the systems required of a CDO while still working as a non-certificated applicant or a delegated organization; and

(3) identifying how the FAA can transition from its traditional role of project involvement to a role of coach and mentor with system oversight responsibilities, as envisioned in this report.

There is another transition that occurs when a CDO seeks to change the scope of its certificate, which is also addressed in this section.

Assuring CDO's Workability. The ARC has discussed two methods that may be used to gain higher confidence in the workability of the CDO concept as defined within this report:

- One method is using simulation or a challenge session with FAA and Industry participants to work through a theoretical application and identify areas that may not be clearly defined.

- The second method is to find an organization that is willing to prototype a CDO process, which the ARC considers to be a real possibility. If a company is in the process of developing its systems and processes in advance of a final rule on CDO, they may be willing and able to work jointly with the FAA to evaluate the effectiveness of the program and identify areas where the associated rule or guidance materials may need improving.

The ARC recommends pursuing some prototype or simulation to validate the CDO concepts and provide a more operational review of guidance material and standards in advance of widespread implementation.

Establishing Processes and Systems Required by CDO. The second primary transition issue is how an organization may put the processes and procedures defined within this report into place as part of its normal operation, and how they may then develop and test these processes without being subject to enforcement action. The ARC believes that an applicant for a CDO certificate must do a self-assessment of its capability to comply with the requirements for a CDO before it makes application to the FAA. This necessitates that the potential applicant gain experience on any substantially new processes it develops as part of its compliance with the CDO principles.

The processes defined for the CDO are essentially improved compliance "showing" processes. An applicant for a CDO who is a non-certificated applicant should be able to develop and put these processes in place without interference with the compliance finding by the FAA or designees. An organization developing its processes in anticipation of applying for a CDO certificate should not have any increased risk of enforcement action associated with its processes. In this manner, the organization would be able to develop its processes and perform self-assessments to determine their effectiveness prior to applying for a design certificate. This would fundamentally result in two systems operating in parallel during this development phase. When the CDO systems are mature, the compliance finding processes of the FAA or its designees should be uncovering no non-compliances in the showings being made by the company using its proposed CDO processes.

Identifying FAA's Evolving Role. The third issue is the transition the FAA would need to make in performing oversight of the CDO system to assure that it is able to rely on the showings of compliance made by the organization.

One of the key challenges to the FAA is creating a culture that recognizes the CDO is not "taking over" the safety oversight work of the FAA. The CDO concept is an enhanced means of assuring that the CDO makes determinations of compliance with a high degree of certitude and enables the FAA to redefine processes by which it will accomplish its safety mission, such as increased development of systems-based safety oversight. The FAA still has the responsibility to oversee the operation of a CDO to ensure that it continues to comply with FAA regulations and its own internal processes. To accomplish this new CDO oversight focus, the FAA still needs to have highly skilled technical experts who also possess the program oversight, process improvement, and coaching and mentoring skills necessary to oversee the operation of CDO compliance processes and support continuous improvement of the CDO organization.

Expanding the Scope of a CDO's Authority. The ARC discussed the issues involved in an organization's transition from one scope of authority to another. If the new scope involves substantially new processes that have not been previously demonstrated, a method must be developed to allow the organization to demonstrate that it is capable of operating under its proposed processes, prior to receiving an amended certificate with the expanded scope.

The ARC recommends using a letter of authorization from the FAA to allow the organization to operate under the proposed CDO procedures until the CDO demonstrates and the FAA finds that the CDO is fully capable of operating within the changed scope. The letter of authorization would be granted after the organization submits a formal application for the change in scope and demonstrates it has defined the necessary processes and has taken the action to integrate them properly into its existing processes. The application 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. Once the new processes and capabilities are demonstrated, the CDO certificate would be amended to reflect the new scope. If the change in scope is minor, the CDO self-assessment may be sufficient to allow the FAA to expand the certificate scope with no further demonstration.

A key CDO principle is that the certificate holder makes all determinations of compliance within the scope of its certificate. However, when the CDO is seeking to expand the scope of its certificate, the CDO cannot make determinations of compliance within the new areas of the proposed scope revision. While the letter of authorization would allow the CDO to exercise its new processes as if it had been granted the expanded scope, it would be necessary for the FAA to approve all "proposed" determinations of compliance made by the CDO in those areas outside its existing scope.

Another matter for consideration under a change of scope authorization is how it would effect the statement of compliance made by the certificate holder at the end of a program. The ARC has defined a determination of compliance as being either a determination of compliance with applicable regulatory requirements or airworthiness standards, or a determination that previously approved data are valid and applicable for their intended application. When operating under a letter of authorization, the ARC believes the CDO should be authorized to submit a statement of compliance encompassing all determinations of compliance. This includes those made by the CDO within its existing scope, the validity and applicability of those "proposed" determinations of compliance approved by the FAA in areas of the expanded scope being sought, as well as the validity and applicability of those related to previously approved data that also lie within the area of the expanded scope being sought. It will remain the responsibility of the CDO to manage these and all other project management activities when working under a letter of authorization.

Once the FAA is satisfied that the CDO is capable of reliably executing its compliance responsibilities under the changed scope, the FAA will amend the CDO certificate to include the new scope. The FAA is under no obligation to complete its assessment within a minimum time limit or number of projects. The FAA may also withdraw its letter of authorization if the CDO does not promptly work to satisfy the requirements for obtaining CDO privileges under the new scope. In addition, a letter of authorization should not be used for a one-time expansion of scope or to supplement a lack of capability on a particular project.

IV.I.(2) CDO Self-Assessment

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 FAA may use this assessment in focusing its assessment activities.

In the case of an expansion in scope for a CDO in good standing, the FAA may also rely on the self-assessment in issuing the expansion to the CDO certificate. 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. As a tool in the performance of the self-assessment and the FAA evaluation, the CDO applicant should have traceability between its processes and the regulatory requirements they are intended to address.

IV.I.(3) CDO Appointment

The ARC discussed issues related to the difficulties of determining when an organization is capable of assuming the responsibilities of a CDO.

The Industry members of the ARC highlighted past experiences with different FAA interpretations of similar requirements dealing with delegated organizations, and have suggested that a centralized office for CDO applicant evaluation might be appropriate.

The FAA members of the ARC agreed that there are difficulties with standardization in some circumstances, but consider that the local FAA offices have the best ability to evaluate the qualifications of applicants because of their past experience in certification programs. The local FAA offices also need to be thoroughly familiar with the CDO regulations, processes, and advisory material in order to properly perform FAA oversight.

The establishment of an organization that manages CDO appointments is the responsibility of the FAA. The ARC recommends that consideration be given to

creating clear lines of responsibility that will encourage standardization of the procedures for obtaining and holding a CDO certificate. One suggestion is to have a team evaluation of CDO applications that includes members from:

- a central office that participates in CDO applicant evaluation and provides standardizing input,
- the applicable FAA Directorates for the products that the CDO applicant seeks authorization for the design of, and
- the cognizant ACO, MIDO, and AEG located in the same geographic area as the CDO applicant.

This will help to ensure there is communication between the FAA organizations with the best qualifications to assess the specific issues each applicant brings forward. It also will encourage communication between the field offices implementing the CDO guidance and the central office responsible for maintenance of the policy and assisting with standardization.

As an example, the process of determining the acceptability of a company for issuance of a CDO certificate becomes more complicated when an applicant desires a certificate that covers more than one CFR part, for instance both Part 23 and Part 25. This would involve two accountable Directorates and two accountable AEG offices, in addition to the local ACO, MIDO, and Headquarters policy offices (should policy issues arise with respect to the intent of the CDO regulations).

In all cases, there must be uniform policy and processes that all regions and offices are operating to, so that the CDO applicant is not placed in the unfeasible position of trying to satisfy conflicting FAA processes.

IV.I.(4) FAA/CDO Communication:

The FAA and the CDO will have a formal conduit for communication, including:

- means for the CDO to request guidance,
- means for the FAA to provide guidance to the CDO on general matters, and
- means for exchanging information concerning FAA involvement and guidance in CDO projects.

The rationale for a formal means is that the CDO project managers and planners need to be aware of potential/identified areas of FAA involvement to facilitate project planning and compliance determination activities.

As noted later in the report in the section detailing FAA oversight, any corrective actions identified by the FAA should be communicated to the CDO in writing after their review by the FAA oversight team.

IV.I.(5) Issue Resolution

With the CDO making all determinations of compliance, it is fully responsible for the appropriateness and adequacy of those determinations, including interdependent compliance issues. If a situation arises where the certificate holder believes the regulatory requirements, policy, guidance, or method of compliance provided by the FAA is inconsistent or inappropriate, the CDO may use the full FAA appeal process that is available to any applicant.

The appeal process should be initiated through the CDO Executive to the FAA oversight team to ensure CDO appeals and FAA positions receive proper executive oversight.

Should the FAA direct that compliance be determined in a specific manner different from that proposed by the CDO, the FAA must advise the CDO in writing of its decision so that the certification files at the CDO properly reflect that the FAA directed that action.

IV. J. FAA Evaluation, including Oversight and Guidance

This section of the report addresses FAA oversight evaluation of the CDO, the FAA role in providing guidance to the CDO, FAA involvement in projects, and the methods recommended for developing oversight evaluation standards. The ARC has defined all of the activities related to measuring the performance of the CDO as evaluation. Included in these evaluation activities are:

- assessing the organization has met the requirements and obligations to qualify to be a CDO (evaluation of qualifications);
- performing routine oversight to monitor that the CDO is performing as intended; and
- performing an appraisal using a capability maturity model that the organization meets the desired level of process performance.

IV.J.(1) Evaluation of Qualifications

The FAA will assess whether an applicant for a CDO has met the basic requirements and obligations to qualify for a CDO before establishing a team to perform an appraisal of the organization and its processes. This evaluation of

qualifications is a simple survey of each of the requirements and obligations to see that each is met by the organization. It is a necessary gateway for the appraisal phase, but the appraisal will determine if the processes and methods employed by the organization meet the standard for a CDO.

IV.J.(2) FAA Oversight

The ARC agrees that the FAA has a fundamental responsibility to oversee the functioning of the CDO to ensure that it is meeting its certificate obligations. Industry is concerned that currently much FAA oversight is ad-hoc, with individual opinions driving significant efforts that sometimes have little or no effect on safety.

FAA Oversight Team. The ARC believes that oversight of a CDO organization should be performed by a team. If the organization also has a production certificate, an approved production and inspection system, fabrication inspection system for PMA, or quality system for TSO manufacture, this FAA oversight team should include inspectors from the Manufacturing Inspection Office as well as engineers from the Aircraft Certification Office. Inspectors from the FAA's Flight Standards Service should also be on the oversight team to address issues related to maintenance and operations.

Oversight Plan. This FAA oversight team should establish an oversight plan to ensure that the organization is meeting its certificate obligations. This plan should include activities where:

- the day-to-day operations of the CDO are observed and evaluated against the CDO procedures, and

- the CDO Procedures Manual and overall CDO operation are evaluated against the standards for a CDO.

Any corrective actions identified by either type of oversight activity should be communicated to the CDO in writing following a review by the oversight team.

Observation and Review by the Oversight Team. One of the objectives of the oversight team is to observe the CDO performing its normal activities. Observation of CDO compliance related activity by the FAA should be a normal element of CDO operation. The FAA should be able to observe consistent procedures that result in valid compliance findings during its oversight activity. If some activity necessary to finding compliance is not observable, consideration should be given to how it would be audited by the FAA, as well as the CDO.

The FAA team providing oversight will also review the internal CDO audit results to identify areas for additional oversight and to observe the CDO corrective action processes in operation.

Location of Oversight Activities. The CDO processes and activities may take place at a number of locations under control of the applicant, as outsourcing and offshore production will continue to develop. The FAA must make a determination of "no undue burden" if any of the facilities necessary to conduct the operations of the CDO are located outside of the United States. The CDO main design and production facilities must be in the United States.

The FAA oversight team will need to plan to support oversight of these outsourced activities of the CDO. This may involve travel to overseas locations, similar to the oversight of foreign suppliers currently done by FAA Manufacturing Inspection District Offices. The Aircraft Certification Offices may also wish to review the systems used by manufacturing inspection to coordinate oversight activities of domestic suppliers among their local offices, in order to minimize travel to the extent possible while maintaining proper oversight.

The FAA's oversight of the CDO is also necessary so that the FAA will have sufficient knowledge and understanding of the particular product in order to fulfill its obligations to support the type validation and continued operational safety (COS) processes. This oversight serves to validate the CDO processes, provide the familiarity necessary to support the COS processes, and, in some cases, provide for cross-product experience that the CDO representatives may not have.

Process Review Methods. As part of its oversight of the CDO, FAA may wish to shadow some projects to assure the CDO's continued compliance with the regulations and its Procedures Manual. It is important that the FAA understand what stage the CDO is in with regard to the compliance activity, prior to any determination that there may be an apparent issue (for example, the CDO may be in mid-process, not yet having completed its compliance determination activity).

If the FAA uncovers an apparent non-compliance during this process review, that matter must be presented to the CDO Executive through the FAA oversight team. At that point, the CDO would review the matter, discuss its assessment with the FAA oversight team, and make any changes necessary to the CDO processes. The FAA should be free to attend meetings to observe the CDO processes in action, but FAA should not expect these meetings to be used to educate FAA attendees regarding past decisions or other issues unrelated to the specific meeting underway. If the FAA needs further clarification on matters discussed in such meetings, the FAA should request a separate meeting for that purpose.

Maintaining FAA Technical Capability. The ARC discussed whether or not there was an issue associated with keeping the FAA engineers and inspectors sufficiently familiar with new technology since they would be making no determinations of compliance. A point was made that the reduced involvement by the FAA may leave a void in FAA skills training that may impact on their ability to properly perform their oversight functions. Another point made was, that by allowing the CDO to make all determinations of compliance, it actually may allow FAA employees to

become more familiar with new technology, as they would not have to perform routine compliance activities and could concentrate on more complex technology and high risk issues. The ARC made no specific recommendations in this area, as it recognized that the FAA is solely responsible for the training of its personnel. The Industry members of the ARC do see a benefit for the FAA personnel it works with being knowledgeable on technologies embodied in their products. They suggested that it would be possible for the Industry to assist the FAA in the training of its personnel through more detailed familiarity briefings on major programs, and through attendance at company training programs to the degree allowed by company and FAA ethics requirements and FAA budget.

Alternative Ways to Perform Compliance Activity. During oversight of the CDO, the FAA may identify alternative ways for the CDO to perform compliance activities, given its broader perspective of the whole aviation system. There are benefits to the CDO certificate holder for the FAA to share any alternatives they have identified. All suggestions have the ability to trigger other ideas when they are discussed, even if they are not implemented by the certificate holder. This is a means for the FAA to continue its transition toward coaching the Industry in safety matters. Those enhanced coaching skills may necessitate special training courses. The FAA oversight team and CDO management should take advantage of teambuilding opportunities that may arise; this may enhance the open communication and trust that is essential to the CDO concept.

IV.J.(3) FAA Guidance Role

A major FAA regulatory role on any certification program is to establish the certification basis, approve acceptable methods of compliance, issue general guidance on regulatory matters, and issue special conditions, exemptions and equivalent safety findings. The FAA then determines which findings of compliance it wishes to make itself and those it wishes to delegate.

Under the CDO concept, once the certification basis has been determined and methods of compliance established, the FAA role is to oversee the compliance activity of the CDO. All interaction with the CDO for that project becomes oversight activity and any FAA concerns as a result of that oversight would be communicated to the CDO Executive from the FAA oversight team. FAA direction to the CDO staff without formal communication to the CDO Executive would be inappropriate, as it could be misinterpreted as FAA management of CDO activities; all management must come from within the CDO to maintain the appropriate accountability.

The FAA always has the right to re-inspect or re-examine any aspect of the CDO's processes, activities, or products. If in doing so it determines that additional regulatory guidance is necessary, that guidance should be promptly provided by the FAA oversight team to the CDO Executive.

IV.J.(4) FAA Involvement in Projects

The FAA would continue to issue special conditions, equivalent safety findings, and alternative methods of compliance, and concur with the means used to establish compliance. Once compliance requirements and acceptable means of compliance are established, the defined system within the CDO must be fully capable of determining compliance. The only FAA involvement is oversight of the CDO.

The certificate holder must provide sufficient instructions to its appropriate organizational elements and persons so they can properly establish compliance. How those instructions will be accomplished should be addressed in the FAA-approved CDO Procedures Manual.

IV.J.(5) Development of Appraisal Standards

The ARC discussed how the FAA may appraise the performance of a CDO. It is the desire of the ARC that appraisals be objective, based on well defined national goals and objectives, and be repeatable and consistent across all offices. The ARC did not define the detailed processes that a CDO must use, but did define the objectives that must be attained. Thus, this report does not define specific process appraisals.

Capability Maturity Model. The ARC investigated use of a capability maturity model (CMM) to form the basis of the appraisal technique. A CMM uses specific processes to appraise the capability of the organization to perform specific tasks (capability levels for specific processes) and a summary of the appraisals to determine the maturity of the organization (assessment of the desired capability level across the range of necessary processes). This provides a model for oversight that is consistent with the discussions in the FAA oversight section of this report, where some oversight is supervisory (day-to-day observations of specific tasks) and other oversight is appraisal (evaluation of the overall system).

FAA iCMM. The FAA Office of Information Services (AIO) has developed an integrated CMM called the "FAA iCMM." It integrates several capability maturity models into a single version that may be used for self-appraisals or for external appraisals of business processes. It is the intent of the ARC that the FAA iCMM approach will be tailored to produce specific guidance on how the FAA will perform capability and maturity assessments of organizations seeking and holding a CDO certificate.

The ARC has used the material from the FAA iCMM in developing proposed rules that would require the organization to demonstrate a certain level of capability and maturity. These levels correspond to what the capability maturity model identifies as "level 3 – Defined." The ARC's proposed NPRM, however, does not reference the specific capability maturity model or its levels. This provides some flexibility in case better appraisal techniques are developed during the lifetime of the rule. The

ARC does not envision that the FAA would require the CDO organization to use the FAA iCMM appraisal techniques for its own evaluations, but expects the organization to be familiar with the FAA iCMM approach and appraisal scales so it may assess it own readiness to be evaluated by the FAA.

Advantages of iCMM. The ARC discussed several advantages that using the FAA iCMM provides to both the FAA and the CDO. One advantage is that this is a mature non-process-specific appraisal method that is designed to provide business value. Another is that there are FAA resources available to assist with training. Another is that external consultants are available with additional expertise in these methods. The process areas defined in the FAA iCMM may be used as a taxonomy to assist with the classification of process performance data saved.

There are alternative integrated capability maturity models designed to provide similar benefits. The ARC felt that the FAA iCMM was the best available choice considering the wide number of models and standards it had integrated, the traceability the FAA iCMM provides to other recognized standards, the ability to use the material prepared by the FAA with no service fees or charges, the availability of the FAA iCMM version 2.0 definition documents, the availability of the FAA iCMM appraisal method version 2.0 documents, and the FAA ownership of the FAA iCMM which would allow tailoring as experience is gained with its use.

Appendix I of this report contains more information on the FAA iCMM appraisal criteria and how it could be applied relative to CDO.

IV. K. Records Retention

The CDO certificate holder will create records as required by the processes and procedures contained in its Procedures Manual. The CDO certificate holder also creates records associated with the application for, and approval of, FAA certificates or other design approvals, as well as for design approvals it holds. These records include the type design and compliance data. These records are substantially identical in scope with those that any applicant or design approval holder would create, including those that a delegated organization, like ODA, would create. To decide what records the CDO certificate holder should retain and what should become of those records when the certificate is terminated or surrendered, the ARC looked to 14 CFR Parts 21 and 183 for guidance on record retention requirements.

Relative Requirements under Part 21. The ARC discovered that there were no record retention requirements in Part 21 that were applicable to a design approval holder, except for production records and those related to ODA. After considerable discussion, the ARC recognized that it is logical for the FAA not to require a design approval holder to retain type design and compliance determination records, as the FAA had copies of those records.

Before delegation, all compliance and type design data were submitted to the FAA for its direct approval. Once approved, the FAA maintained a record of all the data it had approved or, in some cases, it executed records retention agreements with design approval holders. Those agreements allowed the approval holder to retain the records on behalf of the FAA, required access to the FAA as it desired, and required the records to be returned to the FAA if the design approval were surrendered.

As the FAA instituted the concept of representatives of the Administrator, to make approvals on behalf of the FAA, it required all approved data to be submitted to the FAA. Thus, it propagated the policy that the FAA must retain copies of all approved data. When it instituted organizational delegations, FAA placed a recordkeeping requirement on the organization, as is evidenced by §21.293 for DOA, §21.493 for DAS, and §183.61 for ODA. These requirements define what records must be retained, the period of their retention, and what records must be sent to the FAA when the organizational delegation is terminated or surrendered. Since the latest FAA thinking with regard to records retention is found in the ODA requirements, the ARC looked to §183.61 for guidance that could be applicable to CDO.

Relative Requirements under Part 183. The ARC agrees that the records required to be retained for the duration of the CDO certificate are identical to those that an ODA would be required to retain under §183.61(a), with a couple of exceptions.

Section 183.61(a)(1) states:

> *(a) Each ODA Holder must ensure that the following records are maintained for the duration of the authorization:*
>
> *(1) Any records generated and maintained while holding a previous delegation under subpart J or M of part 21, or SFAR 36 of this chapter.*

The list of previous delegations specified in §183.61(a)(1), for which records must be retained must include ODA, as a CDO certificate holder may have previously held an ODA. Additionally, since the CDO certificate holder would also likely have an organizational delegation from the FAA to issue certain certificates, the records created under that delegation must also be retained as they are under an ODA.

CDO-Specific Records to Retain. The CDO would also be generating records under its SMS related to decisions it made with respect to safety matters, and those records should be retained for the duration of the certificate, as they constitute an historical record of how the CDO dealt with safety matters.

The CDO should also maintain a file of all “CDO FAA-approved Data” forms provided to third parties.

The ARC decided that service difficulty reports need not be retained for the duration of the certificate, but a summary of decisions made with respect to those service difficulties, and data supporting those decisions, must be retained for the duration of the CDO certificate.

Other Considerations. As with ODA, the records required to be kept under CDO would be submitted to the FAA upon surrender or termination of the CDO certificate. These include all type design and compliance records, as well as records created in compliance with CDO manual requirements. The submittal of type design and compliance records is consistent with existing FAA practice to retain those records. A copy of the records would certainly be retained by the company that held the CDO certificate if it continued to hold design approvals issued by the FAA.

The FAA and company may also execute a records retention agreement, should the company be willing to perform that function and should the FAA decide to have the company retain any records on its behalf.

IV. L. TSO Under CDO

Design organizations holding TSO design approvals could obtain a CDO. However, the decision to obtain a CDO by these organizations will likely depend on the type of TSOs being sought or held by the company.

For the majority of TSO applicants, the TSO process is relatively straightforward and requires very little FAA project involvement. The applicant follows a predefined minimum performance standard issued by the FAA for the article under consideration, and then submits to the FAA a statement of compliance along with a copy of the technical data required by the TSO and a description of the applicant's quality control system. The FAA then reviews the data package and associated quality system, approves the design, and permits production of duplicates by issuing a TSO authorization.

However, some TSO programs involving software and complex electronic hardware often require a great deal of FAA involvement, especially when those programs involve highly integrated or advanced avionics systems. For example, FAA engineers are frequently involved in oversight of the applicant's means of complying with the guidelines of RTCA Document (DO)-160 for environmental qualification, RTCA DO-178 for software design assurance, and RTCA DO-254 for hardware design assurance. As a result, the TSO process often mirrors the activities of a typical TC or STC project through its use of designees, the amount of auditing and oversight of the applicant's staff by the FAA, and the degree to which the FAA relies on the applicant's statement of conformance. For companies working on these types of complex TSOs, obtaining a

CDO will allow them to obtain the same benefits as previously outlined for design organizations working TC, STC, and PMA programs.

IV. M. Effect of FAA Orders on CDO Procedures

The CDO Procedures Manual will need to address all areas where there is the need for an interface or interaction with the FAA. For instance, when coordinating with the FAA on such activities as the approval of the type certification basis, acceptable methods of compliance, special conditions, and equivalent safety findings, the CDO will be expected to follow the normal FAA process defined in advisory material and FAA Orders. FAA Orders related to other certification processes would not need to be followed, provided that the CDO proposes, and the FAA accepts, an alternative procedure. The acceptability of the alternative method would be measured against the regulatory requirements and not the FAA Orders.

Existing FAA Orders are written to implement important compliance principles that a CDO would be expected to review for their inclusion in the processes contained in the CDO's Procedures Manual. When developing these procedures, the CDO should consider that existing FAA Orders are familiar to the FAA and that they have facilitated the current level of compliance assurance. Therefore, there may be advantages to both the FAA and the CDO in those areas where existing procedures can be maintained.

IV. N. Need for an FAA Order and Advisory Circular on CDO

The ARC recommends that an FAA Order be developed to address the FAA's functions necessary to manage a CDO. The ARC believes that this Order should reference the same Advisory Circular that will provide guidance to the Industry. The ARC drafted, but did not complete, an Advisory Circular. The ARC's proposed draft is provided in Appendix K of this report. The ARC recommends that the FAA use this draft as the basis for development of its guidance material.

V. PROCEDURES MANUAL

The CDO Procedures Manual contains the CDO organization's procedures for meeting its regulatory requirements. The manual must address all relevant CDO requirements.

The Manual addresses compliance and process objectives, including those details necessary to ensure that the regulatory requirements are met. The process and procedures must be sufficient for the FAA to determine that they properly address regulatory compliance. The Manual is intended to be a top level document that will guide the development of lower level processes and work instructions that the CDO 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 CDO 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 CDO 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 CDO regulatory compliance would not be referenced in the Procedures Manual and would not be auditable by FAA as part of its CDO 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 CDO is obligated to respond to FAA's request within an agreed upon time frame.

The Procedures Manual must be consistent with all issued FAA regulations and guidance related to the proper functioning of a CDO. 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 CDO Procedures Manual may be in any format proposed by the CDO and acceptable to the Administrator. There is no expectation that each CDO Manual would be formatted the same.

The detailed Procedures Manual requirements have been addressed in the draft advisory circular in Appendix K; however, the general manual requirements, as envisioned by the ARC, are summarized on the following pages:

Organizational Requirements	**Identify the CDO Executive as the accountable company representative.**
	Identify point(s) of contact for FAA coordination on projects and other CDO issues.
	Identify all persons authorized by the CDO Executive to make statements of compliance to the Administrator.
	Maintain a list, with contact information, of all design suppliers authorized to make determinations of compliance.
	Show the accountability relationship of the authorized signatories to the CDO Executive, and the CDO Executive to company leadership.
	Identify the staff with the knowledge base to support the CDO's scope of authority.
	Identify the location of the main design facility.
	Contain a statement, signed by the senior management of the company, affirming, on behalf of the company, the agreement to meet its responsibilities as outlined in the CDO regulations and the CDO procedures manual.

Processes and Procedures for:	**Implementing the scope and limitations of the CDO.**
	Making all compliance determinations.
	Making statements of compliance to the Administrator.
	Using existing design approvals (i.e., TC, STC, PMA, and TSO).
	Establishing the viability and applicability of previously approved data.
	Creating and using eligible data.
	Creating FAA-approved data and the manner in which the data will be identified.
	Including the following privileges when granted by the FAA: • **Procedures for use of FAA designees for issuance of design approvals and certificates.** • **Procedures for use of FAA voluntary self-disclosure policy.** • **Procedures for making compliance determinations and statements of compliance with CAA regulations.**

Obligations	**Establish a process for submitting a statement of compliance as a prerequisite to FAA issuance of a certificate or other approval.**
	Establish a process for determining that its staff has the skills necessary to meet the CDO requirements.
	Establish processes defining its CAS, QMS and SMS.
	Establish processes fulfilling the CDO reporting requirements.
Coordination and Communication with the FAA	**Process for changing the Procedures Manual.**
	Process for notifying and coordinating project activity.
	Process for formal communication with the FAA.
	Process for notifying FAA of changes affecting the CDO's ability to meet the requirements of its certificate.
	Process for responding to FAA requests and inquiries.
Records Retention	**Process for retention of CDO specific records.**
	Process for storage of both active and inactive CDO specific records.
	Process for identification of CDO specific records: • **CDO specific records must include all approvals and determinations of compliance made by the CDO and any supporting data used by the CDO in creating them.**
	Process for retention of specific records produced under a previously held organizational delegation.

Safety Management System	**A safety policy**
	A formal safety risk management process
	A safety assurance process that continually assess activity to identify new hazards and to ensure risk controls achieve their intended objectives throughout the system life cycle
	Safety promotion

Quality Management System	**Implements processes and procedures for determining that the CDO continues to meet its qualification requirements.**
	Ensures high level management commitment to meet its defined processes and procedures through surveillance and regular audits with a closed-loop corrective action process to update processes and procedures as required.
	Continually assesses its procedures for their adequacy in demonstrating compliance.
	Incorporates a Procedures Manual configuration management process, including a change control process, to ensure its approved processes and procedures continue to meet their intended purpose.
	Verifies the qualifications of its personnel to understand and operate in accordance with its processes and procedures.
	Ensures its processes and methods are adequate for proper supervision of partners, suppliers, or subcontractors in its supply chain.

Compliance Assurance System	**Processes that collectively define compliance <u>planning,</u> such as:** • **Acquiring current FAA regulations and implementing policy;** • **Defining compliance requirements;** • **Showing compliance;** • **Establishing and maintaining design practices and standards as applicable;** • **Establishing, approving, and revising compliance plans; and** • **Reviewing and approving compliance project planning prior to compliance execution.**
	Processes that collectively define compliance <u>execution</u>, such as: • **Creating and approving analytical reports;** • **Defining test articles and conducting compliance testing;** • **Performing and documenting safety assessments (FHA, PSSA, SSA, CCA);** • **Implementing specific compliance processes for subjective regulatory standards;** • **Generating and managing "eligible data" and previously approved data;** • **Generating and managing repair documentation and approval** • **Performing function and reliability test requirements, objectives, and failure dispositions;** • **Preparing and approving required documents; and** • **Reviewing and approving compliance project execution prior to compliance verification.**
	Process for compliance verification.
	Process to develop, approve, and disseminate required continued airworthiness instructions.
	Process for preparation and signing of the statement of compliance.
	Process controlling compliance data configuration management.
	Process for compliance-related liaison between the certificate holder and the FAA.
	Where the compliance system is dependent on the qualifications of certain individuals, the processes for the qualification, selection, and management of those individuals.
	Where the compliance system is dependent on the qualifications of certain tools, the processes for the control and verification of those tools.
	Process for oversight of suppliers, partners, and sub-contractors engaged in compliance assurance.

Production	**A CDO must address the following for performing prototype production activities in order to obtain a design approval:** • **A process by which the configuration is documented.** • **A means by which any changes are properly controlled.** • **Methods used to determine that the initial and ongoing conformity is maintained.** • **Procedures by which nonconforming products, parts, and appliances are reviewed and properly dispositioned** • **To the extent applicable, procedures for flight, endurance testing and teardown inspections.**
	For CDOs performing both prototype manufacturing and post-design approval production as part of its scope of activities, in addition to the above, the quality system must also contain procedures for: • **Controlling design data and subsequent changes.** • **Controlling quality system documents and data.** • **Ensuring that each supplier furnished product, part or appliance conforms to its approved design.** • **Controlling manufacturing processes to ensure conformity to its approved 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 approved design.** • **Ensuring that only products, parts, or appliances that conform to their approved design are installed on a type-certificated product.** • **Ensuring that discarded articles are rendered unusable.** • **Implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or non-compliance with the approved quality system.**

- **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 quality system.**
- **Receiving and processing feedback on in-service failures, malfunctions, and defects.**
- **Identifying, analyzing, and initiating appropriate corrective action for products, parts, or appliances that have been released from the quality system and that do not conform to the applicable design data or quality system requirements.**

VI. REGULATORY REQUIREMENTS

The ARC was chartered to develop a draft notice of proposed rulemaking (NPRM) that would implement the CDO principles and attributes recommended in this report. The ARC is recommending that a new subpart P be added to 14 CFR Part 21 to specifically address CDO requirements. A proposed NPRM containing the ARC's detailed regulatory proposal is provided in Appendix J of this report.

The ARC's proposed NPRM incorporates the principles described within this report. There have been extensive discussions on the privileges to be granted as part of the CDO certificate, as well as other important privileges that may be necessary for a CDO and the FAA to maximize the full benefits of the CDO program.

"Other Privileges." While the proposed rule addresses only those privileges that are part of the CDO certificate, the preamble to the rule discusses other privileges that the ARC recommends be granted to a qualified CDO certificate holder. Since these other privileges are not part of the CDO certificate, and are only extended at the discretion of the Administrator, the FAA members of the ARC did not consider it appropriate to address these privileges in the rule language itself. These FAA members recommended that the privileges be recognized in the preamble as other discretionary privileges that may be granted under existing FAA authority and programs already in place. Industry members of the ARC prefer language in the preamble or the rule committing the FAA to granting these other privileges to the CDO holders, provided they meet established qualification requirements. There is no disagreement within the ARC on the privileges being appropriate for a CDO holder; the only disagreement is with respect to the method used to grant them.

Appendix A.
Section 227 of the Reauthorization Act

VISION 100 – CENTURY OF AVIATION REAUTHORIZATION ACT

SECTION 227

DESIGN ORGANIZATION CERTIFICATES

SEC. 227. DESIGN ORGANIZATION CERTIFICATES.

(a) GENERAL AUTHORITY TO ISSUE CERTIFICATES.—Effective on the last day of the 7-year period beginning on the date of enactment of this Act, section 44702(a) is amended by inserting ‘‘design organization certificates,’’ after ‘‘airman certificates,’’.

(b) DESIGN ORGANIZATION CERTIFICATES.—

(1) PLAN.—Not later than 4 years after the date of enactment of this Act, the Administrator of the Federal Aviation Administration shall transmit to the Committee on Transportation and Infrastructure of the House of Representatives and the Committee on Commerce, Science, and Transportation of the Senate a plan for the development and oversight of a system for certification of design organizations to certify compliance with the requirements and minimum standards prescribed under section 44701(a) of title 49, United States Code, for the type certification of aircraft, aircraft engines, propellers, or appliances.

(2) ISSUANCE OF CERTIFICATES.—Section 44704 is amended by adding at the end the following:

‘‘(e) DESIGN ORGANIZATION CERTIFICATES.—

‘‘(1) ISSUANCE.—Beginning 7 years after the date of enactment of this subsection, the Administrator may issue a design organization certificate to a design organization to authorize the organization to certify compliance with the requirements and minimum standards prescribed under section 44701(a) for the type certification of aircraft, aircraft engines, propellers, or appliances.

‘‘(2) APPLICATIONS.—On receiving an application for a design organization certificate, the Administrator shall examine and rate the design organization submitting the application, in accordance with regulations to be prescribed by the Administrator, to determine whether the design organization has 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 and minimum standards prescribed under section 44701(a).

''(3) ISSUANCE OF TYPE CERTIFICATES BASED ON DESIGN ORGANIZATION CERTIFICATION.—The Administrator may rely on certifications of compliance by a design organization when making a finding under subsection (a).

''(4) PUBLIC SAFETY.—The Administrator shall include in a design organization certificate issued under this subsection terms required in the interest of safety.

''(5) NO EFFECT ON POWER OF REVOCATION.—Nothing in this subsection affects the authority of the Secretary of Transportation to revoke a certificate.''.

(c) REINSPECTION AND REEXAMINATION.—Section 44709(a) is amended by inserting ''design organization, production certificate holder,'' after ''appliance,''.

(d) PROHIBITIONS.—Section 44711(a)(7) is amended by striking ''agency'' and inserting ''agency, design organization certificate, ''.

(e) CONFORMING AMENDMENTS.—

(1) SECTION HEADING.—Section 44704 is amended by striking the section designation and heading and inserting the following:

''§ 44704. Type certificates, production certificates, airworthiness certificates, and design organization certificates''.

(2) CHAPTER ANALYSIS.—The analysis for chapter 447 is amended by striking the item relating to section 44704 and inserting the following:

''44704. Type certificates, production certificates, airworthiness certificates, and design organization certificates.''.

Appendix B.
FAA Report to Congress

Federal Aviation Administration Plan for the Development and Oversight of Certified Design Organizations

Congressional Requirement

Section 227 of the Vision 100-Century of Aviation Reauthorization Act (P.L. 108-176) (the Act), requires the Administrator of the Federal Aviation Administration (FAA) to submit a plan for the development and oversight of a system for certification of design organizations. The Act allows the Administrator to issue a certificate to design organizations authorizing them to certify compliance with the airworthiness standards prescribed under 49 USC 44701(a), for the type certification of aircraft, aircraft engines, propellers, or appliances. The Act allows the Administrator to rely on certifications of compliance by these organizations when making the finding of compliance necessary to issue a type certificate. The FAA interprets amended type certificates, supplemental type certificates, and amended supplemental type certificates to be included in the term "type certificate."

FAA Plan & Schedule

An Aviation Rulemaking Committee (ARC) is being formed to ensure that FAA responds effectively in developing a Certified Design Organizations (CDO) program. The ARC will make its recommendations, which may include proposals for rulemaking, suggested processes, policies, and guidance that will serve as the foundation of the program, and further action the agency may need to take in support of the program. The ARC proposals will be presented to the Administrator through the Associate Administrator for Aviation Safety. As part of its task, the ARC may also review existing regulations and make recommendations to amend or delete them as consistent with its mission. The ARC will function solely in an advisory capacity, but is expected to present and discuss whatever input, guidance, and recommendations the members of the committee consider relevant to the ultimate disposition of the development of CDO.

The proposed plan, as shown in Table 1, indicates an overlap of activity between CDO implementation and FAA's newest phase of organizational delegation program, Organization Designation Authorization (ODA). The ODA is scheduled to begin implementation at the end of 2006. The ODA broadens the scope to allow Title 14, Code of Federal Regulation (CFR), part 25 aircraft manufacturers the same privileges previously allowed only to part 23 aircraft manufacturers. Lessons learned from the implementation of ODA are expected to provide valuable information with respect to the ongoing development of CDO implementation procedures. The CDO Notice of Proposed Rule Making is scheduled to be issued by the end of 2007, with the final rule expected by December 2009. Implementation would be completed by January 2012. This would be more than two years later than originally required by the Vision 100 legislative language. We believe this delay is appropriate, so that the FAA can obtain valuable experience and working knowledge of how to oversee and manage the complexity associated with part 25 aircraft manufacturers. This would include procedures to support a global design and production environment of oversea suppliers that would need to be managed under a CDO approach.

Task	Scheduled To Begin
Plan Submitted to Congress	**November 30, 2006**
Experience with ODA	**2007 – 2009**
ARC submittal to FAA	**September 2006**
NPRM out of the FAA	**September 2007**
Final Rule	**December 2009**
Final supporting policy	**December 2010**
Complete training (FAA & Industry)	**December 2011**
Implementation	**January 2012**

Table 1 – FAA Schedule for CDO Implementation

Basics of the CDO Concept

A CDO must be selected, examined, and certified by the Administrator to have an enhanced system of engineering design and testing capabilities controlled by appropriate processes and safeguards to ensure design compliance with specific airworthiness standards. The FAA envisions the CDO to be a process-based approach to design certification similar to our ODA program. The most significant difference will be CDO relies on a 'certificate management' concept rather than a delegation. Unlike FAA organizational delegations, under which representatives of the Administrator make specific 'findings' of compliance, CDO will place on the organization the full responsibility to make all compliance determinations. The FAA will then make a single finding of compliance at the end of each certification project through the act of issuing the design approval, i.e., a type certificate. Most FAA findings are expected to be based on a single statement of compliance from CDO.

A CDO may be a small or large organization, and may have extensive or limited authority depending on its experience and capability. In keeping with FAA's corporate strategy of becoming more systems focused, we will require CDOs to develop, maintain, and use a Safety Management System (SMS) that we are capable of overseeing. The SMS must ensure that the CDO organization maintains its qualifications, that an active internal system of processes and process oversight exist to ensure that the designs comply with all applicable standards, and that the operational safety of its designs are continually validated.

Failure of a CDO to adhere to its processes or a failure to properly show compliance will result in appropriate enforcement penalties and FAA-directed corrective actions. While enforcement actions may be mitigated if communicated through a formal self-disclosure process, CDOs will be subject to a more rigorous compliance and enforcement atmosphere than most design organizations have been accustomed to under current delegation programs.

While a CDO applicant must be a corporate entity willing to accept additional levels of responsibility, the CDO is not limited to the confines of the corporation. We expect that many CDOs will make use of individuals, suppliers, and design organizations outside of their corporate structure and control. In these cases, CDO will be responsible for the qualifications and performance of all outside sources whether they are individual experts, suppliers, or organizations (including other CDOs). If a CDO uses an individual who has an existing FAA designee privilege, the individual is considered to be working under the auspices of the CDO rather than exercising his authority as an FAA designee. The CDO is responsible for managing any such individual as an agent of the CDO and must accept all liability for the individual's actions.

The CDO will be responsible for complete integration of a design into a compliant product, regardless of the source of data, analysis, tests, or inspections. Determinations of compliance will be the sole responsibility of CDO. The FAA will determine, as appropriate, when to perform its oversight function for each CDO, including enforcement and corrective actions as necessary.

Currently, there are 39 entities that hold organizational delegations from FAA that could become potential candidates for CDO. Other type certificate and design approval holders, which in the past have not pursued organizational delegation due to business reasons, should find CDO to be beneficial.

Limitations with Statutory Language

In discussion with representatives of the aviation industry on the scope of the CDO statutory language, the FAA has determined that the scope of its authority under CDO is limited. Under the current legislative language, CDO was added to allow the FAA to issue, to a qualified organization, a CDO certificate, for the purpose of supporting a type certificate or supplemental type certificate. However, the FAA finds the scope of this statutory authority granted to itself to be limiting in terms of enhancing overall safety of aviation. The scope as written would not allow for the production certification to be aligned with the type certificate under this authority. This would cause the FAA to have to develop and rely on separate privileges for a qualified production organization. The FAA would see that as a step backwards from the recent advances made by the new ODA rule and would force inefficient and duplicate effort of FAA resources.

Additionally, the limitations under the CDO statutory language would prevent other approval holders, such as Parts Manufacturer Approval holders, Technical Standard Approval holders and direct suppliers of technical data to hold authority under CDO. In today's environment, these approval holders are starting to evolve to more sophisticated approval organizational structures, promulgated by FAA's new rule on ODA. This evolution by small entities that hold approvals requires them to have quality and engineering system level capability which in the past have been lacking and forced the FAA to be more hands-on in their use of resources. The FAA wants the CDO's statutory language to encourage these types of smaller approval holders to continue to move in this direction to make the system of approval holders more capable. Because the statutory language is silent in this area, the FAA is limited on its ability to interpret broader use of CDO.

In summary, the FAA believes that the statutory language should include a broader scope and applicability of CDO than would production certificate and other design approval holders. Therefore, the FAA will propose amendments to the statute to expand the scope and applicability of CDO to other qualified organizations and to extend the date by which rules to implement CDO must be in place.

Appendix C.
CDO ARC Team Members

NAME	ORGANIZATION
Industry Representatives:	
McSweeny, Tom (Co-chair)	Boeing
Covington, Jeff	United Airlines
Desrosier, Walter	GAMA
Dicken, Linda/Mill, Jack	Piper
Durkin, Chris	Honeywell (Avionics)
Fidducia, Paul	SAMA
Hill, Paul	GE Aircraft Engines
Kerr, John	Bell Helicopter
Mackiewicz, Stan	NATA
MacLeod, Sarah	ARSA
Szpunar, Steve	HEICO
Trusis, Rick/Tigue, John	Gulfstream
Van Dyke, Larry	Cessna
Van Zummerman, Michael/Carr, Ranee	AIA
Wingfield, Dawn/Johnston, Keith	Bombardier Aircraft Services/Learjet
FAA Representatives:	
Geddie, Scott (Co-chair)	AIR-140
Forde, Phil/Slentz, Sam	Seattle ACO
Fradette, Mike/Linsenmeyer, John	AIR-220
Tinkle, Ron	AIR-140
Wojnar, Ron	AFS-300/AEG
Supporting FAA Representatives:	
Josephson, Steve	AIR-40
Leach, Daniel	APO-320
Lucke, Karen	AIR-140
Michel, Gary	AGC-200
Stroman, Shirley	ARM-200
Foreign Civil Aviation Authority Representative:	
Morin, Gilles/ Thieringer, Martin	Transport Canada

Appendix D.
CDO ARC Charter

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
National Policy

ORDER 1110.145

Effective Date:
May 22, 2006

SUBJ: Certified Design Organization (CDO) Aviation Rulemaking Committee

1. Purpose. This order constitutes the charter for the Certified Design Organization (CDO) Aviation Rulemaking Committee (ARC) that is designated and established pursuant to the Administrator's authority under Title 49 of the United States Code, Section 106(p)(5).

2. Distribution. This order is distributed to the Associate Administrator for Aviation Safety; the Office of the Chief Counsel; the director and division level in the Aircraft Certification and Flight Standards Services; and the director level of the Offices of Rulemaking, Budget, and Financial Management.

3. Background. Congress included in the *Vision 100-Century of Aviation Reauthorization Act* of 2003 the requirement for development and oversight of a system for certification of design organizations. These certified design organizations (CDOs) will be authorized to certify compliance with the requirements and minimum standards prescribed under Title 49 USC 44701(a). The Act also allows the Administrator to rely on certifications of compliance by a design organization when making a finding to issue a type certificate.

The FAA has determined that the language under the current legislative intent is limited. The FAA is currently submitting a Congressional Report addressing broader statutory authority for other design approval holders, including production approval holders, as well as a revised schedule.

4. Objectives and Scope of Activities. An ARC will enable the FAA to respond effectively in developing a CDO program. The committee will make its recommendations, which may include proposals for rulemaking, suggested processes, policies and guidance that will serve as the foundation of the program, and further action the agency may need to take in support of the program. As part of its task, the ARC may also review existing regulations and make recommendations to amend or delete them as consistent with its mission. The ARC will function solely in an advisory capacity, but is expected to present and discuss whatever input, guidance and recommendations the members of the committee consider relevant to the ultimate disposition of the development of CDO.

A CDO Working Group Report, dated August 9, 2005, addressing the CDO concept has been submitted for consideration. This report should be used as additional reference material during ARC deliberations. Although the current statutory language for certification of design organizations is limited to type certificates, amended type certificates, supplemental type certificates, and amended supplemental type certificates, the committee may make recommendations to include any organization seeking or holding any design and/or production approval, e.g., Parts Manufacturer Approval, which the FAA will consider consistent with its legislative authority at that time.

Distribution: A-W(VS/IR/FS/GC/)-1/3; A-W(RM/BU/FM)-1 Initiated By: AIR-140

5. Deliverables. By September 30, 2006, the ARC will submit an initial report detailing its recommendations. The report should identify significant areas of agreement as well as areas where consensus could not be reached. The report should contain recommendations detailing the guiding principles necessary to propose regulatory language for drafting an NPRM. The ARC will continue to work on guidance and policy related issues through September 30, 2007, and will submit a final report by that date. The Associate Administrator for Aviation Safety may extend these deadlines for up to 6 months if it is in the interest of the FAA to do so. The Associate Administrator for Aviation Safety may amend the tasking to ensure that the objectives and the scope of the activities are met.

6. Organization and Administration.

a. The Associate Administrator for Aviation Safety shall have the sole discretion to appoint members or organizations to the committee. The committee shall consist of members of the aviation community, including the public and/or other federal government entity representatives of various viewpoints. The FAA shall provide participation and support from all affected lines of business.

b. The Associate Administrator for Aviation Safety shall receive all committee recommendations and reports. The Associate Administrator, through the Aircraft Certification Service, shall be responsible for providing administrative support for the committee.

c. The Associate Administrator for Aviation Safety is the sponsor of the committee, and shall select FAA and industry co-chairs for the committee. The co-chairs shall:

(1) Determine, in conjunction with the other members of the committee, when a meeting is required.

(2) Arrange notification of all committee members of the time and place for each meeting.

(3) Formulate an agenda for each meeting and conduct the meeting.

(4) Form working groups as necessary to conduct its business in the most efficient manner possible.

7. Membership.

a. The membership of the committee may include the following public and government organizations:

(1) Industry representatives; including representatives from air carriers, manufacturers, repair stations, and other private sector aviation industry associations.

(2) The Federal Aviation Administration Aviation Safety line of business

(3) Other Federal Aviation Administration lines of business as required to meet committee objectives.

(4) Foreign authorities (Note: Representatives will be encouraged to fully participate in committee discussions, but foreign authorities will not vote on committee issues.)

b. The membership shall be balanced in points of view, interests, and knowledge of the objectives and scope of the committee. While representatives of their employers and/or associations, committee members will be expected to contribute fully in all areas of the committees' work.

8. Costs and Compensation. The estimated operating cost (including pro rata share of salaries of FAA employees) is $274,000. Non-government representatives serve without government compensation and bear all costs related to their participation on the committee.

9. Public Participation. Interested persons or organizations who are not members of this committee, but wish to attend a meeting, must request and receive approval in advance of the meeting from both co-chairs.

10. Availability of Records. Subject to the conditions of the Freedom of Information Act, 5 U.S. Code, Section 522, records, reports, agendas, working papers and other documents that are made available to or prepared for or by the Committee shall be available for public inspection and copying at the Aircraft Certification Service, 800 Independence Avenue SW, Washington, DC 20591. Fees shall be charged for information furnished to the public in accordance with the fee schedule published in Part 7 of Title 49, Code of Federal Regulations.

11. Public Interest. The formation of the CDO ARC is determined to be in the public interest in connection with the performance of duties imposed on FAA by law.

12. Effective Date and Duration. This committee is effective May 22, 2006. The committee shall remain in existence until May 22, 2008, unless sooner terminated or extended by the Administrator.

Marion C. Blakey
Administrator

Appendix E.
Glossary of Terms

ACCOUNTABILITY FRAMEWORK: An established set of responsibilities and commitments of the FAA and Industry.

APPROVED DATA: Data approved by FAA employees, its designees, or a CDO acting under the authority of its certificate.

ASSESSMENT: Informal FAA monitoring of on-going CDO certificate holder processes and project activity. Assessment is part of FAA's Certificate Management function.

AUDIT: Formal scheduled review by the FAA or the CDO of the CDO's processes, projects, and compliance with CDO regulatory requirements, as determined by the FAA or the CDO 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.

CDO EXECUTIVE: The company individual directly responsible for ensuring that the CDO meets all of its regulatory responsibilities.

CDO POINT(s) OF CONTACT: The individual(s) within the CDO responsible for all communications with the FAA.

CERTIFICATE MANAGEMENT: FAA actions to monitor the CDO certificate holder and to determine the holder's compliance with the provisions of its certificate(s).

COMPLIANCE ASSURANCE SYSTEM: CDO 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.

CULTURE OF COMPLIANCE: Knowledge, beliefs, attitudes, and behaviors of an organization that are focused on ensuring regulatory compliance within all its activities.

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 CDO 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.

ELIGIBLE DATA: Data developed under an approved CDO system, assuming a specified, but not FAA-established, certification basis, and product type design if appropriate.

FAA OVERSIGHT TEAM: FAA personnel assigned to provide guidance and oversight of the CDO in meeting its regulatory requirements.

FINDING OF COMPLIANCE: FAA decision that the applicable regulatory requirements/standards have been met.

QUALITY MANAGEMENT SYSTEM: A set of interrelated or interacting quality processes accomplished by the organization through the establishment of policy and objectives, and achieving those objectives.

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.

SENIOR COMPANY MANAGEMENT: Those in the company management chain above the CDO Executive who are accountable for the actions of the CDO.

STATEMENT OF COMPLIANCE: A statement from the CDO to the Administrator certifying that compliance with the applicable regulatory requirements has been determined and the procedures listed in its FAA-approved CDO Procedures Manual have been followed.

Appendix F.
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
CDO	Certified Design Organization
CMM	Capability Maturity Model
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
US	United States
USC	United States Code

Appendix G.
Summary of Top Level CDO Principles and Attributes

Statutory/Regulatory

Eligibility

- The CDO applicant must be a design organization, not an individual.
- The CDO applicant must be a holder of a design approval.
- A CDO must be located in the US, and must have applied for and received an FAA design approval, for which the US is the State of Design in accordance with ICAO Annex 8.

Requirements

- The CDO applicant must submit a self-assessment of it qualifications to hold the certificate it seeks.
- The scope of a certificate will be limited to those design approvals that the certificate holder has demonstrated its capability to support. This capability should be demonstrated by the certificate holder's previous design approval experience.
- The FAA will change the scope of a CDO certificate when the design organization has demonstrated a new level of capability to the FAA.
- A CDO must identify an accountable executive and point(s) of contact with the FAA.
- A CDO must establish a project activity notification system.
- A CDO holder has an obligation to make determinations of compliance with applicable regulations when exercising its rights under CDO.
- A CDO must make a statement of compliance to the Administrator for all design approvals that it seeks.
- A CDO holder must allow the Administrator to make any inspection deemed necessary.
- A CDO is required to have a Procedures Manual approved by the FAA.

- A CDO must possess the "full complement of capabilities" to make determinations of compliance in accordance with its certificate authority.
- A CDO must have a Compliance Assurance System that:
  - is commensurate with the type of "design approval" sought;
  - identifies compliance processes used by the company;
  - identifies individual qualification processes used by the company; and
  - identifies tool qualification processes used by the company
- A CDO must have an Safety Management System (SMS) that encompasses the entire lifecycle of products designed by the company. The SMS must include:
  - safety policy,
  - safety risk management,
  - safety assurance, and
  - safety promotion.
- A CDO must have a Quality Management System (QMS) that provides for:
  - process assurance,
  - closed-loop corrective action,
  - Internal audits,
  - configuration management,
  - verification of personnel qualification, and
  - management review.

Certificate Privileges

- CDO is not a delegation of the FAA, but a certificate with privileges.
  - A CDO may not "revert back" to use of the FAA delegation system in fulfilling its compliance determination responsibilities, under its certificate.
- The CDO certificate remains effective until suspended, surrendered, rescinded, or revoked.
- A CDO may approve data for the design approvals it holds and is seeking.
  - A CDO may mark or identify data it has approved.

Other Features

- The CDO certificate is an entitlement to organizations that qualify.
- Under certain circumstances, a company may have more than one CDO.
- A CDO certificate can be issued to a consortium of companies if the consortium management company meets the requirements to hold a CDO certificate.

Compliance Determinations and Approvals

In order for the CDO concept to be viable, CDO determinations of compliance and data approvals must be internationally recognized.

- The CDO must make all compliance determinations.
  - The CDO is responsible and accountable for all compliance determinations made for the initial design approval, and for all changes to the initial design approval.
  - CDO use of previously approved data requires that the CDO make a determination that the data are applicable and valid for their intended use.
- An official FAA form, recognized internationally, is essential to properly convey CDO approvals outside of the CDO. It is not necessary that this form be used to track approvals within the CDO.
- Use of CAA technical assistance under a bilateral agreement to make determinations of compliance is not applicable to the CDO.
- The FAA will issue all certificates, TSO authorizations, and PMA approvals; and the ARC recommends that the FAA use a form of delegation to the CDO certificate holder to accomplish this function.

Design Suppliers

- A CDO can extend its system to suppliers under CDO-approved processes.
  - The CDO must qualify its suppliers, provide oversight, and define the process by which suppliers function under the CDO.
- Data approved in support of an existing TC, STC, TSO, or PMA can be considered approved data by the CDO, provided applicability and validity of the data are demonstrated.

Process Features

- CDO is not "self-certification" – FAA continues to maintain an essential oversight role.
  - CDO requires an FAA-approved CDO Procedures Manual.
  - Projects require no FAA compliance involvement other than oversight after establishment of the certification basis and FAA acceptance of the methods of compliance.

- FAA will conduct project and system reviews/audits as it deems necessary.

- A CDO must have a compliance assurance system incorporating necessary safeguards, which must include independent checking functions or equivalent.

- Under CDO, there will be a formal process for:
  - issues resolution -- both within the CDO and between the CDO and FAA;
  - self-disclosure;
  - internal audits; and
  - use of design suppliers.

- The CDO may create “eligible data” for future use.

- Compliance determinations must be accomplished in accordance with means of compliance acceptable to the Administrator.

- The CDO must comply with published FAA policy interpreting or defining the intent of a regulation.

- The CDO Procedures Manual must not be used to change the regulations or invalidate previously acceptable methods of compliance.

- The CDO shall have a process defining a path for input of FAA guidance and its dissemination within the CDO.

- Under CDO, the traditional regulation-by-regulation show/find process is replaced by FAA-approved CDO processes leading to a statement of compliance by the CDO and resulting in an approved design or approved data.

Cultural Attributes

- A CDO must have and maintain a culture of compliance encompassing all management levels, from top management down to its employees, for all activities.

- A CDO must have and maintain a safety culture.

Appendix H.
Sufficiency of FAA Regulations for CDO Delegation of Certificate Issuance

Section 44702(d)(1) of Title 49 United States Code authorizes the FAA Administrator to delegate a matter related to:

> *"(A) the examination, testing, and inspection necessary to issue a certificate under this chapter; and*
>
> *(B) issuing the certificate."*

In 1983, the FAA created a concept of delegation under 14 CFR §183.33 called the Designated Airworthiness Representative (DAR) in Amendment 183-8 (Docket No. 23140). That regulation, as recently modified under Amendment 183-11, authorizes the DAR to *"perform examination, inspection, and testing services necessary to issue and to determine the continuing effectiveness of, certificates, including issuing certificates."*

The language in section 183.33 is substantively identical to the full scope of delegation authorized under section 44702(d)(1). It is clear that the intent of section 183.33 is to allow the delegation under that section of anything the Administrator is authorized to delegate under section 44702 of Title 49.

The preamble of Amendment 183-8 also addresses how the FAA intends to define what specific delegations it will authorize under the broad regulatory intent of section 183.33. The preamble states:

> *"Since every examination, inspection, and testing function delegated to DARs under the amendment cannot presently be envisioned, it is not possible to specify by regulation all areas in which a DAR may serve consistent with the safety objectives of the amendment. Accordingly, those functions which may be delegated by the Director of Airworthiness* are described in an advisory circular (AC) which is being published concurrently with this amendment …" The preamble goes on to say "The FAA intends to revise and republish the advisory circular to seek public comment each time it is proposed to add or delete an authorization. Additional areas of delegation will be selected and authorized by the Director of Airworthiness based on recommendations from other FAA elements and the aviation community."*
>
> *It should be noted that at the time the amendment was issued the FAA's Director of Airworthiness had responsibility for all engineering, production, and maintenance

> functions. Since the maintenance functions are currently the responsibility of the Director of Flight Standards, the section was changed to indicate that the Director of Flight Standards would be the authorizing official in the area of maintenance and the Director of Aircraft Certification Service would be the authorizing official in the areas of manufacturing and engineering.

It is clear from the preamble to Amendment 183-8 that the regulation was intended to authorize delegation to encompass all the authority to delegate granted to the Administrator for engineering, production, and maintenance. The preamble makes it clear that no further regulatory action is necessary to authorize any delegation within the authority already granted to the Administrator. The FAA would authorize specific functions through the issuance of a revised AC, and committed to obtaining public comment before any revisions were made to the delegation authorizations.

In response to a comment submitted to the docket in this rulemaking, the FAA also addressed its intentions with respect to organizational delegation, as follows:

> *"Since the term 'person' is defined in the Federal Aviation Regulations, Part 1, to include an individual, firm, partnership, corporation, company, association, and joint-stock association, such organizations may be considered for appointment as DARs."*

The preamble continues on to define some conditions under which organizational delegations would be authorized. The FAA has authorized ODAR organizational delegations in accordance with its stated intentions in this preamble.

It is clear that under section183.33 the Administrator has established the regulatory basis necessary to delegate virtually everything that the Administrator is authorized to delegate under section 44702(d)(1) of Title 49. Thus, it is clear that any delegation to the CDO certificate holder that is necessary to allow it to issue certificates needs only require the FAA to define and authorize it in an AC. It is also clear that the delegation may be to individuals within the CDO or to the CDO holder.

Appendix I.
iCMM Appraisal

The ARC recommends that the FAA utilize the FAA Integrated Capability Maturity Model (iCMM) to perform appraisals of candidate and operating CDOs. The FAA-iCMM Appraisal Method was selected for the following reasons:

First, the practices in the iCMM have been integrated from 10 sources, including ISO 9001, ISO/IEC 12207, ISO/IEC 15288, ISO/IEC 15504, Malcolm Baldrige National Quality Award Criteria, EIA 731, CMMI, Software Acquisition CMM, CMM for Software, and Systems Engineering CMM. Use of the iCMM affords improvement against all source models simultaneously and can result in appraisal results/certifications against several source models via a single appraisal.

Second, the iCMM is a powerful tool for any organization pursuing or maintaining a CDO to use as it constructs and evaluates its CDO processes. Due to its integrated nature, the iCMM addresses management at several levels, acquisition, supply, engineering, the full product or service lifecycle, quality management, high performance, and a broad range of supporting processes. Since it crosses all of these systems, support, and lifecycle processes the iCMM is especially applicable to a systems-based concept such as CDO versus other source models that are more narrowly focused. When using the iCMM for evaluation purposes, the organization begins by examining its certification objectives and the processes it performs to accomplish those objectives. Within this context, the organization compares its practices to those in the relevant parts of the iCMM to determine the applicant's (or CDO's) maturity and capability levels compared to the regulatory requirement, and to identify areas where improvements might be pursued. When using the iCMM for construction purposes, the iCMM goals, base practices, and generic practices can be used as a reference if an applicant is creating their CDO and is in need of an organizational guide to craft internal processes.

Finally, the FAA-iCMM is readily available within the FAA system; its materials may be distributed, copied, and modified among the user community without the acquisition costs or copyright concerns associated with commercially available capability maturity models.

The practices in the iCMM are structured into 2 parts: the ***process dimension***, with practices specific to performing a selection of processes, and the ***capability dimension***, with practices that are used generically to improve the way any process is performed. Within the process dimension, practices are grouped into Process Areas (see Table 1), and within the capability dimension, practices are grouped into Capability Levels. Both Process Areas and Capability Levels contain goals expressing what should be achieved if their associated practices are performed.

When candidate and operating CDO appraisals are conducted, the appraisal will need to observe the presence of all CDO - applicable iCMM processes. The process areas of the

FAA iCMM are categorized by the type of activity: management, life cycle, and support as shown in Table 1. They are also staged -- or grouped -- to represent certain maturity levels as shown in Table 2. The concept of staging is that certain process areas are necessary for specific performance levels of an organization, with the higher performance levels corresponding to higher maturity levels. The processes areas for any maturity level include those staged at that level plus those staged at a lower level; they are cumulative.

The iCMM defines 24 process areas, grouped into three categories:

- 5 of the iCMM Process areas are categorized as **Management**
- 8 of the iCMM Process areas are categorized as **Life Cycle**
- 11 of the iCMM Process areas are categorized as **Support**

The following table shows the process area names with the related category:

Table 1. Process Areas

Process Dimension	
Category	***Process Area***
Management	PA 00 Integrated Enterprise Management
	PA 11 Project Management
	PA 12 Supplier Agreement Management
	PA 13 Risk Management
	PA 14 Integrated Teaming
Life Cycle	PA 01 Needs
	PA 02 Requirements
	PA 03 Design
	PA 06 Design Implementation
	PA 07 Integration
	PA 08 Evaluation
	PA 09 Deployment, Transition, and Disposal
	PA 10 Operation and Support
Support	PA 04 Alternatives Analysis
	PA 05 Outsourcing
	PA 15 Quality Assurance & Management
	PA 16 Configuration Management
	PA 17 Information Management
	PA 18 Measurement and Analysis
	PA 19 Work Environment
	PA 20 Process Definition
	PA 21 Process Improvement
	PA 22 Training
	PA 23 Innovation

Certain process areas must exist at the applicant company to address the "what we do" element of iCMM or the Process Dimension of the iCMM architecture.

The "How well we do it" element is the Capability Dimension of the iCMM architecture, and is the objective measured during an iCMM appraisal via the iCMM Appraisal Method(s). The iCMM and its related appraisal methods are the basis of the FAA's quantitative component of an applicant's overall evaluation.

An appraisal is a comparison of processes being practiced to a reference model or standard, in this case to the iCMM. An iCMM appraisal determines an organization's capability to perform a process. In practice, this entails reviewing the organization's implementation of base and generic practices and its achievement of the associated goals through a capability level. For example, to achieve capability level X for a process area, the organization's activities are reviewed against the base and generic practices and goals through capability level X. The process area and capability level goals through capability level X must be satisfied.

An appraisal will typically identify strengths and weaknesses in the appraised entity's processes and produce a findings briefing and an appraisal report. The findings may be presented in the form of a Process Capability Profile that compares the appraised entity to the iCMM standard. The process capability profile can help the organization to determine the necessary improvement activities.

The CDO ARC recommends a threshold level (of how well the organization is performing) that must be met in order for the applicant company to be found sufficiently capable and mature to become certificated by the FAA as a design organization. The organization should perform such that it would be rated at an ***overall*** MATURITY LEVEL 3**.** This level was selected as appropriate for a process-centered design organization based on the CDO objectives of repeatable and reliable certification processes. To achieve overall Maturity Level 3, the appraisal outcome must reveal that all of the CDO-applicable processes staged at Maturity Level 2 and Maturity Level 3 (there are a total of 20) have satisfied Capability Levels 1, 2, and 3.

The specific process areas staged at each of the maturity levels through level 3 are defined in the table 2 below:

Table 2: Process Area Staging

Maturity Level	Maturity Level Name and Staged Process Areas
0 and 1	**Maturity Level 0 and Maturity Level 1 are not specifically defined, except to indicate that Maturity Level 2 has not yet been achieved.**
2	**Maturity Level 2 is called the Managed: Planned and Tracked level. The following nine process areas are staged at maturity level 2:** ***Lifecycle/Engineering Processes*** • **PA 02 Requirements** • **PA 08 Evaluation** • **PA 09 Deployment, Transition, and Disposal** ***Management/Project Processes*** • **PA 11 Project Management** • **PA 12 Supplier Agreement Management** ***Supporting Processes*** • **PA 05 Outsourcing** • **PA 15 Quality Assurance and Management** • **PA 16 Configuration Management** • **PA 18 Measurement and Analysis** **To achieve Maturity Level 2, the nine process areas listed above must have satisfied Capability Levels 1 and 2 according to an iCMM appraisal.**
3	**Maturity Level 3 is called the Defined level. The following eleven process areas are staged at maturity level 3:** ***Lifecycle/Engineering Processes*** • **PA 01 Needs** • **PA 03 Design** • **PA 06 Design Implementation** • **PA 07 Integration** ***Management/Project Processes*** • **PA 00 Integrated Enterprise Management** • **PA 13 Risk Management** • **PA 14 Integrated Teaming** ***Supporting Processes*** • **PA 04 Alternatives Analysis** • **PA 20 Process Definition** • **PA 21 Process Improvement** • **PA 22 Training** **To achieve Maturity Level 3, all 20 process areas staged at Maturity Level 2 and Maturity Level 3 must have satisfied Capability Levels 1, 2, and 3 according to an iCMM appraisal.**

The appraiser should look to see that each process under assessment:

- Has achieved those goals associated with it (check for Capability Level 1- PERFORMED);
- Is institutionalized as a managed, planned, and tracked process (check for Capability Level 2 - MANAGED, PLANNED & TRACKED); and
- Is institutionalized as a defined process (check for Capability Level 3 - DEFINED).

The appraisal method facilitates determinations that the criteria described above are met (or not). During the assessment the goals of the base practices are demonstrated to the appraiser; the goals of the generic practices are also demonstrated for each of the capability levels through the desired maturity level (in this case 3). Table 3 describes how this is accomplished for all 20 processes staged at Maturity Level 3:

Table 3. Goals and Generic Practices for Certain Capability Levels

CAPABILITY LEVEL 1: PERFORMED	
Goal:	The process achieves the goals of the process area.
Generic Practices:	**1.1 Identify Work Scope.** Identify the scope of the work to be performed and work products or services to be produced, and communicate this information to those performing the work.
	1.2 Perform the Process. Perform a process that implements the base practices of the process area to provide work products and/or services to a customer.
CAPABILITY LEVEL 2: MANAGED, PLANNED, AND TRACKED	
Goal:	The process is institutionalized as a managed, planned, and tracked process.
Generic Practices:	**2.1 Establish Organizational Policy.** Establish and maintain an organizational policy for performing the process.
	2.2 Document the Process. Document the process for performing the practices of the process area.
	2.3 Plan the Process. Establish and maintain a plan to accomplish the objectives of the process.
	2.4 Provide Adequate Resources. Provide resources that are adequate for performing the process as planned.
	2.5 Assign Responsibility. Establish responsibility, authority, and commitment for performing the process.
	2.6 Ensure Skill and Knowledge. Ensure that the people performing the process have the needed skill and knowledge.
	2.7 Establish Work Product Requirements. Establish and maintain requirements on work products and services that result from the process.

	2.8 Consistently Use and Manage the Process. Consistently use the documented plans, standards, processes, or procedures in implementing and managing (planning and tracking) the process.
	2.9 Manage Work Products. Place identified work products of the process under appropriate levels of configuration management.
	2.10 Objectively Assess Process Compliance. Objectively assess adherence of the performed process to the documented process.
	2.11 Objectively Verify Work Products. Objectively verify adherence of work products and services to established requirements.
	2.12 Measure Performance. Measure performance against the plan.
	2.13 Review Performance with Higher-level Management. Review the activities, status, and results of the process with higher-level management.
	2.14 Take Corrective Action. Take corrective actions to address problems.
	2.15 Coordinate with Stakeholders. Coordinate and communicate among those performing the process and with appropriate stakeholders**.**
CAPABILITY LEVEL 3: DEFINED	
Goal:	The process is institutionalized as a defined process.
Generic Practices:	**3.1 Standardize the Process.** Establish and maintain a set of standard processes for the organization, including tailoring guidelines
	3.2 Establish and Use a Defined Process. Establish and use a defined process, designed to meet specific business objectives, that is tailored from the organization's set of standard processes.
	3.3 Improve Processes. Collect and use work products, measures, measurement results, and improvement information to improve the standard and defined processes.

In general, the appraisal assesses each process area against the generic practices. The base practices should be viewed as guidance on the basic performance of the topics that need to be addressed. The generic practices deal with improvement in the way the base practices are performed. In many cases, the generic practices are supported by process areas that provide more detail about them. Thus by looking at the generic practices, an appraisal ascertains how those supportive process areas have been deployed. Process area goals and capability level goals summarize practices. Strengths and weaknesses found in particular practices are considered in relation to the goals to which they are mapped, and a determination is made as to whether the goals have been achieved.

An appraisal will have a defined scope and may be performed in discrete portions with separate elements being appraised within each portion and the completed appraisal requiring several compartmentalized appraisals. This approach will likely be employed for the larger organizations or more complex CDOs where a single appraisal of all of the facilities or all aspects of the authorization is difficult to achieve and resource intensive for the FAA and the organization being appraised.

A full external appraisal will consist of three phases; the Plan & Prepare Phase, the Conduct Appraisal Phase, and the Report Results Phase. Figure 1, below, is a flow chart that graphically depicts the suggested appraisal process containing discrete elements of the three phases.

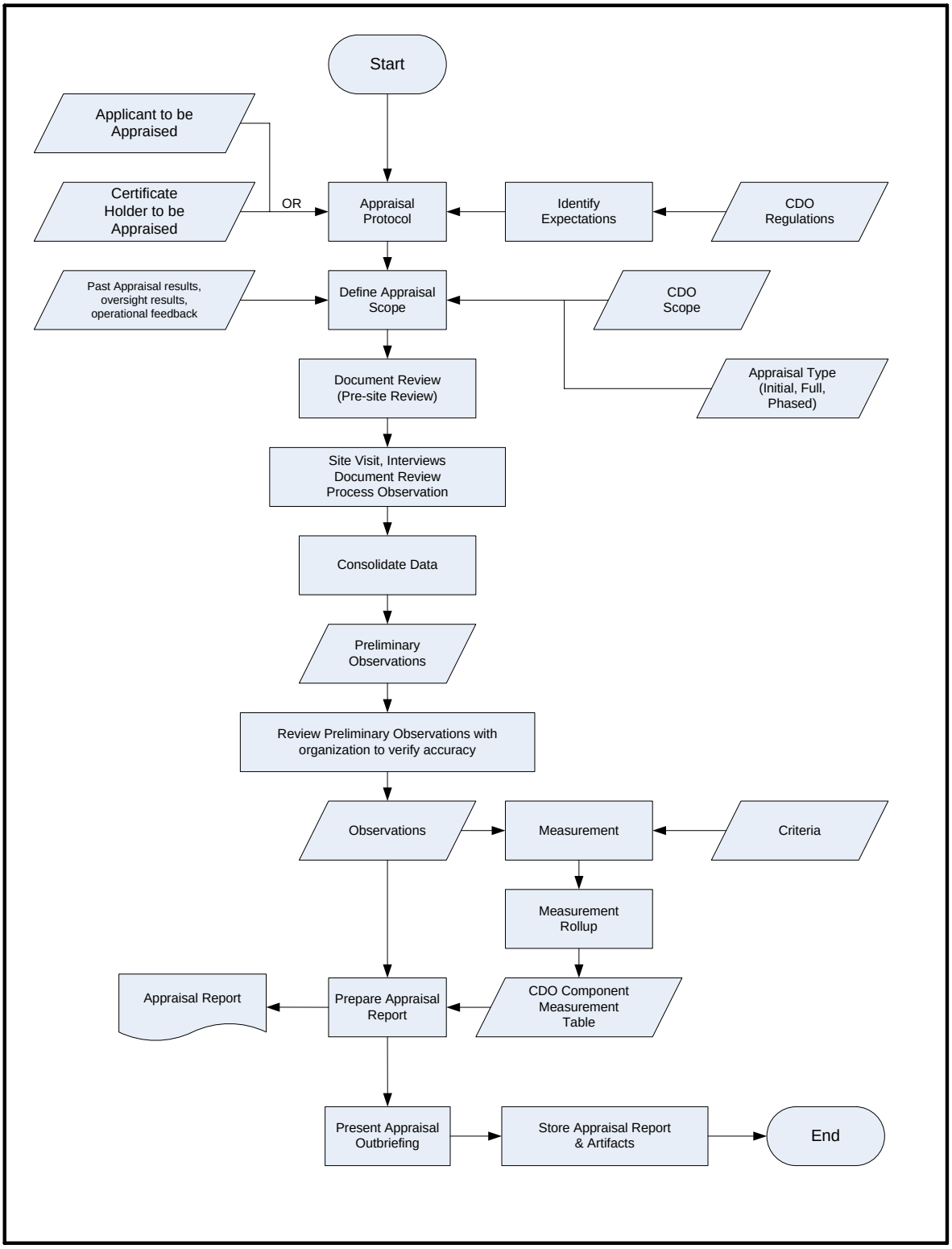

Figure 1. Appraisal Process

Appraisal Protocol:

The basic protocol for a CDO appraisal is a team based review of documentation and operations to determine compliance with the requirements of Subpart P. The team shall consist of members of the local FAA Certification, Manufacturing, and Aircraft Evaluation Group (AEG) offices charged with oversight of the CDO.

Identification of Expectations:

The appraisal team should identify expectations. The performance expectations for the organization being appraised are defined by the guidance material performance criteria. The team may have expectations based on the organization being appraised, the status of the organization (applicant or certificate holder), or special considerations due to the scope of the CDO certificate or the applicants history with the oversight office.

Definition of Appraisal Scope:

The appraisal team defines the scope of the evaluation. The team should consider whether they are evaluating an applicant (initial) or certificate holder (follow-on), past evaluation results (if applicable), oversight results, operational feedback, the scope of the CDO certificate authority, and the evaluation type (initial, full, or phased, (compartmentalized)).

The initial and full evaluations are both intended to evaluate the complete CDO operation but the initial evaluation should review all the procedures completely where the full evaluation may rely on spot checks or the observation of interfaces with processes to determine that those processes are working. The compartmentalized appraisal should identify the areas that are being appraised and those that are being left for another appraisal event.

A site visit appraisal plan will be developed using this guidance and the appraisal team briefed on the planned activities for the subsequent site visit.

Site Visit:

The site visit is the main fact gathering mechanism for the appraisal and consists of an Appraisal Briefing, Interviews, Document Review, and Process Observation.

The visit begins with a briefing to the company representatives of the appraisal team members, objectives, and methods to be used during the visit. This briefing includes a summary of the processes used to collect data, how the data will be consolidated into preliminary observations, how the company will be given the opportunity to provide additional data relative to the preliminary observations, and how the preliminary observations will be evaluated to provide performance measures for the organization.

The document review activity is the primary focus of the appraisal. The evaluation team should use the document review to examine the process documents and perform an appraisal that will meet the objectives for the scope of the appraisal and allow efficient use

of the team's time while on site. The intent is to follow threads of activity through the processes to determine that the processes interface with one another properly and are appropriately recorded. The team, in examining the operational documentation of the CDO, will select areas to review in detail. These areas may be selected based on the past appraisal results (if applicable), oversight observations, operational feedback, risk based targeting, and appraisal coverage considerations.

Interviews are used to gather data from appraisal participants and to understand process implementation issues not resolvable during document reviews. The interviews are planned following the document review and questions are scripted to resolve the issues not resolved by the document review. Additional documents may be requested during the interviews as they are identified in response to interview questions. These may be procedure or process documents or records of activity performed.

Process Observation is a form of interview where the focus is on the process being performed. This allows the understanding of how tools or other resources fit in the process and support process objectives. Process observation also supports evaluation of how the processes are working from an observer's perspective rather than only from the participant's perspective that the interview provides. During process observation, documents reflecting process artifacts or records may be requested and be reviewed as part of the site visit activities.

Consolidation of Data:

The evaluation team gathers and sorts their individual observations into organization-wide observations. These should represent the consensus of the evaluation team and identify whether the observations (good and bad) are systemic, or localized. Observations should be backed up with artifact evidence such as interview notes, documents, and etc. as appropriate.

Development of Ratings:

The appraisal team will produce a Process Capability Profile (PCP). The capability rating of each process is determined by establishing the extent to which the appraised organization meets the goals of each process and capability level within the scope of the appraisal. These capability ratings together constitute the process capability profile. A maturity rating can then be derived from the profile. There are seven steps for development of ratings:

1. **Determine the Classification of the Process Goal**

   Review each goal for each process. Classify and record that goal as:

   - Not Rated
   - Not Applicable
   - Satisfied
   - Satisfied with Insignificant Weakness
   - Unsatisfied

2. **Determine the Classification of the Process Implementation**

   Review the process goal classifications for each process. Classify and record that process as:

   - Not Rated
   - Not Applicable
   - Implemented
   - Not Implemented

3. **Determine the Classification of the Capability Level Goals for the Process**

   For each implemented process, review each capability level goal. Classify and record that goal as:

   - Not Rated
   - Satisfied
   - Unsatisfied

4. **Determine the Institutionalization Classification (Capability Level) for the Process**

   Review each process implementation classification and its capability level goal classification. Classify and record the process as:

   - Not Rated
   - Not Applicable
   - Institutionalized at level (X)

5. **Check for Consistency**

   Compare the capability rating with the strengths and weaknesses of each process to ensure consistency

6. **Develop the Process Capability Profile**

   Chart each process capability level (0-5) or classification to create the process capability profile. This is a chart showing the results of the appraisal rolled up into a graphical form. A sample is shown below.

Process Capability Profile

LEVEL 2			Activities Performed				
Key Process Area	**KPA Rating**		**1**	**2**	**3**	**4**	**5**
PA 11 Project Management			S	S	S	S	S
PA 12 Supplier Agreement Management			S	S	S	S	S
PA 02 Requirements			S	S	S	S	
PA 08 Evaluation			S	S	S		
PA 09 Deployment, Transition, and Disposal			S	S	S	S	S
PA 05 Outsourcing			S	S	S		
PA 15 Quality Assurance & Management			S	S	S	S	S
PA 16 Configuration Management			S	S	S	S	
PA 18 Measurement and Analysis			S	S	S		

Legend:

S	= Satisfied
SW	= Satisfied with Insignificant Weakness
US	= Unsatisfied
NA	= Not Applicable

LEVEL 3			Activities Performed				
Key Process Area	**KPA Rating**		**1**	**2**	**3**	**4**	**5**
PA 00 Integrated Enterprise (CDO) Management			S	S	S		
PA 11 Project Management (CDO certification project)			S	S	S	S	S
PA 12 Supplier Agreement Management			S	SW	S	S	S
PA 13 Risk Management (Safety Risk and Risk of Non-compliance)			S	S	SW	S	
PA 14 Integrated Teaming (applicable only to team arrangements, teaming implies groups formed from multiple lines of accountability)			S	S			
PA 01 Needs (Compliance and safety related)			S	S	S	S	
PA 02 Requirements			S	US	S	S	
PA 03 Design			S	S	S		
PA 06 Design Implementation			S	S			
PA 07 Integration			S	S	S		
PA 08 Evaluation			S	S	S		
PA 09 Deployment, Transition, and Disposal			S	S	S	S	S
PA 10 Operation and Support			S	S	S		

PA 04 Alternatives Analysis		S	S	S			
PA 05 Outsourcing		S	S	S			
PA 15 Quality Assurance & Management		S	US	S	S	S	
PA 16 Configuration Management		S	S	S	S		
PA 18 Measurement and Analysis		S	S	S			
PA 20 Process Definition		S	S	S			
PA 21 Process Improvement		S	S	S			
PA 22 Training		S	S	S			
		S					

Legend:

S	= Satisfied
SW	= Satisfied with Insignificant Weakness
US	= Unsatisfied
NA	= Not Applicable

LEVEL 4		Activities Performed				
Key Process Area	**KPA Rating**	**1**	**2**	**3**	**4**	**5**
		NA	NA	NA	NA	NA

Legend:

S	= Satisfied
SW	= Satisfied with Insignificant Weakness
US	= Unsatisfied
NA	= Not Applicable

LEVEL 5		Activities Performed				
Key Process Area	**KPA Rating**	**1**	**2**	**3**	**4**	**5**
PA 23 Innovation		NA	NA	NA		

Legend:

S	**= Satisfied**
SW	**= Satisfied with Insignificant Weakness**
US	**= Unsatisfied**
NA	**= Not Applicable**

7. **Determine the Maturity Rating**

A maturity level rating is determined from the capability level ratings.

Appraisal Report:

A preliminary report is prepared and reviewed with the organization being appraised so that they may identify errors or omissions in the observations. The conclusions are then used with the criteria from the appraisal guidance (derived from FAA iCMM guidance and regulatory requirements) to determine compliance with regulatory requirements. This compliance is documented in the appraisal report along with the observations and any specific findings of non-compliance. The appraisal report is briefed to the organization that has been appraised and the oversight team. The appraisal report is filed with the artifacts collected during the evaluation in the records kept for the CDO by the oversight team.

The applicant company is strongly advised to self-appraise using the iCMM appraisal methodology before applying and subsequently being externally appraised by the certificating agency (FAA).

Further information on the FAA iCMM and the appraisal methods are contained in the following documents:

- FAA iCMM Version 2.0
- FAA iCMM Version 2.0 Frequently Asked Questions (FAQ)
- FAA-iCMM Appraisal Method (FAM) Version 2.0

Appendix J.
Proposed NPRM

[4910-13]

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 13 and 21

Docket No. FAA-_____; Notice No. _____

RIN 2120-_____

Certified Design Organization (CDO) Procedures

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action implements section 227 of Vision 100-Century of Aviation Reauthorization Act of 2003 by proposing requirements for a new Certified Design Organization (CDO) certificate and the applicable regulations. These organizations design and produce aviation products, parts, and appliances, and would be authorized by the FAA to certify that they meet regulatory requirements.

This action is necessary to align FAA certification processes with the high level of maturity and capability of some design organizations. Also, there is no expected corresponding increase in FAA resources to offset the forecast growth in demand for aviation products and services.

This proposal promotes safety through a new systematic approach for FAA certification of aviation products, parts, and appliances, recognizing the safety and compliance processes within design organizations.

DATES: Send your comments on or before [Insert date 120 days after date of publication in the Federal Register].

FOR FURTHER INFORMATION CONTACT: For technical questions concerning this proposed rule contact _____. For legal questions concerning this proposed rule contact _____.

SUPPLEMENTARY INFORMATION:

Later in this preamble under the Additional Information section, we discuss how you can comment on this proposal and how we will handle your comments. Included in this discussion is information about the docket, privacy, and the handling of proprietary or confidential business information. We also discuss how you can get a copy of this proposal and related rulemaking documents.

Authority for this Rulemaking

The FAA's authority to issue rules on aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart iii, Section 44704(e) Design Organization Certificates. Under that section, the FAA is authorized to issue regulations that implement a system for the certification of design organizations to authorize the organization to certify compliance with the requirements and minimum standards prescribed under section 44701(a).

This rulemaking fulfills the statutory authorization for the legislation embodied in the Vision 100-Century of Aviation Reauthorization Act of 2003**.**

Authority for this particular rulemaking is derived from_____.

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C. The Role of the FAA

D. CDO Concepts and Principles

E. Accountability Framework

F. Systematic Approach to Compliance and Safety

V. Section-by-Section Discussion of the Proposed Regulatory Requirements

I. Glossary of Terms

ACCOUNTABILITY FRAMEWORK: An established set of responsibilities and commitments of the FAA and industry.

CDO EXECUTIVE: The company individual directly responsible for ensuring that the CDO meets all of its regulatory responsibilities.

CERTIFICATE MANAGEMENT: FAA actions for monitoring the CDO certificate holder and to determine the holder's compliance with the provisions of its certificate(s).

COMPLIANCE ASSURANCE SYSTEM: CDO holder’s system for ensuring that it complies with the applicable regulations.

CULTURE OF COMPLIANCE: Knowledge, beliefs, attitudes and behaviors of an organization that are focused on ensuring regulatory compliance within all its activities.

DETERMINATION OF COMPLIANCE: A decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. 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.

ELIGIBLE DATA: Data developed under an approved CDO system, assuming a specified, but not FAA-established, certification basis, and product type design if appropriate.

FAA OVERSIGHT TEAM: FAA personnel assigned to provide guidance and compliance oversight of the CDO in meeting its regulatory requirements.

FINDING OF COMPLIANCE: FAA decision that the applicable regulatory requirements/standards have been met.

QUALITY MANAGEMENT SYSTEM - A set of interrelated or interacting quality processes accomplished by the organization through the establishment of policy and objectives, and achieving those objectives.

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.

SENIOR COMPANY MANAGEMENT: Those in the company management chain above the CDO executive who are accountable for the actions of the CDO.

STATEMENT OF COMPLIANCE: A statement from the CDO to the Administrator certifying that compliance with the applicable regulatory requirements has been determined and the procedures listed in its FAA-approved CDO Procedures Manual have been followed.

II. Acronyms

ARC	Aviation Rulemaking Committee
CAA	Civil Aviation Authority
CAS	Compliance Assurance System
CDO	Certified Design Organization
CFR	Code of Federal Regulations
CMM	Capability Maturity Model
DAR	Designated Airworthiness Representative
DAS	Designated Alteration Station
DER	Designated Engineering Representative
DMIR	Designated Manufacturing Inspection Representative
DOA	Delegation Option Authorization
DPE	Designated Pilot Examiner
FAA	Federal Aviation Administration
FIS	Fabrication Inspection System
ICA	Instructions for Continued Airworthiness
ICAO	International Civil Aviation Organization
iCMM	Integrated Capability Maturity Model
ODA	Organization Designation Authorization
ODAR	Organizational Designated Airworthiness Representative
PAH	Production Approval Holder
PMA	Parts Manufacturer Approval
QMS	Quality Management System
SFAR 36	Special Federal Aviation Regulation Number 36
SMS	Safety Management System
STC	Supplemental Type Certificate
TC	Type Certificate
TSO	Technical Standard Order
US	United States
USC	United States Code

III. Background

A. Reauthorization Act of 2003

In the *Vision 100-Century of Aviation Reauthorization Act of 2003*, the U.S. Congress authorized the Federal Aviation Administration (FAA) to develop and oversee a system for the certification of design approval applicants or holders, referred to as a Certified Design Organization, or CDO. In accordance with Section 227 of the Reauthorization Act, a CDO will be authorized to *"certify compliance with the requirements and minimum standards prescribed under Title 49 USC (Title 49) 44701(a)."* The FAA may then, at its discretion, *"rely on certifications of compliance by a design organization when making a finding"* for the issuance of a certificate.

This proposed rule enables the FAA to issue a CDO certificate when the FAA determines *"whether the design organization has adequate engineering, design, and testing capabilities, standards, and safeguards to ensure that the product being certified is properly designed and manufactured, performs properly, and meets the regulations and minimum standards prescribed under section 44701(a)."* When a CDO certificate holder completes all activities necessary for the issuance of a design approval, it would be allowed to submit to the Administrator a statement of compliance indicating that the product, part, or appliance complies with the applicable certification requirements.

Historically, the FAA has determined the amount and extent of the compliance data that it needed to review before it issued a design approval. That program-by-program decision was based on an assessment of what data were critical to establishing the airworthiness of the design approval. The FAA's goal has been to tailor its review to maximize the safety benefits of its oversight, which is consistent with the statutory discretionary authority it has when conducting oversight of the industry it regulates. By setting high standards for the issuance of a CDO certificate, the FAA will be able to place more reliance on the certificate holder's system for demonstrating compliance with applicable FAA requirements.

B. The Enabling Legislation

Section 44704 of Title 49 authorizes the issuance of Design Organization Certificates. That regulation specifies that the *"Administrator may issue a design organization certificate to a design organization to authorize the organization to certify*

compliance with the requirements and minimum standards prescribed under section 44701(a) for the type certification of aircraft, aircraft engines, propellers, or appliances." The FAA may issue a CDO certificate to any qualified design organization to certify compliance with the requirements and minimum standards prescribed in the Federal Aviation Regulations.

C. Aviation Rulemaking Committee

On May 22, 2006, the FAA Administrator chartered an Aviation Rulemaking Committee (ARC) to assist the FAA in developing the CDO program. The committee consisted of a cross-section of members of the civil aviation community and FAA personnel. The ARC was tasked with making recommendations, including proposals for rulemaking, suggested processes, policies, and guidance that would serve as the foundation of the program. The ARC discussed principles, guidance, and recommendations that the members of the committee considered relevant to the implementation of the CDO concept. The ARC's report and its associated recommendations form the basis for the majority of the material in this notice. A copy of its report is included in the public docket for this rulemaking.

D. The Case for CDO

Today, the flying public enjoys an unprecedented level of safety as a direct result of the design certification, production, maintenance, and operational approaches used today by industry and the FAA. The last decade in particular has brought about a substantial increase in safety – almost a 5-fold reduction in air carrier accidents. FAA and industry co-operation, the use of structured data and analysis, and the shared commitment to safety have all played a part in this success. This has been accomplished, in part, with advances in technology and improved processes for the design certification, production, maintenance, and operation of aviation products.

The FAA has also increasingly recognized industry's expertise and resources in creating its system of individual and organizational delegations. A brief chronological outline showing the history of the FAA's delegation system follows:

- 1940's - DER, DMIR, DPE, etc. individual designees
- 1950's - DOA organizational delegations for small airplanes, propellers, and engines

- 1958 – Federal Aviation Act reaffirms delegation
- 1960's - DAS organizational delegation for repair stations
- 1970's - SFAR 36 authorizations for operators
- 1980's - DAR individual designees
- 1990's – ODAR organizational delegations
- 2006 – ODA organizational delegations for all products and organizations; replaces DOA, DAS, ODAR, and SFAR 36

Industry growth has far outpaced FAA's growth in resources, and reliance upon designees or delegated organizations to make discrete findings of compliance with regulatory requirements has become a common and necessary tool the FAA has used to leverage its resources.

The CDO concept is intended to build on this legacy of cooperation between industry and the FAA. It is a natural step toward more FAA reliance on industry compliance expertise for those companies within the industry that can demonstrate they have the competency, capability, and organizational maturity to meet the CDO requirements. This will allow FAA resources to focus more intensely on critical safety issues, technology development, and identification of important precursors necessary to prevent safety mishaps.

While aviation technology has been maturing over the last century, the relationship between the FAA and industry has also been maturing. The industry has assumed more and more of a role in facilitating FAA's finding of compliance (e.g., organizational delegation), in addition to its responsibility of having to comply with the regulations. For decades, the aviation statutes and regulations have contained the provisions for delegation to both individuals and companies, and have also allowed FAA to rely on industry expertise through non-delegation concepts, such as TSO authorization.

CDO parallels delegation where the industry resources acting under FAA-delegated authority have determined compliance with FAA requirements. Industry, operating within the delegation systems, has demonstrated that it can meet the requirements necessary to provide the FAA with the confidence that it can properly carry out the responsibilities associated with its authorized functions. In the delegation model, FAA has the ultimate responsibility for the oversight of its designees' performance. Similarly, the FAA will

retain ultimate responsibility for oversight of the CDO performance of its approved system, with the full authority to participate, assess, review, audit, or in other ways determine the health of that system, and the products and processes that result.

The FAA and industry joint challenge for the future is to continue the unprecedented safety improvements of the last decade, given the anticipated growth in aviation for the foreseeable future. Simply stated, the current safety trend must continue or there may be an unacceptable increase in the number of safety incidents and accidents. The level of safety the public has come to expect will be challenged not only by this growth, but also by the effects of new technology, acute global competition, and global engineering and manufacturing. These challenges will also impact the FAA. History shows 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 its resources.

The FAA has an Internet web site (http://www.airweb.faa.gov) that contains its regulations, policy, guidance material, and documents that describe the basis for its decisions. The availability of these documents has enabled the industry to be more aware of FAA safety objectives, practices, and procedures. This also enables the industry to ascertain more quickly, and with more certainty, that they comply with the regulations. The FAA website also enables FAA to readily provide guidance to industry on its compliance expectations, so it can better focus its resources on emerging technologies and critical safety issues; this, in turn, enables the FAA to focus more of its activities toward identifying and eliminating the precursors of safety mishaps.

The CDO concept, then, takes advantage of the experience gained from the use of FAA delegation systems and interactions with industry, so that, with FAA oversight, greater confidence can be placed on industry systems and procedures that ensure compliance. This strengthened confidence in documented industry systems and procedures to show compliance with safety regulations and standards enables the FAA to propose this new CDO concept. This confidence is the hallmark of the CDO concept that is defined within this rulemaking. This rulemaking defines how the CDO concept would be applied within the FAA regulatory framework

IV. General Discussion of the Proposal

The management of regulatory responsibilities through the issuance and oversight of certificates (i.e., pilot, airworthiness, air carrier, repair station, production certificates) has existed and been successful for decades. The concept of a design organization certificate has also existed for at least two decades. Given (1) recent statutory changes authorizing CDO; (2) the increased availability of FAA information concerning regulatory compliance; (3) the rapid pace of technological change and growth in aviation; and (4) globalization and increasing industry capabilities; the FAA recognizes that it is time to develop the CDO concept into a workable program. As validation of this conclusion, the CDO concept is very similar to systems of this type currently in use or being developed by other competent aviation authorities.

A. CDO Enhances Compliance by the Industry

The current process of obtaining a design approval places no requirement on the applicant to establish a system of documented processes and procedures to show compliance. This makes the certification process highly resource-intensive for the FAA to deal effectively with the variety of applicant capabilities that exist. Even with discrete findings of compliance made by a designee or directly by the FAA as steps in the process of bringing a product to market, there still exists a possibility that something will be missed. With CDO, the design organization operates in accordance with its own processes and compliance assurance system, which are FAA approved. If non-compliance is found by the CDO or by the FAA, the CDO compliance assurance system is subject to review and change. The design organization 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 FAA.

Under CDO, the establishment and determination of compliant designs will be made through a compliance assurance system (CAS) that is embedded within the company, with appropriate internal checks and balances to ensure it is functioning properly. Organizations must be fully knowledgeable about what constitutes compliance and have a thorough understanding of the regulatory requirements. They must incorporate design and quality systems so that compliance is "designed into" the product along the path toward certification. Then, 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 CDO 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 the assurance that compliance with the requirements has been established by the applicant. The FAA will be able to rely on this increased assurance when making its finding for the issuance of the certificate, rather than requiring FAA's direct involvement in making discrete findings.

In addition to the CAS, the CDO is subject to requirements for a safety management system (SMS) and a quality management system (QMS). This systematic approach to the engineering certification process coupled with CAS and enhances the organization's overall ability to consistently perform the compliance assurance function, and to identify and correct problems that may arise. These three system requirements are further explained elsewhere in this notice.

B. CDO is not Self Certification

Under CDO, all determinations of compliance within the certificate holder's authority will be made by the CDO organization. This does not mean that CDO is self-certification by industry. The FAA will retain the right to review, audit, and otherwise oversee the operation of the CDO while it makes compliance determinations, as well as after the FAA has issued design, airworthiness, and production certificates, and other design approvals. That retention of oversight and the continued FAA issuance of type certificates and other approvals differentiate this from any self-certification process.

C. The Role of the FAA

Historically, there has been a shared safety responsibility between the FAA and the industry it regulates. The sole responsibility for complying with FAA regulations has always resided with the industry, and will remain so under CDO. This responsibility is described in a Supreme Court ruling [United States v. Varig Airlines, 467 U.S. 797 (1984)], which noted:

> *"The FAA certification process is founded upon a relatively simple notion: the duty to ensure that an aircraft conforms to FAA safety regulations lies with the manufacturer and operator, while the FAA retains the responsibility for policing*

compliance. Thus, the manufacturer is required to develop the plans and specifications and perform the inspections and tests necessary to establish that an aircraft design comports with the applicable regulations; the FAA then reviews the data for conformity purposes by conducting a "spot check" of the manufacturer's work."

In this case, the Court ruled that the FAA does not ensure or insure safety; it only promotes safety through its high safety standards. It further ruled that the FAA has discretion to review industry compliance to the degree it deems necessary in the public interest. Except where statutes direct otherwise, the FAA is free to choose what it wishes to review and how it wishes to do so.

As discussed previously, the FAA has augmented its resources through the use of designees. Private individuals and organizations have been delegated the responsibility to "find" compliance on behalf of the FAA. The FAA has the authority to decide in what aspects of a project it wants to be involved, whether to delegate its involvement, and, if so, to whom. The FAA has tailored its delegation programs to ensure that critical safety oversight remains the sole responsibility of the FAA.

CDO is the next logical step in that it allows the FAA to rely upon demonstrated industry competencies and processes (rather than FAA designees) to determine compliance with FAA requirements. The ability of the CDO to submit a statement of compliance is a privilege of the certificate; it is not a delegation. The FAA approves the design organization's systems and processes that enhance regulatory compliance, and oversees the organization in its adherence to these systems and processes. The FAA's process for certifying the design organization, coupled with a strong oversight system, gives the FAA the assurance that it can rely on the compliance determinations made by the design organization.

The CDO concept does change the FAA's involvement in the certification process; however, key aspects remain the same, specifically:

- The FAA retains sole responsibility for the issuance of safety regulations, establishing the certification basis for aeronautical products, and development of special conditions necessary during certification programs to ensure that novel or

unusual design features of a product meet a level of safety equivalent to that established in the regulations.

- The FAA also retains the sole responsibility for the issuance of equivalent safety findings and exemptions, and the approval of acceptable means of compliance for products in accordance with issued safety regulations.
- The FAA retains the authority to conduct audits of the CDO, including compliance with safety regulations, and the processes contained or referenced in the CDO procedures manual.
- In addition, the FAA will continue to issue all certificates and original design approvals.

D. CDO Concepts and Principles

CDO is a new concept for the FAA to exercise its responsibility for the design approval of aviation products, parts, and appliances, their production, and continued operational safety. It is not a delegation in any sense of the concept as defined in §44702(d) of Title 49 and FAA regulations that have implemented that statutory authority. It is a certificate, as defined in §44704, and is subject to the full oversight of the Administrator under §§44709 and 44711. The authority of the CDO to perform authorized functions, such as making determinations of compliance, is a privilege of its certificate.

Under CDO, the determinations of compliance are the result of actions by numerous individuals within the CDO carrying out the processes established to ensure compliance with the requirements, rather than through specified company individuals acting on behalf of the FAA. Simply stated, CDO is not a separate entity within the certificate holding organization; it is the entire organization. The CDO concept necessitates a highly structured "culture of compliance" within the organization such that compliance is a result of every task of design, production, and airworthiness certification. It is a result of committed executive leadership and oversight and, at the same time, an individual commitment to doing the assigned task in accordance with the strong corporate value placed on compliance and safety.

With compliance established through adherence to process, the CDO system may include compliance through supplier processes. This will support the globalization of aviation design, production, and airworthiness certification. This globalization trend is

expected to continue as aviation makes use of global talents and capabilities to keep up with its anticipated growth.

E. Accountability Framework

The foundation for development of the CDO program, as with any design certification program developed by the FAA, must be an accountability framework that begins with congressional statutes, as applied through FAA regulations that establish clear roles and responsibilities between 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.

This accountability framework clearly distinguishes the roles and responsibilities of both industry and FAA. The basic precepts of the accountability framework are summarized below:

1. **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.
2. **Applicants for a design approval have a regulatory obligation to:**
    - Use means of compliance acceptable to the FAA.
    - Show that their designs are compliant.
3. **Applicants for a production approval have a regulatory obligation to:**
    - Establish a quality control system or fabrication inspection system.
    - Demonstrate they can produce products that meet the approved type design.
4. **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.

F. Systematic Approach to Compliance and Safety

The requirement for the CDO to have a systematic approach to compliance and safety is based on the need to have consistent performance that can be overseen and managed on the basis of demonstrated capability. This is accomplished by using defined procedures implementing:

- a compliance assurance system,
- a quality management system, and
- a safety management system.

The systems implemented at a particular CDO may have different names, or the functions of these systems may be arranged differently within company processes and procedures, but as long as the regulatory objectives are met and there are clear lines of accountability, the CDO will be in compliance.

Procedures that will be used to comply with CDO requirements must be contained in an FAA-approved CDO procedures manual. The manual must include those details necessary to ensure that the regulatory requirements are met and must be sufficient for the FAA to make that determination.

The CDO procedures manual is intended to be a top level document that will guide the development of lower level processes and work instructions that the CDO 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. Non-compliance with any procedure contained or referenced in the procedures manual may result in enforcement action.

Internal company procedures that are not required to show CDO regulatory compliance would not be referenced in the procedures manual and would not be audited by FAA as part of its CDO oversight.

The **compliance assurance system (CAS)** is intended to provide adequate confidence that a design is compliant with all applicable regulations and has no unsafe features. Development of a suitable CAS allows the FAA to rely on the statement of

compliance made by the CDO holder when the FAA makes its overall finding of compliance concurrent with the issuance of a certificate.

This proposed rule would allow the development of a performance-based system that may be appropriately scaled to the organization, as long as the regulatory objectives are met. The goal is for the CAS to be as effective as a skilled independent check.

The CAS described in this proposed rule establishes top level objectives that must be met, but it does not specify explicit implementation methods or organizations that must be established to meet the requirements. This allows scaling of the CAS to the organization and designing a system that best fits the organizational structure and culture. Any FAA review of compliance determinations by the CDO will be accomplished through FAA oversight of the CDO organization.

The **quality management system (QMS)** must have processes in place to accomplish the following objectives:

- Process assurance: Those activities that are accomplished to provide confidence that the defined processes are adequately documented and are being followed.
- Closed-loop corrective action: The process by which adjustments are made to the processes when deficiencies are identified; it includes root cause identification of the deficiency and follow up activity to measure the effectiveness of corrective actions.
- Internal audits: Those checks that the organization conducts to confirm compliance with the existing processes, and that those processes perform their intended function.
- Configuration management: the activity taken to control process changes, and products that result from application of the company methods and processes.
- Verification of personnel qualification: Activity accomplished by the organization to ensure that the personnel hold the qualifications identified for the activities they perform.
- Management review: Management oversight of the quality system to ensure the quality system remains suitable and effective

The **safety management system (SMS)** requirements provide a set of objectives for a CDO applicant to meet when establishing a compliant SMS for their organization. This will improve the practice of safety management by moving to a more process-oriented system safety approach that stresses not only application of technical standards, but an increased emphasis on risk management and safety assurance. The SMS is intended to be a proactive approach to identifying risks, their potential consequences, and corrective actions. This is in addition to the traditional reactive approach to safety events. The SMS must be approved by the FAA and any actions taken or not taken by the CDO as a result of its compliance with approved SMS procedures are considered to be proper actions by the certificate holder

For QMS and SMS, compliance with the proposed rule would be shown through the CDO developing and implementing systems that meet the regulatory objectives of the proposed rule. The CAS is designed to allow alternative methods for the showing of compliance, but those methods must result in an FAA-agreed compliance with the regulatory requirements. For QMS and SMS the FAA does not intend to measure compliance by its agreement with the detailed outcomes of these systems. However, the CAS must produce outcomes that the FAA finds to be compliant, whether that finding is concurrent with the issuance of a design approval or as part of FAA oversight. Should the FAA at any time determine that any system is not in compliance with the regulatory requirements, the FAA may take whatever action is available to the FAA under issued statutes and regulations, that it determines appropriate to correct that deficiency.

V. Section-by-Section Discussion of the Proposed Regulatory Requirements

14 CFR Part 13 – Investigative and Enforcement Procedures

Section 13.19 Certificate action

This section codifies the authority of the Administrator under 49 U.S.C. §44709 to re-inspect any civil product, appliance, air navigation facility, or air agency certificate. Under this section, the Administrator may issue an order amending, suspending, or revoking all or part of specifically defined certificates. Section 44704(e), authorizing the issuance of CDO certificates, clarifies that the rights of the Administrator found in §44709

also apply to the CDO certificate. For this reason the list of certificates in 14 CFR §13.19(b) would be revised to include the CDO certificate.

14 CFR Part 21 – Certification procedures for products and parts

Section 21.1 Applicability

This section would be revised to add requirements for issuing certificates to design organizations within the scope of part 21.

14 CFR Part 21, subpart P – Certified design organization

This proposal would establish new subpart P to 14 CFR Part 21 for certified design organizations. It would identify the requirements for the issuance of CDO certificates, and any changes to them.

Section 21.701 Applicability of subpart P

This section states that subpart P prescribes requirements for the issuance of CDO certificates, and any changes to them. The subpart would also provide requirements, privileges, and obligations for the holders of those certificates.

Section 21.703 The meaning of terms used in this subpart.

This section indicates how specific terms would be used with respect to the requirements of this subpart.

Section 21.705 Who is eligible to apply

There are several criteria that must be met for an applicant to apply for a CDO certificate. Essentially any person, as defined in part 1 of 14 CFR, may apply for a certificate, including a consortium of companies. Proposed §21.725 addressing compliance assurance systems, would require the CDO to have a system for determining compliance with a high degree of assurance, consistent with what would result from an independent review of compliance. While it is not precluded by this section, it is hard to conceive of a situation where an individual person could establish a system of checks and balances necessary to meet the requirements for the issuance of a CDO certificate.

An applicant would be required to demonstrate the ability to manage all activities necessary to fully determine compliance under the CDO concept, for the scope of the certificate being sought. The FAA considers that only through having previously obtained a design or production approval of the scope being applied for under CDO, can the FAA be

assured of the capabilities of the applicant. Those approvals must have been sought and issued under the FAA domestic certification process and the US must be the State of Design or State of Manufacture, for the issued design approvals or production certificate activities, respectively. It is also important for the CDO applicant to be experienced, so it would be required to hold a design approval of the scope it is seeking under CDO. Many of the proposed obligations of a CDO certificate holder deal with the ability to perform continued operational safety responsibilities, so holding a design approval is essential for the FAA to make a determination that the applicant can perform those responsibilities after a CDO certificate is issued. Accordingly, an applicant would not be permitted simply to purchase an approved design and apply for a CDO to cover the scope of activities inherent in that design approval. The FAA must have observed the performance of the applicant in:

- obtaining and holding a design approval,
- maintaining that approval including properly accomplishing its continued operational safety responsibilities, and
- obtaining and holding a production approval, if the applicant is seeking to include production activities under the oversight of its CDO.

For a consortium to be eligible for a CDO certificate, the consortium would be required to meet the definition of a "person" in 14 CFR part 1. It would also be required to demonstrate that the consortium operates as one entity with regard to its CDO responsibilities. If one or more of the consortium members is a CDO certificate holder, they would be permitted to use their own unique processes and procedures to support the consortium CDO certificate, provided the consortium CDO has determined that these processes and procedures meet the consortium CDO requirements. In its simplest form, the consortium processes and procedures could be comprised of individual member processes and procedures approved under their individual certificates. In all cases, the consortium would be responsible for demonstrating that the individual company processes and procedures, taken as a whole, are in compliance with the consortium CDO requirements and are properly integrated.

If the consortium is not a CDO certificate holder, but one or more of its members hold a CDO certificate, determinations of compliance made under a member's CDO certificate would be permitted to be used by the consortium without any further FAA

approval. The consortium would be required to establish the validity of those CDO determinations of compliance for the program/project on which they are to be used. This acceptable use of consortium member CDO determinations of compliance is an exception to the requirement in proposed §21.721 that a CDO may not use its certificate privileges to make determinations of compliance on third-party programs.

To qualify for a CDO certificate, the applicant would be required to have previously applied for, received, and currently hold a design approval for the scope of activities for which it desires a CDO certificate. If taken literally, this could be an impediment to consortiums obtaining a CDO certificate, as a consortium is usually created for one product, or a limited number of products. The FAA considers that, in the case of consortiums, this qualifying criterion should be assessed using the collective experience of the member companies. For instance, if the members of a consortium meet the qualifying criteria because of their own unique certification activities for large turbofan engines, then a consortium addressing the full scope for a new engine would be able to apply for a CDO certificate. If a foreign company is a member of a consortium and its experience in past programs is being used to help justify the scope of the consortium certificate, then such credit would be possible only if the FAA has issued a design approval to that company demonstrating their capability to contribute to the scope of CDO certificate being sought by the consortium. The FAA also must have previously accepted products, parts, or appliances produced by the foreign member of the consortium, within the scope of the CDO certificate being sought, if that certificate is to include production activities.

It should be noted that, as proposed in this notice, the FAA would not issue a CDO certificate for production certificate activities only. Any certificate that includes production may only be issued to the holder of the design approval with which that production is associated.

Section 21.707 Scope of a CDO certificate

This section defines the scope of certificates that would be issued under the CDO concept. A CDO certificate may cover:

- type certification activities,
- supplemental type certification activities,
- activities leading to the issuance of TSO authorizations or PMAs, and

- activities associated with a production certificate.

Within each of these broad categories the FAA may find it necessary to further limit the scope of activities that might be accomplished by a particular CDO. For instance, 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 type certificate. For this reason, the FAA may restrict a CDO certificate to each separate part in this subchapter that contains product airworthiness requirements, such as 14 CFR parts 23, 25, 27, 29, 31, 33, or 35. The FAA does not intend to issue a CDO certificate with Part 26 as its sole scope.

The FAA may further limit the scope of CDO certificate activities within a given part of 14 CFR. For instance, it is likely that a manufacturer would only have the experience necessary to properly comply with CDO requirements for a particular range of 14 CFR part 25 airplanes for small transport airplanes, but not large transport airplanes; or 14 CFR part 33 reciprocating engines, but not large turbofan engines. The FAA may use other parameters it determines to be necessary to further limit the scope of a CDO certificate. The intent is to allow the widest scope of certificate that the applicant has been able to demonstrate, and that the FAA is able to determine complies with the requirements of this subpart.

In the case of supplemental type certificates, the scope of the CDO certificate would 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 part (part 23 structures, for instance), or the complexity of the product (large turbofan engines, for instance), or by other generic parameters that the FAA determines to be appropriate.

In the case of TSO authorization holders, the scope would likely be further limited, based upon the technical capabilities of the applicant. For instance, some companies have broad technical capabilities across many avionics products, while others have expertise in just one TSO area yet possess several different TSO authorizations. In the case of PMA, the scope would likely be tailored to each certificate holder.

When determining an appropriate scope for a CDO certificate, the FAA must ensure that the certificate holder has, and will continue to maintain, the capability to meet all the requirements of this subpart within the scope of its certificate. As part of this

determination, the FAA may consider providing multiple CDO 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 collocated design and production facilities, and the use of common processes and procedures. The scope of any CDO certificate will be clearly defined so that all persons, including other civil aviation authorities, will be able to understand the scope of authority for data that is approved under that certificate**.**

Section 21.709 CDO application procedures

An applicant would be required to apply for a CDO certificate in a manner that the FAA will define in future guidance material. The applicant would be required to identify the certificates it holds and its past design approval experience, in order for the FAA to make a determination of eligibility under this subpart.

The applicant would also be required to submit with its application a self-assessment of its ability to comply with the requirements of this subpart. That assessment must address the processes and procedures necessary for compliance, and the experience gained in implementing them. Not all detailed processes and procedures would need to be implemented at the time of application, but they all must be implemented prior to the granting of a CDO certificate.

When reviewing the CDO processes and procedures, the FAA will use Capability Maturity Model (CMM) principles. There are several existing CMM processes, all of which operate under the basic principle of determining the capability of a company to meet its objectives using processes that have a specific degree of certainty (maturity). The FAA will define the exact process it intends to use in later advisory material, but plans to use the FAA Integrated Capability Maturity Model (iCMM) process it has developed to evaluate suppliers for certain agency acquisitions. In conducting the required self assessment, the CDO applicant need not directly use the iCMM process, but it would be required to provide a bridge between whatever process it uses and the principles embodied in the iCMM process. (See a further discussion of iCMM principles under the discussion material for proposed §21.731.)

Section 21.711 Issuance of the CDO certificate

The FAA would issue the certificate with appropriate limitations in scope when the applicant shows that it meets the requirements of this subpart for that scope.

Section 21.713 Duration of the CDO certificate

The CDO certificate would be effective until it is surrendered by the holder, or suspended or revoked by the FAA. Any suspension or revocation of all or part of a certificate would be in accordance with 14 CFR part 13.

Section 21.715 Transferability of the CDO certificate

The issuance of a CDO certificate is based upon the demonstrated capability of the applicant. For this reason, the FAA would not permit it to be transferred to another person. The purchase of the rights to a product, part, or appliance design covered by an existing CDO certificate would not entitle the new owner to a CDO certificate. A purchase by another person of the organization covered by an existing CDO certificate also would not automatically entitle the new owner to a CDO certificate. If continued operation under a CDO certificate is desired, the new owner must apply for a CDO certificate. In assessing an application by the new owner, the FAA would give credit to processes and procedures it had found acceptable under the previously issued certificate, as long as the new owner demonstrates the necessary ability and commitment to follow them.

Section 21.717 Changing the scope of a CDO certificate

Any requested change to the scope of an existing certificate would require an application from the certificate holder. A change in the category of a type certificate is a change in scope. The CDO certificate holder would be required to assess its capability to operate under the proposed scope and present that assessment to the FAA with its application. The applicant would only need to address the changes to the certificate it already holds and how those changes will be integrated into its existing certificate.

If the new scope involves substantially new processes that have not been previously demonstrated, the FAA would issue a letter of authorization to allow the organization to operate under the proposed CDO procedures until the CDO demonstrates, and the FAA finds, that the CDO is fully capable of operating within the changed scope. Once the new processes and capabilities are demonstrated, the CDO certificate would be amended to

reflect the new scope. If the change in scope is minor, the CDO self-assessment may be sufficient to allow the FAA to expand the certificate scope with no further demonstration.

While the certificate holder would be required to make all determinations of compliance within the scope of its certificate, it would not be permitted to make determinations of compliance within the new scope until the certificate has been revised. The letter of authorization would allow the CDO to exercise its new processes as if it had been granted the expanded scope, but it would be necessary for the FAA to approve all "proposed" determinations of compliance made by the CDO in areas outside its existing scope.

A determination of compliance has been defined as being either a determination of compliance with applicable regulatory requirements or airworthiness standards, or a determination that previously approved data are valid and applicable for their intended application. When operating under a letter of authorization, the CDO would be authorized to submit a statement of compliance encompassing all determinations of compliance. This includes those made by the CDO within its existing scope, the validity and applicability of those "proposed" determinations of compliance approved by the FAA in areas of the expanded scope being sought, as well as the validity and applicability of those related to previously-approved data that also lie within the area of the expanded scope being sought. It would remain the responsibility of the CDO to manage these and all other project management activities when working under a letter of authorization.

Once the FAA is satisfied that the CDO is capable of reliably executing its compliance responsibilities under the changed scope, the FAA would amend the CDO certificate to include the new scope. The FAA will look for proper execution of the changed processes and proper regulatory compliance by the CDO when making its decision to amend the CDO certificate. There is no obligation to complete the FAA assessment within a minimum time limit or number of projects. The FAA may rescind its letter of authorization if the CDO does not promptly satisfy the requirements for obtaining CDO privileges under the new scope. In addition, a letter of authorization should not be used for a one-time expansion of scope or to supplement a lack of capability on a particular project.

Section 21.719 Certifying statement

Under Title 49 U.S.C. §44704(e), a CDO certificate holder is authorized to make a statement certifying compliance (certifying statement) with the requirements and minimum standards prescribed by the Administrator in accordance with §44701(a). This certifying statement is only required when the CDO has completed its design compliance activities and is requesting that the FAA issue a new or amended type or supplemental type certificate, PMA, or TSO authorization.

Certifying compliance is more than just making a statement of compliance, as is the practice when the industry is required to show compliance under part 21. Certifying compliance is a privilege of the CDO certificate and requires a high degree of integrity and assurance that compliance has been achieved.

When the certificate holder makes a certifying statement, it is declaring that it has followed all processes and procedures contained in its procedures manual, and that the product, part, or appliance complies with the applicable airworthiness standards and procedural requirements in part 21. Should that certifying statement be in error or otherwise inappropriate, the certificate holder would be subject to the enforcement procedures of part 13 that apply to false or erroneous statements made by a certificate holder, in addition to sanctions defined in §21.2.

The FAA may rely on the certifying statement made by the certificate holder when the FAA makes its overall finding of compliance leading to the issuance of a new design approval. In implementing this section, the FAA intends to rely on the certifying statement, unless it has reason to question the accuracy or validity of the statement or, in the case of an aircraft type certificate, if it believes that an unsafe design feature exists within the product to be approved. In the latter case, the FAA may review determinations of compliance made by the CDO as it finds necessary to ensure correction of the unsafe condition.

When issuing a CDO certificate, the FAA finds that the certificate holder is qualified to make certifying statements within the scope of its certificate, and has confidence that it can routinely accept those certifications. Should the FAA find a need to assess the appropriateness of certifying statements made by a particular certificate holder, it would also reassess the qualifications of the certificate holder to comply with the requirements in this subpart.

Section 21.721 Privileges granted to a CDO certificate holder

The holder of a CDO certificate would be granted the privilege of making all determinations of compliance within the scope of its certificate. Those determinations of compliance would be required to be supported by sufficient data that demonstrates appropriate regulatory compliance. Neither the FAA nor its designees would make discrete findings of compliance under the CDO concept. Once the FAA has established the applicable airworthiness standards and other basis for approval, the FAA would rely on the CDO to make all discrete determinations of compliance. The FAA will still make an overall finding of compliance associated with the issuance of a type certificate, a PMA, and any determinations associated with the issuance of a TSO authorization. The FAA will continue to issue special conditions, approve alternate means of compliance, grant exemptions, and issue approvals to deviate from TSO performance standards, which it finds necessary and appropriate. As discussed under §21.737, the FAA would have the right to assess and audit the operation of the CDO, including its determinations of compliance.

Similar to what is authorized under §21.95 for minor type design changes, the FAA has determined that the FAA-approved CDO procedures manual is an acceptable method for creating FAA-approved data before submitting any substantiating or descriptive data to the FAA. Once a determination of compliance has been made by the CDO in accordance with its procedures manual, the FAA would consider the type design and compliance data associated with that determination of compliance to be "FAA-approved." On this basis, there is no need to revise any other regulations, policy, guidance, or orders that refer to “approved” or “FAA-approved” data to accommodate the CDO process. The CDO concept does not create any new definition of “data” or “approved data” different from that commonly used under 14 CFR subchapters A through H.

It should be noted that there are situations in which a determination of compliance does not result in approved data. That situation exists whenever a rule, for which the CDO is making a determination of compliance, indicates the FAA will only make a determination that something is acceptable, and not approved. In those cases the determination by the CDO that the rule has been complied with only results in the creation of acceptable data. An example of this situation is the airworthiness standards related to instructions for continued airworthiness (ICA). In the case of the ICA, only the limitations section is approved by the FAA, and the rest of the manual is found to be acceptable to the FAA. In

this case, the CDO certificate holder's determination of compliance under paragraph (a) of the proposed rule would result in the limitations section of the ICA being approved data and the rest of the ICA being data acceptable to the FAA. Another example is the Aircraft Flight Manual for which the regulatory requirements result in both approved and acceptable data.

In addition, the CDO would be authorized to mark or otherwise indicate the FAA-approval of that data, in a manner to be specified in FAA guidance material. The marking of FAA-approved data would be required only when it is intended to be sent or referenced outside of the CDO certificate holder's system.

The CDO certificate would not grant the privilege of creating approved data solely for design approvals that a third party is seeking (see exception for consortiums under §21.705 discussion). The CDO concept is not intended to be another avenue through which third parties can obtain approved data for use on their products, parts, or appliances. The CDO would be permitted, however, to make determinations of compliance -- and thereby create FAA-approved data -- related to the design approvals they hold, for the use of others wishing to repair, maintain, alter, or otherwise modify the design of products, parts, or appliances covered by its CDO certificate. This includes all activities related to:

- continued operational safety,
- the approval of service bulletins,
- the approval of repair data, and
- providing approved compliance data for use by others.

Every holder of a CDO certificate has prototype manufacturing privileges, which include conducting conformity inspections for parts, articles, test setup, and installations. Once a production approval has been issued by the FAA related to the design approval, the CDO certificate holder has the option of conducting certain production activities under its CDO certificate. Those activities must be accomplished in accordance with procedures contained or referenced in the CDO procedures manual. The procedures must conform to the basic tenants of the CDO concept (such as being accomplished under the SMS, QMS, and CMS; being able to establish compliance through procedures; etc.). The privileges obtained by exercising this option are identified in §21.741(l), (m), (n), and (q).

Paragraph (c) of this proposed section would grant the CDO certificate holder the privilege of making all determinations of compliance to maintenance and operational activities associated with type certification. Maintenance aspects are associated with the determination of compliance for instructions for continued airworthiness (ICA) in §XX.1529 contained in 14 CFR parts 23, 25, 27, and 29; §31.82; §33.4; and §35.4. The CDO certificate holder would be required to include procedures for the determination of compliance with those maintenance aspects in its CDO procedures manual.

There are several boards that have been created by FAA's Flight Standards Service to assist in determining the initial operational evaluation of aircraft during a type certification program:

- Flight Operations Evaluation Board (FOEB),
- Flight Standardization Board (FSB), and
- Maintenance Review Board (MRB).

The FAA would continue to initiate and chair those boards, but any associated determinations of compliance to airworthiness standards would be made by the certificate holder, consistent with the privileges in paragraph (a) of this proposed section. Some additional responsibilities associated with the operation of the boards might be assigned to a CDO certificate holder, under Flight Standards' policy, after experience is gained. No rule change would be necessary to implement that policy under the general provisions of §21.721(c). A revision to the CDO procedures manual would be necessary to implement any new guidance.

It is commonplace for a company to develop products, parts, components, processes, and data for use in future type certification, TSO, and PMA programs. If the development is accomplished under the approved CDO system, it could be eligible for inclusion in subsequent designs. It would be inappropriate to consider such development as a compliance determination and the associated data as FAA-approved, since it does not relate directly to a project having an FAA-specified type certification or other approval basis. However, credit may be given for any demonstration of compliance activities accomplished under a CDO certificate. The FAA has created the term "eligible data" to describe the data produced by this kind of activity.

"Eligible data" are data developed under an approved CDO system, given a specified, but not necessarily final, approval basis, and product type design if appropriate. To convert "eligible data" into a completed compliance determination for a particular application, the CDO holder would be required to assess its compliance against the specified approval basis of the product, part, or appliance and, if appropriate, final design in which it is to be used. It would not be necessary to repeat the demonstrations of compliance, provided those demonstrations were appropriate for the final design and its approval basis. Eligible data is intended for use internal to the CDO. No approval or compliance determination would be inferred upon the data if the eligible data is provided for use outside the CDO.

There are additional privileges that the FAA may wish to grant to a CDO holder that are not conveyed through its holding of a CDO certificate. These privileges are not an entitlement, but would be privileges the FAA considers could provide additional benefits to both the holder and the FAA. The FAA may exercise its discretionary authority to grant the following additional privileges to certificate holders who request and comply with the requirements associated with obtaining and maintaining the privileges:

- Allow the holder, or an individual identified by the holder, to obtain a delegation for the issuance of certificates and design approvals, except for the issuance of new model type certificates;
- Allow the holder to participate in the FAA's program for voluntary self disclosure of regulatory and procedural non-compliance by a certificate holder; and
- Allow the holder to make statements of compliance to certification and airworthiness requirements of other importing authorities, on behalf of the FAA, when allowed through bilateral aviation agreements.

The FAA may wish to grant other privileges to CDO certificate holders in the future. Advisory material would be issued by the FAA to identify all additional privileges that may be granted to the CDO

Section 21.723 General responsibilities of a CDO certificate holder

Subchapter C of 14 CFR contains procedural requirements, such as application for a type certificate, conducting tests and analyses, submitting data, and other regulated matters.

Unless specifically mentioned otherwise in section §21.741, all other requirements of 14 CFR Chapter 1 subchapter C would apply to a CDO certificate holder as appropriate. While this could be inferred from the existing requirements, it is restated here for clarity.

The CDO would not be required to comply with FAA Orders, since Orders apply only to the FAA and its designees. However, all of the Orders and much of the guidance material is based upon proven procedures for demonstrating and finding compliance. The CDO applicant and certificate holder would be expected to consider those Orders and guidance material in the development of procedures for its CDO procedures manual. The FAA would determine the acceptability of the CDO procedures by comparing them with the requirements in this subpart, and would not require equivalence to the procedures in FAA Orders and advisory material. However, in working with the FAA in the approval of the type certification basis, acceptable methods of compliance, and equivalent safety findings, the CDO would be expected to follow normal FAA processes defined in advisory materials and FAA Orders, as those are the standard processes for all applicants and are based on internationally accepted principles. Defined processes for making applications for certificates and working under bilateral airworthiness agreements with other States would also be required to be followed to the same degree any other applicant is required to follow them.

The CDO certificate defines the scope of the activities that may be conducted under the certificate. The FAA expects that all activities within that scope would be conducted under the provisions of the certificate. That applies to all legacy products for which the CDO holds a type certificate. The FAA does not intend to allow activities within the scope of a CDO certificate to be conducted under any other non-CDO procedures, such as delegation.

The FAA expects that a single company executive, referred to as the CDO Executive, would be responsible for ensuring that the CDO meets all of its regulatory responsibilities. The FAA would not require that this executive have functional responsibility within the company for all technical and support disciplines encompassed by the CDO certificate. However, the FAA would expect that the CDO executive have the authority to ensure that all the CDO functions operate properly in accordance with CDO processes and procedures. The senior management of the company would be required to

submit a declaration to the FAA prior to issuance of a CDO certificate, indicating their commitment to complying with the CDO requirements. Replacement of the CDO executive, or a substantive change in the responsibilities of that person, would be required to be approved by the FAA before being implemented.

The certificate holder would be required to implement a process for identifying, by title and discipline only, and qualifying the individuals who constitute the minimum management and technical staff necessary to execute the responsibilities of the CDO certificate. These individuals would have to have the appropriate mix of knowledge, skills, and abilities necessary to allow the organization to make a statement of compliance and perform other functions authorized under its certificate. The minimum staff must be able at all times to determine that all the work performed by the CDO, including that accomplished by its suppliers or any temporary resources, is compliant with the requirements of their compliance assurance system. The minimum staff relates only to the staff necessary to make all determinations of compliance, and not the speed with which those determinations can be made. A CDO certificate holder would be able to augment that minimum staff with other resources, as dictated by the project or certification issue.

The FAA recognizes that there may be temporary gaps in the minimum management and technical staff necessary to execute the responsibilities of a CDO certificate because of normal changes in personnel. Such temporary gaps would not invalidate the CDO certificate as long as FAA is notified of those gaps in a timely manner, and CDO determinations of compliance cease in those areas where qualified personnel are temporarily unavailable.

The CDO procedures manual would not need to identify by name all persons having responsibilities to execute the procedures contained in the manual. However, it would have to identify the organizational structure that the CDO intends to use to execute its certificate responsibilities, including the functional responsibilities under each organizational element. If the CDO Executive chooses to authorize others to make a statement certifying compliance under §21.719(a), that authorization must be to specific persons within the company, and those persons would be identified by name and title, in a manner acceptable to the FAA.

With respect to paragraph (d) of this proposed section, a change to the senior company management responsible for CDO would not be a change to the scope of the CDO certificate; that certificate would remain valid as long as the senior company management commits to maintaining the current CDO system. Such changes may warrant further oversight and surveillance of the existing certificate. Additionally, a relocation of the main design facilities, although not a change in scope, could trigger a reassessment of the facility, and possible amendments to the certificate. The FAA encourages early dialogue on such changes to minimize the disruption to the applicant's programs and FAA oversight.

There are many projects that the CDO certificate holder would be permitted to complete without having to notify the FAA, since the CDO would 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 would 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, PMA and TSOA.) The existing required applications will be used to discriminate between those projects that require notification of the FAA and those that do 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 design approval,
- amended type certificates requiring a new model designation,
- new supplemental type certificates, and
- any project that might reasonably be expected to have a revised type certification basis under §21.101.

In all cases, the FAA must be provided access to a record of all compliance activities being performed by the CDO. That could be a hand-written 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. There must be 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 currently 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 involvement.

This complete project listing would provide the FAA with information regarding the CDO's activities and would help guide FAA oversight of the CDO. 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.

The CDO would be expected to develop and implement corrective action plans for all FAA certificate oversight findings. The priority for implementing a resolution to those FAA findings should be commensurate with the potential safety consequences of the findings, and must be acceptable to the FAA. For instance, a finding that would be expected to have a high safety impact should have a high priority for resolution.

The FAA must be provided the access necessary to properly perform its oversight responsibilities. That would require the CDO certificate holder to provide a current physical address for the principal base of operations and contact information so that appropriate responsible parties within the CDO may be readily reached.

Section 21.725 Compliance assurance system required of a CDO certificate holder

The compliance assurance system (CAS) is intended to provide confidence that a design is compliant with all applicable regulations and has no known unsafe features. The CAS enables the FAA to accept the statement of compliance made by the CDO holder when making its overall finding of compliance prior to issuing a certificate. The CAS must provide confidence consistent with a skilled independent check of compliance.

The proposed rule would establish top level objectives that must be met by the CAS system, which is approved by the FAA as part of the procedures manual. In identifying the regulatory objectives to be met, the rule purposely does not identify specific implementation schemes or organizational concepts that must be established. This allows a scaling of the CAS to the size and scope of the organization's CDO certificate, and allows the certificate holder to design systems that best fit how it chooses to comply with the CDO requirements. The proposed rule only identifies certain activities for which processes and procedures must be defined, requirements for qualification and competence verification of

individuals who are a part of the CDO system, and requirements for qualification and verification whenever physical or electronic tools are used.

Section 21.727 Quality management system required of a CDO certificate holder

The quality management system (QMS) requirements within the proposed CDO regulations are intended to ensure that the CDO has defined processes and procedures that meet the requirements to hold the CDO certificate. Under the QMS, audits are intended to provide assurance that the processes defined to meet the CDO objectives are properly documented, controlled, performed, and corrected as needed. The QMS also requires management awareness of the results of those audits. The QMS is intended to ensure that the CDO processes adequately allow for proper supervision of the members of its supply chain. The assurances provided by the QMS program would allow FAA reliance on the performance of all the processes used to show compliance with the CDO requirements.

The proposed rule identifies certain activities within these areas that would be required to be addressed. These activities are:

- self-evaluation to ensure CDO qualification requirements are met,
- surveillance and audits of process and procedures,
- corrective action processes, configuration management and change control of the process documentation,
- verification of personnel qualifications to understand and operate in accordance with CDO processes and procedures,
- management oversight of QMS findings, and
- evaluation of partner, supplier and subcontractor supervision.

The term “supply chain” in paragraph (g) of this proposed section applies to the complete chain of suppliers that are used by the CDO, and includes suppliers of services as well as parts, components, and appliances. The CDO would have ultimate responsibility for the entire chain of suppliers.

Paragraph (d) of this proposed section addresses the need for a configuration management process. This process must ensure that CDO processes and procedures would not be changed without knowing the compliance and safety impact of those changes.

Section 21.729 Safety management system required of a CDO certificate holder

This section defines the essential elements of a required safety management system (SMS). These essential elements, or pillars, provide for a systematic approach to achieving acceptable levels of safety risk. The four pillars of an SMS are as follows:

Pillar 1. Safety Policy. The safety policy element defines the safety program the CDO organization is trying to achieve. It outlines the methods and processes the organization will use to achieve the identified safety process outcomes. The safety program must be guided by a senior management commitment, and an expectation that the organization will incorporate and continually improve the safety outcomes of its business and business processes. The safety program must reflect management's commitment to implementing procedures and processes for establishing and meeting safety objectives that are measurable and attainable, and that support the promotion of a high level of safety performance within the CDO.

The required goal for a CDO safety program is to achieve the level of safety embodied in the applicable FAA safety regulations. For the type certification of products, those are the standards contained in 14 CFR parts 23, 25, 27, 29, 31, 33, and 35. There is no FAA intent to alter the application of existing safety regulations through the imposition of higher standards through CDO safety management system requirements.

Pillar 2. Safety Risk Management. The second element is a process to assess the CDO system design and verify that it adequately controls risk. That risk can be in the form of compliance assurance risk within the system, such as the risk of a non-compliance by a supplier based on the supplier selection and oversight system defined by the CDO, or the risk of non-compliance of the product design.

A formal safety risk management process consists of:

- defining the system of interest to be addressed,
- identifying any hazards integral to or associated with that system,
- analyzing the risk using available tools and processes, and
- then assessing the defined risks.

That assessment involves identifying the possibility and likelihood of risk and comparing that to the level of safety required by the FAA regulations and the goals of the CDO safety policy.

The next step is to implement changes that control, mitigate, or eliminate those risks determined by the CDO to be excessive. Those are accomplished through the implementation of new programs within the CDO, new or revised processes, or changes to the product design.

The FAA recognizes that it may not be possible initially to assess the safety risk of new process that a CDO applicant has developed to implement CDO requirements, as there may be little experience with operating under those processes. The FAA will take that into account when approving initial CDO processes and procedures. Any operational experience obtained under CDO must be used to assess any safety risk associated with revising existing CDO process and procedures.

Pillar 3. Safety Assurance. The validation of system performance, and the effectiveness of implemented risk controls and risk management strategies, occurs under this SMS element. This process continually assesses CDO activity to identify new hazards and to ensure risk controls achieve their intended objectives throughout the system life cycle. New hazards may be those not identified during the SMS process or those that may have been unintentionally introduced by risk controls or other actions. This process includes the assessment of the need for any new controls, or eliminating or modifying existing risk controls that are ineffective or may be unnecessary based on operational data. Every SMS must include a process for continuously monitoring the systems of interest to identify new hazards, or the need to change risk controls or other risk management responses. These monitoring activities apply throughout the CDO system, regardless of whether or not the process is within the CDO or its suppliers. The system implemented to accomplish these activities and control risk is referred to as the "safety system."

Safety assurance must include processes that properly address:

- the gathering of essential information, including from FAA audit findings and comments on previous regulatory compliance issues;
- the analysis of that information in connection with other already gathered information;
- an assessment of the impact of the information on the CDO system; and
- the development of preventive or corrective action when regulatory non-compliances or deviations from the CDO procedures manual are discovered.

Pillar 4. Safety Promotion. Safety promotion includes the actions taken to create an environment where safety objectives can be achieved. Its key objective is a positive safety culture, characterized by an adequate management that actively promotes that safety culture through its leadership. The safety culture is a product of individual and group values, attitudes, competencies, and patterns of behavior that determine the commitment to an organization's safety programs.

In the desired safety culture, persons acknowledge their accountability and act on their individual responsibility for safety. They trust and rely on the organization's processes for managing safety. The environment is characterized by good communication between management and personnel, and people continue to learn and develop through training and coaching.

Some of the attributes that are considered reflective of a positive safety culture are:

- Competent personnel, who understand hazards and associated safety risk, are properly trained, have the skill and experience to work safely, and ensure safe products and services are produced.
- An environment where people are encouraged to develop and apply their skills and knowledge to enhance safety processes.
- Individual opinions are valued within the organization and personnel are encouraged to identify threats to safety and to seek the changes necessary to overcome them.
- Effective communication exists in all directions within the CDO, including a non-punitive environment for reporting safety concerns.
- A just culture that recognizes where disciplinary action may be warranted and there is a commonly understood difference between acceptable and unacceptable actions.
- Adequate resources exist to support the commitment to safety defined in the safety plan.
- A process exists for sharing safety information to develop and apply lessons learned with regard to hazard identification, safety risk analysis and assessment, safety risk controls, and other safety risk management responses.
- The sharing of information related to corrective actions and the result of management reviews is encouraged.

- Safety is a core value of the organization that endures over time, even in the face of significant personnel changes at any level.
- There is a willingness to recognize when basic assumptions should be challenged and changes are warranted, creating an adaptive and agile organization.

Only four of the above attributes are specifically included in the proposed regulation, as the FAA has considered these to be essential attributes. The other attributes may be replaced within the CDO by different factors that contribute to a positive safety culture. Any CDO-unique attributes beyond the four in the regulation must result in actions that "create an environment within the CDO where safety objectives can be achieved and maintained," as would be required under §21.729(d). In other words, the CDO must implement all processes it finds necessary to create the required environment.

The periodic review of processes addressed in paragraph (d)(4) of this proposed section should include an assessment of difficulties associated with the compliance process. Such difficulties would include the lack of clear processes, incomplete FAA guidance, repeated test failures, and unexpected failures to demonstrate compliance. The review process should also include an assessment of FAA feedback on previously conducted risk management processes and other items resulting from FAA oversight of the CDO.

The SMS will generate a significant amount of new data resulting from the CDO assessment of its proprietary processes for making safety and compliance decisions, as well as the service experience with its products, parts, or appliances. This proposed rule does not include any requirement that the data resulting from CDO internal risk or safety assessments be submitted to the FAA. However, the FAA may access the data as necessary to perform its regulatory oversight of the CDO.

Section 21.731 Requirements used to determine capability to operate under a CDO certificate

The proposed requirements for holding a CDO certificate contain specific criteria for various systems and principles that must be implemented. The criteria are not detailed to the point of defining specific process or procedures that must be incorporated within the CDO. Each certificate applicant and holder would be required to design its processes and procedures to meet the regulatory criteria ("what" must be done) using process and procedures that operate best within its company ("how" it must be done).

Industry must have a clear idea of what it must do to comply with the regulations, and the FAA needs to define how it will enforce the regulations. A process has been developed and is currently being used in other venues to address these types of situations where continued organizational capability to comply with requirements must be assessed. That process is called a Capability Maturity Model (CMM), and there are several derivative models that implement the same basic CMM principles. The FAA has developed a series of CMM principles called the Integrated Capability Maturity Model (iCMM). All CMM techniques have several levels by which they characterize an organization's capability to perform process and procedures, and its "maturity" in performing those activities. In accordance with the iCMM principles, the FAA has chosen a "level 3 maturity" and "level 3 capability" as the minimum level for regulatory compliance.

The iCMM material includes descriptors defining the organizational capability and maturity necessary to achieve a "level 3" rating. Those descriptors form the basis for the requirements defined in this section. In doing so, the FAA has chosen not to regulate the iCMM process itself, but to define those principles imbedded within the process against which it will measure regulatory compliance. That leaves the certificate holder free to define whatever measures it believes best fit within its company, for initial and continued assessment of its capability and maturity. If it uses principles different from those of iCMM, then the certificate holder would need to map its principles into those of iCMM so the FAA would be able to perform its regulatory oversight using iCMM, and compare its results with internal CDO audit results. More details about iCMM and how the FAA will use it to measure the initial and continued regulatory compliance will be contained in future advisory material that FAA will issue.

The proposed regulation would require that the CDO certificate holder demonstrate its ability to perform the process and procedures defined and referenced in its procedures manual in a consistent manner. The proper execution of the processes and procedures could not be a matter of chance, nor could any undocumented company process be used, even if they may result in the proper outcome. Compliance with CDO requirements would have to be deliberate, documented, and consistent. Standard processes developed within the company would be required for matters that relate to company-wide objectives and processes, in order to provide the "level 3" CMM rating.

There are likely to be situations where standard processes do not fit well with the compliance and safety activities of a particular part of the CDO organization. In these situations, individual processes may be created. Those individual processes must emanate from the standard processes so as to reflect the intentions of the standard processes. The procedures manual would need to contain defined processes that must be followed when creating these individual processes. The FAA expects that the organization within the CDO that controls the standard process would retain authority over the individual process.

Section 21.733 The CDO procedures manual

The proposed regulations in this subpart identify several items that must be addressed in a procedures manual. The manual would be required to be approved by the FAA and contain all the process and procedures necessary to comply with the requirements of this subpart. Inclusion of specific processes and procedures, and measurement criteria, which demonstrate how the CDO will comply with the regulations, would be required. In addition, the procedures manual would also reference any further processes and procedures that contain the operational details of what must be done to implement those procedures within the company. The FAA would not approve these detailed procedures, but compliance with those procedures would be assessed during CDO certificate surveillance.

The first section of the manual would define the scope of the certificate and its privileges. This section would be considered a part of the CDO certificate.

In addition, the manual would be required to contain processes for making and tracking revisions to the manual, including any FAA requests for change. The FAA and CDO holder should make arrangements for the FAA's review and approval of Procedural Manual changes.

Section 21.735 Records and reports maintenance and retention

A CDO certificate holder would produce two types of required records in the course of exercising the privileges of its certificate:

(1) those related to the processes and procedures identified in the procedures manual that are necessary to comply with the requirements of this subpart; and

(2) those required as part of making determinations of compliance associated with the issuance, amendment, or continued operational safety of type certificates, TSO authorizations, or PMA.

This section proposes specific retention periods for both types of records. Should the CDO certificate be surrendered or terminated, both types of records must be submitted to the FAA. However, a copy of the records described in (2), above, should remain with the design approval holder after their CDO certificate is no longer valid, for as long as they hold those design approvals; they are essential for the design approval holder to continue to meet its regulatory responsibilities.

In accordance with paragraph (a)(4) of this proposed section, the CDO would be required to maintain a record of all determinations of compliance and approved data to enable proper FAA oversight. If FAA-approved data is provided to others outside of the CDO system, in accordance with paragraph (a)(5), the certificate holder must maintain a record of who that data was initially sent to and what data was sent, in case there is a need to notify that party of continued airworthiness issues associated with the data.

Proposed §21.735(b)(2) addresses service difficulties associated with approvals or certificates held by the certificate holder, even if they were issued prior to the person obtaining a CDO certificate. This is included because §21.723(f) would require that all compliance activities be conducted under its CDO certificate. That would include activities associated with legacy products, parts, and appliances.

Section 21.737 FAA oversight of CDO certificate holder

This section would allow the FAA to inspect the CDO facilities, as well as the products, components, parts, and appliances that reside at those facilities, whether completed or not, and all records required to be made and kept as part of the CDO requirements of this subpart. As noted above, this inspection may include records from previously completed projects. Any certificate actions by the FAA resulting from its inspections would be processed in accordance with the provision of part 13.

Section 21.739 FAA determination of no undue burden

The FAA would be required to make a determination of no undue burden if any of the facilities necessary to conduct the operations of the CDO are located outside the United States. The CDO main design and production facilities must be located in the United States.

Section 21.741 Requirements of this subchapter that have different applicability for a CDO

Proposed §21.723(g) would require that the CDO continue to meet all applicable requirements specified under this part that any other applicant for, or holder of, an FAA design or production approval would have to meet, unless otherwise specified. This section specifies those regulations in part 21and part 26 of this subchapter that have different applicability for a CDO than they do for other applicants and certificate holders. That different applicability stems primarily from the fact that the CDO makes all determinations of compliance and, in doing so, must operate in accordance with an FAA-approved CDO procedures manual. The sections requiring explanation are:

Section 21.21 Issue of type certificate – The presumption for delegated organizations is that all compliance records will be retained at the company, with FAA having access to those records when they desire. The records required by §21.21 will be turned over to the FAA when the organizational delegation is terminated, or retained by the type certificate holder under an FAA records retention agreement. This same principle would be applied to a CDO certificate holder.

Section 21.33 Inspection and test –The CDO certificate holder would make all determinations of compliance, and the FAA may rely on those determinations when issuing a design approval. Current §21.33(a) requires the applicant to allow the FAA to make any inspections and tests "necessary to determine compliance." Under the CDO concept, the FAA would not be making detailed findings of compliance that would trigger the application of §21.33(a). The FAA may wish to confirm compliance determinations made by the certificate holder, as a part of its surveillance of that certificate. In exercising its authority to confirm compliance, the FAA would continue the practice of working with the applicant to witness testing it is planning to conduct, or to reach agreement with the applicant on additional testing that the FAA believes is necessary to exercise its oversight responsibilities.

Section 21.35(a)(4) – Even though the flight tests required under §21.35 would be a part of the CDO applicant's demonstration of compliance, the flight test report prepared in compliance with §21.35(a)(4) must include a flight test risk assessment, and the methodology found in FAA Order 4040.26 is considered acceptable. That is because an FAA flight test pilot must be able to conduct certificate oversight activities onboard the

aircraft during the flight tests. The FAA policy does not allow its pilots to participate in or observe any flight testing unless a proper flight test risk assessment has been completed.

Section 21.53 – All compliance testing would be accomplished by the CDO, so there would be no need to submit a statement of conformity to the FAA. The FAA may observe any testing as part of its oversight of the certificate holder.

Sections 21.81, 21.83, and 21.85 – These three sections deal with the issuance of provisional type certificates. Since the CDO would make all determinations of compliance, the certificate holder would not need to submit the referenced reports to the FAA, but would need to make them available to the FAA upon its request. The certifying statements required in each of those sections would be made in accordance with proposed §21.719(a), since those statements deal with the issuance of a type certificate. The FAA would rely on those certifying statements in the issuance of a provisional type certificate to the same degree it does under §21.719(c).

Sections 21.95 and 21.97(a) – The certificate holder would make all determinations of compliance in accordance with its CDO procedures manual, for all changes to a type design. Under proposed §21.721(d) the substantiating data and type design data associated with those changes is FAA-approved. Thus the intent of these sections is met using the CDO procedures manual processes and the privileges afforded the CDO under its certificate.

Section 21.99 – When the FAA finds it necessary to correct an in-service product's unsafe condition, the affected type certificate holder must develop appropriate design changes and submit them to the FAA for approval. The approved changes are then referenced in an FAA airworthiness directive. Under the CDO concept, the determination of compliance for the design changes would be made by the certificate holder, including those associated with an airworthiness directive. The FAA would retain the responsibility for defining the unsafe condition, which forms the basis for determining what design changes are needed. The FAA also would retain the responsibility for establishing the compliance times, inspection intervals, and other such parameters that address the timeliness of the corrective action. Additionally, the CDO certificate holder may make determinations of compliance for changes that it or the FAA finds will contribute to the

safety of the product. The certificate holder would be required to make the compliance and type design data available to the FAA upon its request.

Section 21.113 – The CDO certificate holder would be able to initiate projects and make major changes to its type design without notifying the FAA, except for those changes that would result in a certifying statement being made in accordance with proposed §21.719(a). In accordance with proposed §21.723(i), the CDO certificate holder must maintain a record of all CDO project activity; this would enable the FAA to be aware of all projects and determine if there are any others it wishes to review as part of its certificate management responsibilities.

Section 21.143 – The production certificate quality control data requirements may be included or referenced in the CDO procedures manual and would not need to be submitted as a separate document to the FAA for approval. When including it in the CDO procedures manual, the scope of the procedures in §21.143(a)(1) through (a)(6) would be required to be addressed. Inclusion of the supplier delegation information requirement of §21.143(b) would also be required.

Section 21.147 – The CDO certificate holder would be allowed to make changes to its production quality control system using procedures defined or referenced in its procedures manual. Substantive changes would need to be approved by the FAA prior to their implementation. All other changes would be required to be tracked and provided to the FAA on a regular basis, either in a hard copy or electronically, so that the FAA can perform proper certificate management. Examples of substantive changes include: quality control systems associated with new materials and their associated processes; the use of new inspection tools or the application of old tools to new situations; and the use of substantially new processes and procedures in the performance of quality assurance functions. While it is not possible for the FAA to define each substantive change, the objective is to allow the certificate holder to make all but the most significant changes to the quality control system without prior FAA approval.

Section 21.303 - Similar to the proposal for §21.33, the requirements in §21.303(e) would also apply to situations where the FAA wishes to confirm compliance determinations made by the certificate holder, as a part of its surveillance of the CDO certificate.

Since the certificate holder would make all determinations of compliance, the FAA makes no findings with respect to inspections or tests, as specified in §21.303(d)(1) and §21.303(e)(1). Since those findings the FAA normally makes would lead to the issuance of a PMA design approval, the certificate holder must make a certifying statement with respect to the inspections and tests under proposed §21.719(a) and the FAA may rely on that statement as specified in §21.719(c).

Subpart L Export Airworthiness Approvals – These are not airworthiness certificates as defined in this part. The CDO certificate holder would be authorized to issue export airworthiness approvals for products, parts, or appliances within the scope of its certificate. The processes and procedures in subpart L must be adhered to in the issuance of those approvals.

Section 21.611(a) – This section requires the TSO authorization holder to forward data to the FAA that demonstrates compliance with §21.605(b). Since the CDO certificate holder would make all determinations of compliance, it would not need to submit that data, but must make it available to the FAA. This is consistent with the data retention requirements of proposed §21.735.

Sections 26.43, 26.45, and 26.47 – These three sections require that data and other information be submitted to the FAA oversight office for review and approval, or to a properly authorized designee for review and approval. Since the CDO certificate holder would make all determinations of compliance, there is no need to submit the data or other information for approval. The data and other materials would be required to be retained in accordance with proposed §21.735 and made available to the FAA. The CDO certificate holder must comply with all other requirements in Part 26.

List of Subjects in 14 CFR Part 21

14 CFR Part 13

14 CFR Part 21

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend Chapter I of Title 14, Code of Federal Regulations, as follows:

PART 13—INVESTIGATIVE AND ENFORCEMENT ACTIONS

1. The authority citation for part 13 continues to read as follows:

Authority: 49 U.S.C. _____

2. Amend the end of the first sentence of §13.19(b) by removing the word "or" before the phrase "air agency certificate" and adding the phrase ", or certified design organization certificate" after the phrase "air agency certificate," so that it reads as follows:

§ 13.19 Certificate action.

(a) * * *

(b) If, as a result of such a re-inspection, re-examination, or other investigation made by the Administrator under section 609 of the FA Act, the Administrator determines that the public interest and safety in air commerce requires it, the Administrator may issue an order amending, suspending, or revoking, all or part of any type certificate, production certificate, airworthiness certificate, airman certificate, air carrier operating certificate, air navigation facility certificate, air agency certificate, or certified design organization certificate. * * *

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PART 21—CERTIFICATION PROCEDURES FOR PRODUCTS AND PARTS

3. The authority citation for part 21 is revised to read as follows:

Authority: 49 U.S.C. _____

4. Amend §21.1(a)(1) to read as follows:

§21.1 Applicability

(a) * * *

(1) Procedural requirements for the issue of type certificates and changes to those type certificates; the issue of production certificates; the issue of airworthiness certificates; the issue of export airworthiness approvals; and the issue of certified design organization certificates.

5. Add a new subpart P to part 21 to read as follows:

SUBPART P – CERTIFIED DESIGN ORGANIZATION

Secs.

21.701 Applicability of subpart P

21.703 The meaning of terms used in this subpart

21.705 Who is eligible to apply for a CDO certificate

§21.701 Applicability of subpart P

This subpart prescribes –

(a) Requirements for issuing and maintaining certified design organization (CDO) certificates, and

(b) Privileges and obligations of a CDO certificate holder.

§21.703 The meaning of terms used in this subpart

(a) Unless otherwise indicated, the word “certificate” means CDO certificate.

(b) Unless otherwise indicated, the phrase “type certificate (TC)” includes type certificate, amended type certificate, supplemental type certificate, amended supplemental type certificate, and provisional type certificate.

(c) The phrase “determination of compliance” means a decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. It also means 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.

(d) The phrase “eligible data” means data developed under an approved CDO system, given a specified, but not necessarily final, certification basis, and product type design if appropriate.

(e) For the purposes of this subpart, the phrase “design approval” means a type certificate, a PMA, or a TSO authorization.

§21.705 Who is eligible to apply for a CDO certificate

Any person may apply for a certificate, provided that:

(a) They have previously applied for, been a recipient of, and currently hold a design approval that encompasses the scope of the certificate they are seeking;

(b) The United States is the State of Design for the design approvals in (a), and the United States is the State of Manufacture for the production activities in (a); and

(c) For a certificate covering production activities, the applicant holds the design approval associated with that production activity.

§21.707 Scope of a CDO certificate

(a) A certificate may be issued to a person conducting one or a combination of the following design approval activities:

(1) Type certification of products

(2) Parts manufacturer approval (PMA) under subpart K

(3) Technical standard order (TSO) authorizations under subpart O

(b) In conjunction with the above design approval activities, production activities may also be accomplished in accordance with provisions of this subpart provided that a production approval has been granted under this part.

(c) The FAA must approve and may limit the scope of a certificate.

(d) A certificate will not be issued solely for part 26 compliance activities.

(e) A person may hold more than one certificate if authorized by the FAA.

§21.709 CDO application procedures

(a) An applicant must apply for a certificate in a form and manner prescribed by the FAA.

(b) The application must include a description of the scope of the certificate that the applicant is seeking and a self assessment of the applicant's ability to comply with the requirements of this subpart for that scope.

§21.711 Issuance of the CDO certificate

The FAA shall issue a certificate if the applicant demonstrates, and the FAA finds, that the applicant meets all the requirements in this subpart for the issuance of a certificate.

§21.713 Duration of the CDO certificate

A certificate is effective until surrendered, suspended, or revoked.

§21.715 Transferability of the CDO certificate

A certificate is not transferable.

§21.717 Changing the scope of a CDO certificate

(a) If a certificate holder wishes to change the scope of its certificate, the holder must apply for an amended certificate and provide a self-assessment demonstrating that it complies with the requirements of this subpart with respect to the changes it wishes to make to its certificate.

(b) The FAA may authorize the certificate holder to operate outside of its existing scope, in accordance with its proposed processes and procedures, in order to demonstrate its capability to operate under the changed scope.

(c) When authorized under (b), and until the FAA issues an amended certificate, the CDO will submit for FAA approval all compliance determinations proposed by the CDO in those areas of the expanded scope being sought.

(d) The FAA shall amend the certificate if the holder of the certificate demonstrates, and the FAA finds, that it meets the requirements for the issuance of a certificate in this subpart for the new scope.

§21.719 Certifying statement

(a) The certificate holder is authorized to make a written statement certifying compliance with the applicable regulatory design requirements of this subchapter, including any manufacturing, maintenance and flight operations regulatory requirements of this chapter directly associated with type certification, within the scope of its certificate.

(b) A statement certifying compliance may be issued only after all appropriate determinations of compliance have been made, in accordance with the CDO procedures manual.

(c) The FAA may rely on the statement in (a) when making the finding of compliance for the purpose of issuing a type certificate, PMA, or TSO authorization.

§21.721 Privileges granted to a CDO certificate holder

The certificate holder may –

(a) Make all determinations of compliance to the applicable airworthiness standards, and certification procedures of this subchapter, within the scope of its certificate. Compliance determinations must be supported by data substantiating that compliance.

(b) Make all determinations of compliance for prototype manufacturing activities associated with conformity inspection of parts, test articles, test setup, and installations.

(c) Make all determinations of compliance for maintenance and operational activities associated with type certification.

(d) Refer to compliance and type design data related to type certificates, PMA, and TSO authorizations it holds or is seeking, as FAA-approved data, once a determination of compliance has been made in accordance with its CDO procedures manual.

(e) Mark or otherwise identify FAA-approved data created under (d).

(f) Create eligible data for use in future design approval programs by the certificate holder if:

(1) An assumed certification basis is specified and, where appropriate, product design interface conditions are identified; and

(2) A determination of compliance is made under its CDO processes and procedures.

(g) Exercise other privileges the FAA may find appropriate.

§21.723 General responsibilities of a CDO certificate holder

(a) Identify an executive who has the authority and accountability for executing the responsibilities of the certificate, and is acceptable to the FAA as the CDO Executive.

(b) Identify those persons authorized by the CDO Executive to make statements certifying compliance under §21.719(a).

(c) Implement a process or procedure that identifies and qualifies the management and technical competencies necessary to execute the responsibilities of the certificate, and ensure that those competencies are maintained.

(d) Submit to the FAA a declaration signed by current senior company management indicating their commitment to compliance with the CDO requirements.

(e) Notify the FAA of any decisions made to change or appoint additional persons identified in (a) or (b), or to substantially change the responsibilities of those persons as they relate to the operation of the CDO.

(f) Conduct all design, production, airworthiness, and continued operational safety activities as authorized and prescribed by its certificate.

(g) Comply with all applicable requirements of this part that apply to applicants for, or holders of, type, airworthiness, or production certificates, or any other approvals granted under this part, except as identified in §21.741.

(h) Comply with all applicable requirements of subpart P and all processes and procedures within the CDO procedures manual required in §21.733, and those referenced within the manual.

(i) Maintain a record of all CDO project activities and their status, and make that record available to the FAA.

(j) Notify the FAA when a project has been initiated that may result in a certifying statement authorized under §21.719(a).

(k) Maintain a record of all design and production suppliers, including their location.

(l) Make available to the FAA its certificate, personnel required to be specifically identified under this subpart, FAA-approved procedures manual, and compliance data supporting its determinations of compliance and approvals.

(m) Develop any reports or records required by the FAA in its oversight of the certificate.

(n) Develop a corrective action plan, acceptable to the FAA, for all findings resulting from FAA certificate oversight. This must be developed and implemented in a manner that is consistent with the potential safety implications of the findings.

(o) Maintain a principal base of operations within the United States and provide the FAA with a current physical address and current contact information for the CDO Executive. The FAA must be notified at least 30 days prior to a change to the physical location of its principal base of operations.

§21.725 Compliance assurance system required of a CDO certificate holder

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. The compliance assurance system must:

(a) Provide assurance that its design and production processes, and any changes to them, are in compliance with the applicable requirements of this subchapter. The assurance should be consistent with what would result from a skilled independent

review of compliance. The CAS must include processes and procedures used by the CDO throughout its system to:

(1) Make available all applicable regulations and regulatory guidance material associated with the scope of its certificate;

(2) Perform compliance planning;

(3) Execute compliance plans;

(4) Verify compliance;

(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);

(6) Document processes and procedures for the configuration management of products, components, parts, appliances, and compliance data;

(7) Coordinate with the cognizant FAA office to establish certification requirements and acceptable methods of compliance; and

(8) Ensure the statement certifying compliance in accordance with §21.719(a) is properly executed.

(b) When the system is dependent on the qualifications of individuals, provide processes and procedures to ensure:

(1) The initial qualifications of the individual are appropriate to the tasks being performed,

(2) The continuing qualification of the individual,

(3) A periodic review of the work is performed to verify it is consistent with the compliance assurance system objectives, and

(4) A record is kept of the individual's accomplishment of the compliance activity.

(c) When the CAS is dependent on the use of a mechanical, electronic, or other tool, include processes and procedures that ensure:

(1) The tool performs its required function,

(2) The tool and its output are being controlled under a configuration management program,

(3) The tool is periodically verified for its applicability to the processes and methods for which it is used, and

(4) A record is kept that indicates when the tool was used to accomplish the compliance activity, and the outcome of its use.

§21.727 Quality management system required of a CDO certificate holder

A certificate holder must maintain a quality management system that –

(a) Enables the CDO to ensure it meets the qualification requirements of this subpart for the scope of its certificate and continues to follow the processes and procedures it has defined in its procedures manual;

(b) Conducts surveillance and audits of processes and procedures identified in the procedures manual to assure they are followed and continue to meet their intended purpose;

(c) Uses proactive and reactive corrective action processes, and updates those processes when there is an identified need;

(d) Incorporates a configuration management process which includes a documented change control process;

(e) Verifies its personnel are trained and qualified to understand and operate in accordance with its processes and procedures;

(f) Includes high-level management oversight of surveillance and audit findings, and

(g) Ensures its processes and procedures provide for approval and oversight of its supply chain.

§21.729 Safety management system required of a CDO certificate holder

A certificate holder must maintain a safety management system (SMS) that incorporates the following:

(a) *Safety Policy* that –

(1) Defines the SMS goals and objectives,

(2) Defines how the organization will implement the SMS to attain the goals and objectives of (a)(1),

(3) Establishes senior company management's commitment to safety management and an expectation of high safety performance, and

(4) Commits to a process-based approach to safety promotion within the company.

(b) *Safety Risk Management* processes applied to safety systems; compliance processes; product, part, and appliance designs; and production or in-service events, that are performed as follows:

(1) Describe the system of interest;

(2) Define the hazards associated with the system defined in (b)(1);

(3) Analyze the safety risk of identified hazards, characterizing the likelihood and severity of each hazard;

(4) Assess the safety risk and incorporate that assessment into its decision-making processes; and

(5) Control, mitigate, or eliminate that safety risk consistent within established FAA airworthiness standards through the implementation of programs, processes, or product redesign.

(c) *Safety Assurance* processes that –

(1) Monitor the implementation of the safety policy;

(2) Assess safety systems; compliance processes; product, part, and appliance designs; and production or in-service events, to identify new or potential hazards;

(3) Analyze those assessments as part of its risk management program; and

(4) Continually ensure appropriate safety risk controls are effective for those hazards, based on their safety consequence and likelihood of occurrence.

(d) *Safety Promotion* processes that –

Implement the actions necessary to create an environment within the CDO where safety objectives can be achieved and maintained. Those actions must include –

(1) A program to ensure people are appropriately qualified to perform the necessary safety analysis and use the SMS principles when making safety decisions,

(2) A clear definition of what actions are acceptable and unacceptable in the workplace with respect to the reporting of safety issues,

(3) A program for safety information sharing within the organization to ensure lessons learned are available to others doing the same or similar tasks, and

(4) A periodic review of the safety management program to ensure that the defined processes are achieving their desired outcomes.

§21.731 Requirements used to determine capability to operate under a CDO certificate

(a) The certificate holder must demonstrate and maintain the capability to perform the processes and procedures required under this subpart in a documented and consistent manner that meets CDO standards. The processes and procedures must be managed so that their goals are met. Standard company processes must be used; individual processes may be created from standard processes if they are approved in accordance with a company process contained in the CDO procedures manual.

(b) The certificate holder must demonstrate and maintain the organizational maturity necessary to consistently perform at the capability defined in (a) across the breadth of the process and product lifecycle.

§21.733 The CDO procedures manual

The procedures manual is approved by the FAA and must contain the following:

(a) A section defining the scope of the certificate and its privileges. This section constitutes a part of the certificate.

(b) Procedures and measurable criteria for complying with the requirements of this subpart. Operational details of the procedures must be referenced within the manual, but need not be FAA-approved.

(c) Procedures and operational details for complying with the provisions of §21.741.

(d) Procedures for revising the manual and its referenced procedures.

§21.735 Records and reports maintenance and retention

(a) Each certificate holder must ensure that the following records are maintained for the duration of the certificate:

(1) Any records generated and maintained while holding a previous delegation under subpart J or M of part 21, or SFAR 36 and part 183 of this chapter.

(2) For any approval or determination of compliance made by the CDO, or a certificate, approval, or authorization issued by an FAA designee or delegated organization operating in conjunction with the CDO:

(i) The application and data required to be submitted under this chapter to obtain the certificate or approval, and

(ii) The data and records documenting the approval or determination of compliance.

(3) A summary of any analysis or corrective action accomplished under its required SMS, including that associated with the determination of whether or not corrective action was needed.

(4) A list of all determinations of compliance made on products, components, parts, or appliances within the scope of its certificate; and certificates that an FAA designee or delegated organization operating in conjunction with the CDO has issued.

(5) A list of all persons outside of the CDO system who were provided FAA-approved data, and identification of the data that were provided.

(6) The names, responsibilities, qualifications, and sample signature of each person identified in §21.723(a) and (b).

(7) Any other records specified in the certificate holder's procedures manual.

(8) A copy of each procedures manual required under §21.733 approved by the FAA, including all historical changes.

(9) Any records required to be maintained while holding a previous CDO certificate.

(b) Each certificate holder, from the date it is granted a CDO certificate, must ensure that the following are maintained for at least five years:

(1) A record of each audit and any resulting corrective actions, and

(2) A record of any reported service difficulties received after the CDO certificate is granted, associated with -

(i) Determinations of compliance made by the certificate holder, and

(ii) Those approvals or certificates held by the CDO certificate holder,

(c) For all records required by this section to be maintained, each CDO certificate holder must ensure that the records and data are available to the FAA for inspection at any time.

(d) Required records related to the CDO procedural requirements in this subpart or created solely for use under CDO, must be submitted to the FAA upon surrender or termination of a CDO certificate. Required records related to CDO determinations of compliance, statements of compliance, and associated with the issuance, amendment, or continued operational safety of type certificates, TSO authorizations, PMA, and any production system approvals, must be maintained as specified elsewhere in this part, for design and production approvals that continue to be held by the design or production approval holder after its CDO certificate is no longer valid. Records related to the continued responsibilities as a design approval holder should be maintained.

(e) Each certificate holder must retain any records or reports required to be developed by the FAA in the process of supervising the certificate holder. Those are considered to be CDO procedural records in accordance with (d).

§21.737 FAA oversight of CDO certificate holder

The FAA may, at any time and for any reason, inspect a certificate holder's facilities, products, components, parts, appliances, required procedures and operations, and required records, associated with the requirements of this subpart and within the scope of its certificate, including at its partners, suppliers, and subcontractors.

§21.739 FAA determination of no undue burden

The FAA does not issue a certificate if any of the facilities necessary to conduct operations in accordance with the CDO's procedures manual are located outside the United States, unless the FAA finds there is no undue burden on the FAA in administering the applicable requirements of this subpart.

§21.741 Requirements of this subchapter that have different applicability for a CDO

(a) Section 21.21(b) notwithstanding, the certificate holder need not submit the type design, test reports, and computations necessary to show that the product to be certificated meets the applicable airworthiness requirements of the Federal Aviation Regulations and any special conditions prescribed by the FAA, but must make those records available in accordance with §§21.735 and 21.737.

(b) Section 21.33(a) notwithstanding, the certificate holder must allow the FAA to make any inspections and tests necessary to confirm compliance, in lieu of FAA making findings of compliance under this section.

(c) Section 21.35 (a)(4) notwithstanding, the certificate holder need not submit a flight test report signed by the applicant's test pilot, but must have completed that report in accordance with its CDO procedures manual prior to conducting flight tests per §21.35, and must make the report available to the FAA upon its request. The report must include an appropriate flight test risk assessment.

(d) Section 21.39(a) notwithstanding, the certificate holder need not submit a report showing the computations and tests required in connection with the calibration of instruments used for test purposes and in the correction of test results to standard atmospheric conditions, but must generate the report and make it available to the FAA upon its request.

(e) Section 21.53 notwithstanding, a conformity statement need not be submitted to the FAA, but a conformity determination satisfying other requirements in §21.53 must be available for review by the FAA.

(f) Section 21.81(d) notwithstanding, in lieu of submitting the referenced report to the FAA, the certificate holder must certify in accordance with §21.719(a) that the requirements of §21.81(d) have been met.

(g) Section 21.83(g) notwithstanding, in lieu of submitting the referenced report to the FAA, the certificate holder must certify in accordance with §21.719(a) that the requirements of §21.83(g) have been met. In addition, the certifying statement required by §21.83(c) and (f) must also be made in accordance with §21.719(a).

(h) Section 21.85(d) notwithstanding, the CDO flight test program must be in progress. The certifying statement required by §21.85(e) must also be made in

accordance with §21.719(a). Section 21.85(f) notwithstanding, in lieu of submitting the referenced report to the FAA, the certificate holder must certify in accordance with §21.719(a) that the requirements of §21.85(f) have been met.

(i) In lieu of §§21.95 and 21.97(a), all determinations of compliance for changes in a type design are made by the certificate holder in accordance with its procedures manual.

(j) Section 21.99(a)(1) notwithstanding, the certificate holder may make determinations of compliance when the FAA finds that design changes are necessary to correct the unsafe condition of the product. Section 21.99(b) notwithstanding, the certificate holder may make determinations of compliance for changes that it or the FAA finds will contribute to the safety of the product. The certificate holder must make the compliance and type design data available to the FAA upon its request.

(k) Section 21.113 notwithstanding, the certificate holder need only apply for an amendment to a type certificate incorporating a major change in type design, not great enough to require a new application for a type certificate under §21.19, when the certificate holder expects to make a certifying statement under §21.719(a).

(l) The quality control data requirements of §21.143 may be met through appropriate procedures being included or referenced in the CDO procedures manual.

(m) Section 21.147 notwithstanding, and when exercising its option in §21.741(l) to operate its production activities under CDO, the certificate holder may make changes to the quality control system as authorized under its CDO procedures manual. The FAA must be notified of substantive new or revised procedures prior to their implementation and those procedures must be approved by the FAA. Other changes must be tracked and made available to the FAA on a regular basis.

(n) Section 21.163(a)(2) notwithstanding, and when exercising its option in§21.741(l) to operate its production activities under CDO, the certificate holder is authorized to issue approvals for installation of parts or components on products in service.

(o) Section 21.303(e) notwithstanding, the certificate holder must allow the FAA to make any inspections and tests necessary to confirm compliance, in lieu of FAA making findings of compliance.

(p) Sections 21.303(d)(1) and 21.303(e)(1) notwithstanding, all tests and inspections shall be completed by the PMA applicant and a written certifying statement provided to the FAA in accordance with §21.719(a).

(q) When exercising its option in §21.741(l) to operate its production activities under CDO, a certificate holder is authorized to issue export airworthiness approvals in accordance with the procedures of subpart L and its CDO procedures manual.

(r) Section 21.611(a) notwithstanding, a certificate holder need not forward to the FAA any revised data that are necessary for compliance with §21.605(b), but must make that data available to the FAA upon its request.

(s) Part 26, §§26.43, 26.45, and 26.47 notwithstanding, the certificate holder is authorized to make determinations of compliance in accordance with its CDO procedures manual, in lieu of having to submit the material to the FAA or designees for review and approval**.**

Issued in Washington, DC, on

Appendix K.
Draft Advisory Circular

U.S. Department
of Transportation
Federal Aviation
Administration

Advisory Circular

Subject: GUIDANCE FOR CERTIFIED DESIGN ORGANIZATIONS

Date: DRAFT
Initiated by: AIR-140

AC No: 21- CDO
Change:

INTRODUCTION

1. What is the purpose of this Advisory Circular (AC)?

This AC describes acceptable means, but not the only means, of complying with the Certified Design Organization (CDO) requirements of subpart P of Title 14, Code of Federal Regulations (14 CFR), part 21. However, if the means described in this AC are used, they must be followed in all important respects. See the preamble to Notice XXX and Amendment 21-YY for additional discussions of regulatory intent and methods of compliance.

This AC is not mandatory and does not constitute a regulation, nor will the FAA use it as the basis upon which other means of compliance to the regulation would be accepted. Something else may be used if it complies with the regulations.

2. An overview of CDO.

A CDO is an organization that has applied for, been evaluated, and received a certificate indicating it has adequate engineering, design and production capabilities, standards and safeguards to ensure that the products, parts, and appliances being certificated are properly designed and manufactured, perform properly, and meet the regulations and minimum standards published by the FAA. A CDO is required to have a compliance assurance system, quality management system, and safety management system that meets the requirements specified in the subpart P to part 21, as well as meeting the administrative requirements of that subpart.

The CDO certificate defines the scope of activities for which the CDO has been evaluated for compliance with the CDO requirements. This scope of activities includes the applicable airworthiness standards and products for which the organization's processes and procedures have been evaluated.

The CDO makes determinations of compliance with the applicable regulations for the products, parts, and appliances being developed or modified. These showings of compliance are performed using methods defined within the CDO procedures manual. Each determination of compliance must be supported by appropriate compliance and type design data used to demonstrate compliance. Following completion of the determinations of compliance, the CDO will submit to the FAA a signed statement certifying compliance, which certifies that the CDO procedures manual was followed and the product, part, or appliance complies with the applicable regulations associated with the type certificate, PMA, or TSO being sought. The FAA will rely on that certification of compliance in making a finding to issue the certificate, approval, or authorization related to the product, part, or appliance, unless it has reason to believe the certification of compliance is inappropriate, the compliance is incomplete, or an unsafe condition exists with respect to an aircraft (§21.21(b)(2)). The FAA will issue original type certificates for new products, amended type certificates, original supplemental type certificates, and parts manufacturer approvals. Amended supplemental type certificates, technical standard order authorizations, and airworthiness certificates may be issued on behalf of the FAA by a designee residing within the company holding the CDO certificate.

3. Who does this AC apply to?

The CDO requirements of subpart P of 14 CFR part 21 apply to those who have chosen to apply for the CDO certificate. Persons who are interested in applying for a CDO certificate, who hold a CDO certificate, or who operate products designed or produced by holders of a CDO certificate may be interested in the material contained in this AC.

4. What is the format of this AC?

The sections of this AC are arranged in the same manner as the rule in subpart P. This AC explains the intent of the rule and acceptable methods of compliance. In some cases there are criteria for determining whether a proposed method of operation by a CDO is in compliance with the regulations. The arrangement of the AC is as follows:

INTRODUCTION:

1. What is the purpose of this Advisory Circular (AC)?
2. An overview of CDO
3. What does this AC apply to?
4. What is the format of this AC?

GUIDANCE FOR MEETING SPECIFIC REGULATORY REQUIREMENTS:

5. §21.701 What does this subpart apply to?
6. §21.703 What are the meaning of terms used in this subpart?
7. §21.705 Who is eligible to apply?

8. §21.707 What is the scope of a CDO certificate?
9. §21.709 What must I do to apply?
10. §21.711 Issuance of the certificate
11. §21.713 What is the duration of a certificate?
12. §21.715 Is a certificate transferable?
13. §21.717 How does a certificate holder obtain a change in the scope of its certificate?
14. §21.719 Certifying statement
15. §21.721 What privileges are granted to a certificate holder?
16. §21.723 What are the general responsibilities of a certificate holder?
17. §21.725 A compliance assurance system is required of a certificate holder
18. §21.727 A quality management system is required of a certificate holder
19. §21.729 A safety management system is required of a certificate holder
20. §21.731 What requirements will be used to determine my capability to operate under a CDO certificate?
21. §21.733 What must be included in the procedures manual?
22. §21.735 What records and reports must the certificate holder maintain?
23. §21.737 What FAA oversight is a certificate holder subject to?
24. §21.739 FAA must determine no undue burden
25. §21.741 What requirements in subchapter C have different applicability for a CDO?

MORE INFORMATION

26. Are there any related documents I should look at?
27. How can I get this and other FAA publications?
28. How can I request more information?

APPENDICES

29. Appendix E – GUIDANCE FOR DEVELOPING A CDO PROCEDURES MANUAL

GUIDANCE FOR MEETING SPECIFIC REGULATORY REQUIREMENTS

5. §21.701 What does this subpart apply to?

a. Those wishing to seek a CDO certificate must demonstrate compliance with each applicable requirement of subpart P.

b. Those holding a CDO certificate must continue to comply with applicable requirements of subpart P.

6. §21.703 What are the meaning of terms used in this subpart?

a. Unless specified otherwise, the word **"certificate"** means a CDO certificate.

b. The phrase **"type certificate"** includes type certificates issued under subparts B and E of part 21, and their amendments.

c. The phrase **"design approval"** means a type certificate, a PMA, or a TSO authorization.

d. A **"determination of compliance"** by the certificate holder is a decision made by the certificate holder that compliance has been shown with the applicable regulatory requirements. 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. If the determination is with respect to a regulation where the FAA only accepts data, like with the instructions for continued airworthiness, the determination of compliance only constitutes an acceptance of the data. Those regulatory requirements include applicable procedural requirements in part 21, subpart K of part 21 for parts manufacturer approval (PMA) applicants and holders, subpart O of part 21 for Technical Standard Order (TSO) applicants and holders, and the airworthiness standards in parts 23, 25, 27, 29, 31, 33, and 35.

e. **Eligible data** are generated by a certificate holder for use on future programs. The certificate holder may not make a determination of compliance with respect to the data, as the FAA has not defined an official type certification basis or TSO performance standard, and in some cases the product, part, or appliance on which the data is to be used has not been defined. If the eligible data is generated using an assumed certification basis or TSO performance standard, then any testing or analysis conducted in accordance with the CDO procedures manual may not need to be repeated. To convert the eligible data to a determination of compliance, the certificate holder must demonstrate its validity and applicability to the FAA-

defined certification basis or TSO performance standard, in a manner substantially similar to how it would establish the validity and applicability of previously approved data. If it is valid and applicable, no further testing would be required. Some additional testing or computations may be required if necessary to demonstrate compliance to a different type certification basis or TSO performance standard than that assumed when the eligible data was created, or because of a different product, part, or appliance application.

f. For this AC, the word **"procedures"** includes processes.

7. §21.705 Who is eligible to apply?

a. A person – Technically any person as defined in part 1 may apply for a certificate. Practically, though, it will be impossible for a single person to meet the system requirements of subpart P (see §§21.725 through 21.731). Thus, the FAA will not accept applications for a CDO from an individual person; any application must be on behalf of one of the other entities contained in the part 1 definition.

b. Any size company – There is no minimum or maximum size company or type of corporate entity deemed appropriate for a CDO certificate. The regulations in subpart P are specifically designed so they are applicable to all sizes and complexities of applicant companies, and for any one or combination of products, parts, or appliances.

c. Demonstrated competence – Any applicant for a CDO must have demonstrated its competence to apply for and receive a design approval using any process other than the CDO process. That is necessary for the applicant to properly demonstrate its ability to determine compliance and to manage a design approval program of the scope it is wishing to accomplish under a CDO certificate. In addition, the applicant must presently hold a design approval of the scope it is seeking so there is a demonstrated ability to meet the continued operational safety responsibilities of a design approval holder. For minor changes in the scope of a CDO certificate, the FAA may waive the requirement for having demonstrated its competence under a non-CDO process. This is discussed further under §21.717.

d. Consortiums – A consortium may apply for a CDO as long as the consortium meets the requirements of subpart P. If the consortium members are certificate holders, the members may make determinations of compliance within the scope of their certificate on behalf of the consortium, but the consortium must determine the validity and applicability of those determinations of compliance for the design approval it is seeking. This principle applies whether or not the consortium holds a CDO certificate. It also applies to the use of approved data originating from members of the consortium who hold organization delegations from the FAA, like ODA, or by designees. If a consortium does not have a CDO and one or more of its members do, those members may provide determinations of compliance for use by the consortium. This is the sole situation in which a CDO may provide determinations of compliance to a third party.

e. A U.S. Company – The last condition is that the design and production approval(s) used to comply with the requirements of §21.705(a) must have the U.S. as the State of Design, and the State of Manufacture if appropriate. That means no companies based in other countries may apply for a CDO. If a U.S. office of a foreign company desires to apply for a CDO, that U.S. office must meet all the requirements of subpart P, including being the TC, PC, PMA, or TSO holder and being responsible for all design and supplier quality assurance throughout the life of the product, part, or appliance.

f. Production – A company may apply to include its production activities under its CDO certificate. To be eligible to do so, the company must have already received a production certificate or other production approval under the normal process defined within part 21. A production certificate or approval will still be issued, in addition to the CDO certificate. Section 21.741 identifies additional CDO privileges the certificate holder obtains in this situation, and the responsibilities associated with those privileges. In this situation the scope of the certificate encompasses the design approvals and the production activities associated with those design approvals. If the certificate holder chooses to include production activities under its certificate, it must include all production activities associated with the scope of its design approvals conducted under the certificate.

8. §21.707 What is the scope of a CDO certificate?

a. Each may be different – It is likely that each certificate holder will have a different scope of products, parts, or appliances that will be covered under its certificate. That is because the scope of business for every applicant is likely to be different.

b. Some examples – The first natural break in scope is related to the airworthiness standards in parts 23, 25, 27, 29, 31, 33, and 35. The next likely break could be the size or scope of the product, part, or appliance such as:

(1). Part 23 normal category airplanes with reciprocating engines, less than 6000 pounds

(2) Part 23 airplanes less than 12, 500 pounds

(3) Part 23 commuter category airplanes

(4) Part 25 business jets

(5) Part 27 helicopters, excluding Category A

(6) Part 29 helicopters Category A only

(7) Part 33 reciprocating engines

(8). PMA for engine non-rotating parts

(9) TSO for avionics

(10) TSO for seats

(11) STC for Part 23 airplanes

(12) Structural STC for products operated by a specific airline

c. More than one CDO certificate – There may be situations where the FAA will decide to issue more than one certificate to the same company. That would only be done in situations where a company may have two or more diverse design or production activities, or facilities that were widely separated or in different FAA regions. The ability of the FAA to effectively manage the certificates would be a major factor in any FAA decision.

d. General limitation – Any limitations placed on the scope of a certificate by the FAA will be based solely on the ability of the applicant to meet the requirements of subpart P for that scope.

e. Part 26 limitation – The FAA will not issue a certificate that has part 26 as its sole scope. This is because the requirements of part 26 apply to holders of type certificates issued under part 25. Certificates will only be allowed for a scope that includes part 26 when the scope also covers part 25 requirements.

9. §21.709 What must I do to apply?

a. Make application – The application should be a letter signed by the person desiring to become the CDO Executive, as defined in §21.723(a), or the company executive to who that person will report. The letter must define the scope of the certificate being sought and include attachments that contain:

(1) A justification that the company is eligible in accordance with §21.705;

(2) A copy of the proposed procedures manual required in §21.733;

(3) Examples of how proposed CDO procedures have been used, or shadowed, in previous compliance activities;

(4) Briefing material showing the proposed organizational structure of the CDO, including how roles and responsibilities are to be delegated within the organization; and

(5) An assessment of how each requirement of subpart P will be complied with in the procedures manual.

b. Provide data – The applicant for a certificate has the responsibility of providing data that demonstrates it complies with the requirements of subpart P for the scope of the certificate it is seeking and has defined in its application. Unsupported assertions of compliance are not sufficient.

c. The process – The organization desiring to become a CDO should contact their local FAA office to discuss their plans and may wish to enlist the assistance of the FAA in planning their CDO development. The organization then determines the scope of the CDO certificate it will seek, develops its processes to satisfy the requirements of subpart P of part 21, conducts a self assessment to determine that it is ready to become a CDO, and makes formal application to the FAA. The FAA will assign personnel to an evaluation team that will assess the applicant's processes and procedures for compliance with the regulation, and will do its best to assign people who have a strong likelihood of being on the FAA oversight team if a certificate is eventually issued. This assessment will include an evaluation of technical capability and the capability and maturity of the processes, using iCMM as discussed in the guidance material related to §21.731. On completion of the successful evaluation, the FAA will issue a certificate to the organization.

d. Initial FAA oversight one can expect – During the initial operation of the CDO the FAA will maintain a high degree of oversight to insure that the new processes are being followed. For an organization that had existing processes in place that met the CDO regulations, the initial oversight may be lower due to the established performance record.

10. §21.711 Issuance of the certificate

a. Applicant must demonstrate – The burden is on the applicant to demonstrate they meet the requirements of subpart P, and that the procedures contained in their procedures manual are designed and managed so that compliance with subpart P and the applicable product, part, or appliance certification requirements are met.

b. FAA finds – The FAA must make a finding that compliance with subpart P has been demonstrated. If the FAA finds that the requirements of subpart P have not been met for the scope of the certificate being sought, the FAA will provide a detailed description of the deficiencies it has found. In addressing those deficiencies the FAA will define what regulatory objectives have not been adequately met. The FAA will not define how the procedures should function to meet the regulations, as that is the responsibility of the certificate holder who best understands its company culture and procedures.

c. A right is granted – The applicant has a right to receive a certificate if the FAA finds that the applicant has properly demonstrated compliance with the requirements of subpart P. The FAA will not use any other criteria for making a decision to grant or deny a certificate.

11. §21.713 What is the duration of a certificate?

a. Forever, unless – A certificate is valid until it is surrendered by its holder for any reason or the FAA suspends or revokes the certificate under the procedures in part 13.

b. What constitutes the certificate – The scope of the CDO certificate, as defined in §21.707, along with the privileges defined in §21.721 constitute the certificate. Any change to the scope or privileges is a change to the certificate and if not accepted by the certificate holder will be made in accordance with part 13, which includes rights of appeal by the certificate holder.

c. Suspension – The FAA may take certificate action to suspend all or some certificate functions defined within the procedures manual if it finds that the holder is failing to comply with specific requirements within subpart P related to those functions. In this situation, the CDO may not make determinations of compliance associated with those functions, and compliance must be found by the FAA.

d. Consultation– In all cases where the CDO is considering a surrender or partial surrender of its certificate, it should have early discussions with the FAA. This will enable the FAA to assist the holder in resolving any issues that may be influencing its decision, and give the FAA early warning that additional resources may be needed if the certificate is surrendered. Likewise, if the FAA is considering a complete or partial revocation of the certificate, that action will be taken only as a last resort and only after the FAA has worked with the certificate holder to try and identify means to correct any compliance deficiencies.

12. §21.715 Is a certificate transferable?

a. No – The issuance of a certificate was based on a previous FAA relationship with the CDO certificate holder. Furthermore, a certificate is granted only after the applicant has demonstrated and the FAA finds that the company procedures defined in its procedures manual are in full compliance with subpart P. That FAA relationship and demonstrated compliance can not be assumed by, or transferred to, another person. For these reasons a certificate can not be transferred.

b. But – A new owner of a company that holds a CDO certificate may apply for a new certificate. In assessing that application, the FAA will give credit to procedures it has found to be acceptable under the previously issued certificate as long as the new owner demonstrates and the FAA finds the necessary ability and commitment to follow those procedures.

13. §21.717 How does a certificate holder change the scope of its certificate?

a. It must apply – A certificate holder must apply for an amended certificate, whether the scope is being increased or decreased. That application and associated

demonstration of compliance with subpart P need only address the proposed changes to the certificate.

b. Self assessment – The certificate holder must conduct a self assessment of the new procedures, as is required in the case of a new certificate. The assessment should specifically include an assessment of the interfaces between the existing certificate procedures and those being proposed for the change in scope. The complexity of that assessment should be consistent with the complexity of the change in scope and number of procedures that must be changed.

c. FAA finding – The FAA review and approval will be limited to those procedures associated with the new scope, unless the FAA finds that the new procedures have adversely altered or interfered with the existing procedures in a manner not adequately addressed by the certificate holder. In this case the FAA will ask the certificate holder to reassess its procedures based on the input received from the FAA. In the end, the FAA will either accept that reassessment, or give detailed reasons why it is deficient and will define what objectives must be met for it to accept the new procedures. The FAA will not define how the procedures should function as that is the responsibility of the certificate holder.

d. Scope change– If the new scope involves substantially new processes that have not been previously demonstrated, the FAA will issue a letter of authorization to allow the organization to operate under the proposed CDO procedures until the CDO demonstrates its ability to operate under those procedures. Once the new processes and capabilities are demonstrated, the CDO certificate would be amended to reflect the new scope. If the change in scope is minor the CDO self-assessment may be sufficient to allow the FAA to change the certificate scope with no further demonstration of the new procedures. A letter of authorization may not be used for a one-time expansion of scope or to supplement a lack of capability on a particular project.

e. Who makes determinations of compliance – While the basic premise of CDO is that the certificate holder must make all determinations of compliance within the scope of its certificate, it may not make determinations of compliance within the new scope until the certificate has been revised. Any compliance determinations made outside of the scope of the certificate would normally trigger enforcement by the FAA. The letter of authorization would allow the CDO to exercise its new processes as if it had been granted the expanded scope, but in this case it would be necessary for the FAA to approve all "proposed" determinations of compliance made by the CDO in areas outside its existing scope. The CDO should make proposed determinations of compliance in accordance with its expanded scope as if it had the sole responsibility for making those determinations.

f. The certifying statement – Under CDO, a determination of compliance is defined as being either a determination of compliance with applicable regulatory requirements or airworthiness standards, or a determination that previously approved data are

valid and applicable for their intended application. When operating under a letter of authorization, the CDO would still be authorized to submit a statement of compliance encompassing all aspects of a project. This includes those determinations made by the CDO within its existing scope, the validity and applicability of those "proposed" determinations of compliance approved by the FAA within the expanded scope, and those related to the validity and applicability of all other previously approved data. The certifying statement should clearly define where the CDO has made a determination of compliance and where it has merely made a determination as to the validity and applicability of FAA approved data. It will remain the responsibility of the CDO to manage this mixture of FAA and CDO responsibilities along with all other project management activities, when working under a letter of authorization.

g. The amended certificate – Once the FAA is satisfied that the CDO is capable of reliably executing its compliance responsibilities under the changed scope, the FAA will amend the CDO certificate to include the new scope. The FAA will look for proper execution of the changed procedures and proper regulatory compliance by the CDO when making its decision to amend the CDO certificate. There is no obligation on the FAA to complete its assessment within a minimum time limit, nor is there an obligation on the certificate holder to conduct a minimum number of projects or operate a required amount of time under the new procedures. The FAA may rescind its letter of authorization if the CDO does not promptly work to satisfy the requirements for obtaining CDO privileges under the new scope.

14. §21.719 Certifying statement

a. The compliance process – The CDO follows its procedures and makes determinations of compliance for all the required regulations for the product, part, or appliance under consideration. On completion of the project, the CDO provides a written statement certifying compliance with the regulations, which the FAA will rely on in making its finding associated with the issuance of a type certificate or other design or production approval. A delegation granted to the company holding the CDO certificate may be used to issue design approvals, other than original and amended type certificates, original supplemental type certificates, and PMA approvals. In issuing design approvals the designee may rely on the statement from the CDO certifying compliance.

b. What – The certificate holder must certify that all compliance activities have been completed and that it followed its procedures manual in doing so. The certifying statement must be signed by the CDO Executive identified under §21.723(a) and sent to the person identified by the FAA oversight team. The certifying statement should also cover any maintenance and flight operations regulations associated with the issuance of the design approval. Activities covered in the certifying statement should be consistent with the scope of the certificate as defined in §21.707, the privileges defined in §21.721, and the procedures manual.

c. When – The certifying statement may not be made until all compliance activities leading to the issuance of a certificate are completed. At that point the FAA will not issue a certificate without the signed statement. The CDO need not make a certifying statement for activities leading to an amendment of a design approval, or other certification activities in support of continued operational safety, since the FAA is not going to issue an amended certificate. The traditional reasons for FAA needing to issue a new or amended certificate have not changed because of CDO implementation.

d. FAA reliance on the certifying statement – The FAA will rely on the certifying statement when issuing a certificate, or other design approval. The FAA does not expect to review the data supporting the certifying statement prior to issuing its approval, unless it has a defined reason to question the validity of the certifying statement. Should the FAA choose not to issue a design approval based upon the certifying statement, it will notify the certificate holder in writing of the reasons for that action and what it finds would be sufficient to remedy the situation. In the case of an aircraft the FAA may choose to not issue the type certificate if it finds an unsafe condition in accordance with §21.21(b)(2). In that case the FAA will work with the certificate holder to resolve the unsafe condition.

e. Notification of the appropriate FAA Director – The non-acceptance of a certifying statement by the FAA is expected to be a rare occurrence, since the FAA would have been involved from the beginning of the project with the issuance or validation of the certification basis, special conditions, alternate means of compliance, and any exemptions. As such, the Director of Aircraft Certification or Flight Standards, as appropriate, will be notified when the FAA oversight office has reason to believe that it might take such an action.

15. §21.721 What privileges are granted to a certificate holder?

a. Making all determinations of compliance – The holder of a CDO certificate may make all determinations of compliance within the scope of its certificate. Those determinations of compliance must be supported by data that demonstrates appropriate regulatory compliance. Neither the FAA nor its designees will make discrete findings of compliance under the CDO concept. Once the FAA has established the applicable airworthiness standards and other basis for approval, the FAA will rely on the CDO to make all determinations of compliance as the project progresses. The FAA will still make an overall finding of compliance associated with the issuance of a type certificate, a PMA, and any determinations associated with the issuance of a TSO authorization. The FAA will continue to issue special conditions, approve alternate means of compliance, grant exemptions, and issue approvals to deviate from TSO performance standards, which it finds necessary and appropriate.

b. Determinations of compliance result in FAA-approved data – Similar to what is authorized in §21.95 for minor type design changes, the FAA has determined that

the FAA-approved CDO procedures manual is an acceptable method for creating FAA-approved data before submitting any substantiating or descriptive data to the FAA. Once a determination of compliance has been made by the CDO in accordance with its procedures manual, the type design and compliance data associated with that determination of compliance are considered to be FAA-approved. This FAA-approved data may be used in situations where other FAA regulations, policy, guidance, or orders require "approved" or "FAA-approved" data. The user of the data need only determine that it is applicable for its intended use. This process for creating FAA-approved data under the CDO concept does not result in any new definition of "data" or "approved data" from that commonly used for decades under 14 CFR subchapters A through H.

In the case where the determination of compliance is with respect to a regulation wherein the FAA only determines the acceptability of data, like portions of the instructions for continued airworthiness or the Flight Manual, the determination of compliance by the CDO only results in accepted data, not approved data.

c. Data may be marked as FAA-approved –The CDO is authorized to mark or otherwise indicate the FAA-approval of that data, in a manner to be specified in FAA guidance material. The marking of FAA-approved data is only necessary when the data is intended for use outside of the CDO certificate holder's system. The FAA intends to generate a form to mark data as FAA-approved that is similar, but not identical, to the form designees or delegated organizations use to approve data. The CDO certificate holder may use other methods to identify FAA-approved data within its company; that process must be described in its CDO procedures manual and is subject to FAA certificate surveillance.

d. There are no third-party privileges – The holder of a CDO certificate does not have the privilege of creating approved data solely for design approvals a third party is seeking (see exception for consortiums under §21.705 discussion). A CDO certificate is not intended to be another avenue through which third persons can obtain approved data for use on their products, parts, or appliances. The certificate holder has the right, and some times the obligation, to support the continued operational safety, functionality, and operational suitability of its products, parts, or appliances. In that sense, it may make determinations of compliance and thereby create FAA-approved data related to the design approvals it holds, for the use of others wishing to repair, maintain, alter, or otherwise modify the design of products, parts, or appliances covered by its CDO certificate. This includes all activities related to continued operational safety, the approval of service bulletins, the approval of repair data, and providing approved compliance data for use by others in those endeavors related to its product, part, or appliance.

e. Production privileges – Every holder of a CDO certificate has prototype manufacturing privileges, which include conducting conformity inspections for parts, articles, test setup, and installations. Once a production approval has been issued by the FAA related to the design approval, the CDO certificate holder has the

option of conducting certain production activities under its CDO certificate. Those activities must be accomplished in accordance with procedures contained or referenced in the CDO procedures manual. The procedures must conform to the basic tenants of the CDO concept (such as being accomplished under the SMS, QMS, and CMS; being able to establish compliance through procedures; etc.). The privileges obtained by exercising this option are identified in §21.741(l), (m), (n), and (q).

f. Maintenance and operations privileges – Paragraph 21.721(c) grants the privilege of making all determinations of compliance to maintenance and operational activities associated with type certification. These aspects are associated with the determination of compliance for instructions for continued airworthiness (ICA) in §§XX.1529 contained in parts 23, 25, 27, and 29; and §§31.82, 33.4, and 35.4. The certificate holder must include procedures for the determination of compliance to those maintenance aspects in its CDO procedures manual. In addition, there are several boards created by Flight Standards to assist in determining the initial operational evaluation of aircraft during a type certification program. Those are the Flight Operations Evaluation Board (FOEB), the Flight Standardization Board (FSB), and the Maintenance Review Board (MRB). The FAA will still initiate and chair those boards but any associated determinations of compliance to airworthiness standards would be made by the certificate holder, consistent with its design approval privileges in §21.721.

g. The creation of eligible data – It is a common practice for a company to develop products, parts, components, processes, and data for use in future type certification, TSO, and PMA programs. If the development is accomplished under the approved CDO system, it could be developed without FAA involvement or the need to initiate an FAA project, and the resulting compliance and type design data may be directly eligible for use in subsequent designs. It is inappropriate to consider such developmental activity as a compliance determination and the resulting data as FAA-approved, since it does not relate directly to a project having a formal FAA-specified type certification or other approval basis. However, credit may be given for any demonstration of compliance activities accomplished during this developmental activity under a CDO certificate. The FAA has created the term "eligible data" to describe the data produced by this kind of activity. "Eligible data" are data developed under an approved CDO system, given a specified, but not necessarily final, approval basis, and product type design if appropriate. To convert "eligible" data into a completed compliance determination for a particular application, the CDO holder must demonstrate that the data is applicable, given a specified approval basis of the product, part, or appliance and, if appropriate, final design in which it is to be used. It would not be necessary to repeat the demonstrations of compliance, provided those demonstrations were appropriate for the final design and its approval basis. If the demonstration of compliance is not appropriate, further analysis or testing may be necessary. Eligible data is intended for use within the CDO. No approval or compliance determination can be inferred upon the data if the eligible data is provided for use outside the CDO.

h. Additional privileges granted – There are additional privileges that the FAA chooses to grant to a CDO holder that are not conveyed through its CDO certificate. These privileges are not entitlements but are privileges the FAA believes provide additional benefits to both the certificate holder and the FAA. The FAA will grant the following additional privileges to certificate holders who request and comply with the requirements associated with obtaining and maintaining the privileges:

(1) The certificate holder, or an individual identified by the holder, may obtain a delegation from the FAA for the issuance of some design approvals and certificates;

(2) The certificate holder may participate in the FAA's program for voluntary self disclosure of regulatory and procedural non-compliance by a certificate holder; and

(3) The certificate holder may make statements of compliance to certification and airworthiness requirements of other importing authorities, on behalf of the FAA, when allowed through bilateral aviation agreements.

16. §21.723 What are the general responsibilities of a certificate holder?

a. Compliance with subpart P – The certificate holder is responsible for continued compliance with the requirements of subpart P and following the procedures defined within its FAA-approved CDO procedures manual. If at any time the certificate holder has reason to believe that it is not complying with either, it should notify the FAA. The FAA will consider that notification to be a part of the self-disclosure provisions discussed in paragraph 15.h. of this AC, as long as it meets all the published requirements for consideration as a self disclosure.

b. Compliance with part 21 – The CDO is not required to comply with FAA Orders since Orders apply only to the FAA and its designees, and CDO is not a delegation. However, all of the Orders and much of the guidance material is based upon well-proven procedures for demonstrating and finding compliance. The CDO applicant and certificate holder is expected to consider those Orders and guidance material in the development of procedures for its CDO procedures manual. But, when determining the acceptability of the CDO procedures, the FAA will compare them with the requirements in subpart P, and will not require equivalence to the procedures in FAA Orders and advisory material. However, in working with the FAA in the approval of the type certification basis, acceptable methods of compliance, special conditions, and equivalent safety findings, the CDO is expected to follow normal FAA processes defined in advisory materials and FAA Orders, as those are the standard processes for all applicants and are based on internationally accepted principles. Defined processes for making applications for certificates and working under bilateral airworthiness agreements

with other States must also be followed to the same degree other applicants are required to follow them.

c. Comply with certificate scope – The certificate defines the scope of activities the certificate holder is authorized to perform. All activities within that scope must be conducted in accordance with the CDO procedures manual, including those activities related to legacy products, parts, or appliances that are within the certificate scope. The certificate scope applies to all original design activities, as well as amended design approvals and continued operational safety matters, including repairs and alterations in service. The FAA does not allow activities within the scope of a certificate to be conducted under organizational delegation or designee procedures.

d. Define responsibility – The certificate holder is required to nominate a company executive that will have the responsibility and authority for all activities being conducted under the certificate, and provide descriptive material on how the roles and responsibilities of that executive will be institutionalized within the company. That person will be referred to as the CDO Executive. The FAA must concur that the person has the responsibility and ability to oversee the operation of the CDO. The CDO Executive is not required to have functional responsibility for all technical and functional activities that must occur in the proper execution of the CDO procedures manual. The Executive must have the authority, though, to enforce the proper performance of the CDO procedures even though they may be under operational control of another person, and should be someone with a strong background in compliance activities. Any delegation by the CDO Executive of the authority to make statements of compliance in accordance with §21.719(a) must be in writing to a specific named person, and must be found acceptable to the FAA. The CDO Executive and other senior management officials within the company seeking a certificate must declare in writing their commitment to complying with CDO requirements. Any succeeding CDO Executive selection must be found acceptable to the FAA using the above criteria.

e. Minimum required staff – Section 21.723(c) requires that the CDO implement procedures for defining and qualifying the minimum management and technical staff necessary to meet the requirements of the CDO certificate. The certificate holder need only identify the minimum staff by title and discipline, and not by name. The determination of what constitutes the minimum staff will be based solely on the staff's ability to meet the requirements of the certificate, not how long it might take to meet those requirements, or how difficult the task may be. This minimum staff may be augmented by additional employees or suppliers, but the process for identifying a minimum staff should include how the CDO will meet it obligations using only the minimum staff. If the CDO fails to maintain the minimum staff, it should suspend operations normally conducted by the vacant staff, and immediately notify the FAA of how it intends to remedy the situation. The minimum staff may vary greatly from one CDO to another depending on its process and their level of sophistication. An organization that has highly detailed

procedures and rigorous verification processes may be able to function with a smaller technical staff than an organization that relies on compliance guidelines and skilled individuals performing the CDO procedures. Most organizations will probably have a blend of techniques with some areas of compliance being highly formalized and others having less formal definition and requiring higher skill levels.

f. Temporary minimum staff vacancies – There may be temporary gaps in the minimum management and technical staff necessary to execute the responsibilities of the certificate holder. The FAA recognizes this may occur because of normal changes in personnel. Those temporary gaps do not invalidate the certificate and are not considered to be grounds for certificate action by the FAA, as long as the FAA is notified of those gaps in a timely manner. It is preferred that the notification be in advance of the actual vacancy. That notification should include a plan for how the certificate holder will revise its procedures to ensure that no determinations of compliance will be made in those compliance areas where qualified staff is temporarily unavailable. The FAA must approve this plan.

g. Project activity – There are many projects that the CDO certificate holder is permitted to complete without having to notify the FAA, since the CDO will be making all determinations of compliance in accordance with its FAA-approved procedures manual. There are other projects that the FAA must be made immediately aware of since it is required to validate the existing type certification basis or establish a new one. Part 21 specifies when an application must be made to the FAA, including applications for TC, STC, PMA, and TSOA. The required applications will be used to discriminate between those projects that require notification of the FAA and those that do 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:

(1) Any new design approval,

(2) Amended type certificates requiring a new model designation,

(3) New supplemental type certificates, and

(4) Any project that might reasonably be expected to have a revised type certification basis under §21.101.

In all cases, the certificate holder must create a record of all compliance activities performed by the CDO, and the FAA must be provided access to those records. They could be a hand-written record or they could be electronic. The system of records would include activities such as major and minor changes to an existing design, as well as repair approvals. There must be an updated database of these records that can be accessed by the FAA as it desires. This database should contain the type of information that the FAA currently uses to measure the

significance of a project, similar to the data currently collected through the FAA 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 anticipated FAA involvement in the establishment of the certification basis.

h. **Points of Contact** – The CDO Executive may designate specific individuals to act for the CDO in formally coordinating and communicating official positions with the FAA. These are called points of contact (POC). The CDO POC must have a thorough knowledge of CDO processes and the applicable FAA regulations consistent with their area of responsibility within the scope of the CDO certificate. The CDO POC must also have unencumbered, but not necessarily direct, access to the CDO executive. Any limitations on their responsibilities or authority must be identified in the manual. The line of accountability from the POC to the CDO Executive must be defined in the manual. These persons will be identified in the manual or by a means acceptable to the FAA that is readily available to both the FAA and the CDO organization. The procedures manual will identify the qualification requirements and responsibilities of these persons.

i. FAA-CDO interface process – All official interfaces between the FAA and the certificate holder should be between the CDO Executive's office and the FAA oversight team. Should any FAA oversight result in FAA observations or the need for corrective actions, those matters will be directed to the CDO Executive. The FAA will not make any comments or requests directly to other CDO management or staff, as the CDO Executive is held responsible by the company and the FAA for resolving any matters between the certificate holder and the FAA and should be made directly aware of those matters. Likewise, all routine communication from the CDO will be sent to the oversight team leader for proper action within the FAA. The certificate holder should refrain from making verbal responses to official FAA communications.

j. FAA certificate management – The FAA must be provided the access necessary to properly perform its certificate management responsibilities. That would require the CDO certificate holder to provide a current physical address for the principal base of operations and contact information so that appropriate responsible parties within the CDO may be readily reached. The CDO would be expected to develop and implement corrective action plans for all FAA certificate oversight findings. The priority for implementing a resolution to those FAA findings should be commensurate with the potential safety consequences of the findings, and must be acceptable to the FAA. For instance, a finding that would be expected to have a high safety impact should have a high priority for resolution.

17. §21.725 A compliance assurance system is required of a certificate holder

a. Produce showings of compliance – The compliance assurance system for a CDO must meet the requirements of §21.725. These requirements identify characteristics of the compliance assurance system that must be met. The implementation of these characteristics by the certificate holder should be a system to produce showings of compliance that can be relied on by the FAA in making an overall finding of compliance when issuing a certificate. To maintain the necessary level of assurance in the air transportation system, these showings of compliance need to demonstrate a level of assurance equivalent to what would occur from an independent skilled review. To define a system and find it acceptable, the applicant and the FAA need to have a common understanding of what skilled and independent mean.

b. Skilled – A skilled review generally means that the reviewer has the same qualifications as the person making the original showing of compliance. Likewise, processes should have redundancies that are of the same skill level or same certitude, if one is to take credit for the process redundancy. However for some determinations of compliance, associated with less critical requirements, a reviewer does not need to have all the same qualifications as the person making the original compliance showing, nor do redundant processes need the same level of certitude. If the CDO identifies that the review of compliance may be done by someone with lesser qualifications than the original person/process making the determination of compliance, this should be documented in the compliance assurance system procedures. Tools may be used to meet the requirement of compliance assurance if they can be shown to provide the additional assurance an independent review by a skilled individual would provide.

c. Definition of independent – Independent means achieving the objective of the review with little likelihood for a common error or misunderstanding. The FAA and industry have considerable experience with the independence requirement in the software development processes defined in Annex B of RTCA DO-178B/ED-12B. It contains a definition of independence as it is applied to software. If the software specific reference is removed, a definition results that is consistent with the intentions of the CDO requirements. The modified definition is:

> Independence – Separation of responsibilities which ensures the accomplishment of objective evaluation. For compliance assurance activities, independence is achieved when the verification activity is performed by a person(s) other than the developer of the item being verified, and a tool(s) may be used to achieve equivalence to the human verification activity.

d. What independence means for CDO compliance – Experience in the software development arena shows there are still variations in what is deemed acceptable independence. Some have proposed that independence requires a separate organization to satisfy that independence, others have argued that a technical expert

must conduct the verification activity and it may require the review to be conducted by the designer, and a third perspective is that independence is achieved when another individual conducts the verification activity so there is not a single perspective. For the CDO compliance assurance system, the independent verification activity should reduce the likelihood that an individual misinterpretation or error would pass through the system unchallenged. How that is best achieved under CDO with its requirements for a CAS, QMS, and SMS all working together can best be established by the certificate holder.

In assessing if the compliance verification activities are adequate for a CDO the FAA will assess:

(1) Is the person(s) or tool(s) performing the compliance verification capable of determining that compliance is correct in all significant aspects?

(2) Will the compliance verification activity identify individual misinterpretations or errors?

(3) Will the compliance verification activity identify omissions in the determination of compliance?

e. Compliance by process – Section 21.725 requires processes and procedures to plan, execute, and verify compliance activities, and §21.727(c) requires corrective action processes within the QMS requirements. Together these requirements form the basis of what the FAA has called "compliance by process." This term refers to the idea that compliance determinations are made in a standard manner following standard procedures and that the procedures are corrected if errors are detected, rather than continuing to use the same methods and potentially repeating the same errors. It is through this mechanism that continued improvement in the compliance performance of a CDO is anticipated.

18. §21.727 A quality management system is required of a certificate holder

a. General requirements – At its highest level, the QMS requirements provide for process assurance, corrective action processes, configuration management, personnel qualification, supplier oversight, and management review of the CDO activities contained in and referenced by its procedures manual. This requires the CDO to have processes that result in consistent, expected performance. This allows the FAA to utilize system oversight of industry compliance rather than the FAA having to make individual findings of compliance, directly or through its designees.

b. Internal surveillance and audit – Section 21.727(b) requires the certificate holder to conduct surveillance and audits of its processes and procedures contained in its procedures manual. Surveillance is periodic spot checks of portions of the CDO systems conducted by members of the organization; this should be a formal activity

and records should be kept of the activity and any observations that result, be they positive or negative. Audit is formal reviews of the entire system that are conducted periodically. Although audit is required of the entire system, it may be conducted incrementally in accordance with a plan that identifies how the entire system will be covered. The frequency of the audits and surveillance should be related to the safety significance of the specific procedure. Those of high safety significance should be audited more frequently.

c. Corrective action processes – Section 21.727(c) requires proactive and reactive corrective action processes. The term reactive identifies those corrective action processes that are triggered by an identified event, deficiency, or error. It is usually an action that takes place following an undesirable outcome, but even a desirable outcome accomplished in a manner not consistent with the procedures manual should trigger a corrective action. The term proactive identifies those corrective action processes that are activated by identification of a potential problem. These may be triggered by an analysis that shows a trend toward unacceptable performance, identification of potential errors that would result in unacceptable performance, or other precursor information. Both reactive and proactive corrective action processes should be included in the procedures manual audit corrective action process.

d. Management oversight – Section 21.727(f) requires high-level management oversight of surveillance and audit findings. The objective is to ensure that management has the same overall picture of the organization's performance as do those who are required to assure quality within the organization. The management oversight should be sufficient to allow them to have an accurate view of the organization's performance as measured internally, and awareness of the areas that need improvement, so that necessary resource commitments may be made. The regulation does not intend that the high-level executives within the CDO manage the quality requirements; rather it intends that they have knowledge of the performance of their entire organization, as measured by those who are required to assure quality within the organization.

e. Supply chain oversight – Section 21.727(g) requires the establishment of processes and methods for approval and oversight of partners, suppliers, or subcontractors in its supply chain. This is intended to cover all members of the supply chain regardless of their title/identifier or the goods or services being provided. The processes should identify the level and type of oversight of each member of its supply chain, and how frequently that oversight should be accomplished. The oversight may be by class of supplier or by individual supplier, but it should be based on an assessment of the supplier's capability, history, criticality of the part or data supplied, ability to detect faults in the part or data, and other similar factors that are important to the quality and compliance of goods and service being provided. Oversight of supplier or remote facilities may include the use of remote means such as closed circuit television, web cams, or other monitoring methods if

they will meet the oversight objectives. Use of such methods should not replace on-site visits, but may be used with on-site visits.

19. §21.729 A safety management system is required of a certificate holder

a. Definition – Safety management systems are those means necessary to establish the proper safety risk controls, and to assure their effectiveness. Within the safety management system there are safety policy and safety promotion requirements in addition to the safety risk measurement and safety risk assurance requirements. The safety policy and safety promotion requirements may be viewed as enablers to the safety risk control and assurance system. It is the responsibility of the certificate holder to define how all those elements come together for an effective safety management system. The regulation does not define what procedures are necessary for a proper SMS but instead define the objectives that those procedures must meet. The certificate holder knows best its internal management principles and what safety and compliance culture works best within those operating principles.

b. Safety policy – Section 21.729(a) requires the creation of safety policy that defines the SMS goals and objectives for the CDO organization. These goals should be tailored to the company's products and processes contained in and referenced by its CDO procedures manual, in order to create the desired safety impact on company products and services. As required, safety policy objectives should result from processes being properly executed.

c. Risk management system – Section 21.729(b) requires the establishment and usage of a safety risk management system. This system should result in the systematic assessment of risk for hazards that are identified by the safety assurance function of §21.729(c). The certificate holder should perform quantitative assessments of the likelihood of occurrence of hazards whose severity is classified as catastrophic or hazardous. Hazards of lower severity may be addressed with qualitative assessments that result in the effective management of safety risk. Qualitative assessments may not provide sufficient means to manage large numbers of risks and prioritize efforts to address them. Organizations with a large number of products, and products with a wide range of severity consequences, should consider using quantitative assessments of likelihood for all hazards.

d. Safety assurance – Section 21.729(c) addresses the validation of system performance, and the effectiveness of implemented risk controls and risk management strategies. This process continually assesses CDO activity to identify new hazards and to ensure risk controls achieve their intended objectives throughout the system life cycle. New hazards may be those not identified during the SMS process or those that may have been unintentionally introduced by risk controls or other actions. This process includes the assessment of the need for any new controls, or eliminating or modifying existing risk controls that are ineffective or may be unnecessary based on operational data. Every SMS should include a process for continuously monitoring the systems of interest to identify new hazards,

or the need to change risk controls or other risk management responses. These monitoring activities apply throughout the CDO system, regardless of whether or not the process is within the CDO or its suppliers.

Safety assurance includes processes that properly address:

(1) The gathering of essential information, including from FAA audit findings and comments on previous regulatory compliance issues;

(2) The analysis of that information in connection with other already gathered information;

(3) An assessment of the impact of the information on the CDO system; and

(4) The development of preventive or corrective action when regulatory non-compliances or deviations from the CDO procedures manual are discovered.

e. Safety promotion – Section 21.729(d) requires the CDO to implement the actions necessary to create an environment where safety objectives can be achieved and maintained. The rule identifies four specific actions that must be included, but if there are other actions that are necessary to achieve the goal of an environment where safety objectives can be achieved and maintained, those other actions are required by this rule. If the safety assurance function finds that corrective actions are ineffective due to some element of the safety culture, actions must be taken to address those cultural elements.

20. §21.731 What requirements will be used to determine my capability to operate under a CDO certificate?

a. The regulatory requirements – The requirements for holding a CDO certificate contain specific criteria for various systems and principles that must be implemented within the company. The criteria are not detailed to the point of defining specific procedures that must be incorporated within the CDO. Each certificate applicant and holder would be required to design its procedures to meet the regulatory criteria ("what" must be done) using procedures that operate best within its company ("how" it must be done). Compliance with the regulatory requirements is achieved by having a top-level CDO procedures manual that identifies "what" must be done. Those procedures will be FAA-approved and require prior FAA approval to change them. The lower-level process describe "how" things are done, and are not FAA approved but must be referenced in the CDO procedures manual. FAA will measure compliance with those procedures as part of its certificate management.

b. Measuring compliance – An evaluation process has been developed and is currently being used in other venues to measure continued organizational capability to comply with broad procedural requirements. That process is called a Capability

Maturity Model (CMM), and there are several derivative models that implement basically the same CMM principles. The FAA has developed a series of CMM principles called the Integrated Capability Maturity Model (iCMM). All CMM techniques have several levels by which they characterize an organization's capability to perform process and procedures, and its "maturity" in performing those activities. In accordance with the iCMM principles, the FAA has chosen a "level 3 maturity" and "level 3 capability" as the minimum level for regulatory compliance. The CMM descriptors for level 3 capability and maturity form the regulatory requirements for CDO.

The FAA will use the FAA iCMM and its related appraisal methods as the basis for evaluating the certificate holder's compliance with the system-based regulatory requirements for CAS, QMS, and SMS. This evaluation will be periodic, with a formal assessment performed each time and a written evaluation report generated. The evaluation may be performed in a staged manner with separate elements being evaluated at each stage, and a completed evaluation consisting of the execution of several staged appraisals. This method will likely be employed for the larger organizations or those with complex CDO certificates, where a single evaluation of all the facilities or all aspects of the certificate scope is difficult to achieve at one time and resource intensive for the FAA and the certificate holder. The results of the evaluation will be documented, records generated will indicate the evaluated activities, the evidence of performance will be documented, and the capability level for each process area evaluated. The overall maturity rating is developed from these documented individual capability levels for each process area. The evaluations will also include reviews of the compliance determinations made by the CDO and the records relating to those compliance determinations, certifications of compliance made by the CDO, and the records relating to those certifications of compliance.

c. Specifics of the FAA Integrated Capability Maturity Model – The FAA iCMM is a model for process improvement developed from a number of process improvement models and appraisal standards. The integrated capability maturity model is an extension of the "software capability maturity model" originally developed at Carnegie Mellon University. The integrated capability maturity model broadens the applicability of the model to extend its usefulness to areas outside software development, while retaining the depth of process improvement guidance in a CMM. One of the features of the capability maturity model is the definition of several capability levels. Each process within an organization can be rated on this capability level scale to assess how it is being performed. Each capability level has certain generic practices that define performance at that level. The capability levels and generic practices of the FAA iCMM are defined below. Again, level 3 is required for the issuance and maintenance of a CDO certificate.

CAPABILITY LEVEL	DESCRIPTION	GENERIC PRACTICES
0	Incomplete	None.
1	Performed	Identify work scope, perform the process.
2	Managed: planned and tracked	Establish organizational policy; document the process; plan the process; provide adequate resources; assign responsibility; ensure skill and knowledge; establish work product requirements; consistently use and manage the process; manage work products; objectively assess process compliance; objectively verify work products; measure process performance; review performance with higher-level management; take corrective action; and coordinate with participants and stakeholders.
3	Defined	Standardize the process; establish and use a defined process; and improve processes.
4	Quantitatively managed	Stabilize process performance.
5	Optimizing	Pursue process orientation.

Another feature of the capability maturity model is that it contains defined process areas. The process areas of the FAA iCMM are categorized by the type of activity, and are staged to represent certain maturity levels. The concept of staging is that certain process areas are necessary for specific performance levels of an organization, with the higher performance levels corresponding to higher maturity levels. The processes areas for any maturity level include those staged at that level and those staged at a lower level; they are cumulative. The process areas, maturity level staging, and category of the FAA iCMM are defined in the following table.

PROCESS AREA	MATURITY LEVEL	CATEGORY
Integrated enterprise management	3	**Management**
Project management	2	
Risk management	3	
Supplier agreement management	2	
Integrated teaming	3	
Needs	3	**Life cycle**
Requirements	2	
Design	3	
Design implementation	3	
Integration	3	
Deployment, transition, and disposal	2	
Evaluation	2	
Operation and support	Not Staged	
Outsourcing	2	**Support**
Alternatives analysis	3	
Measurement and analysis	2	
Quality assurance and management	2	
Configuration management	2	
Information management	Not Staged	
Process definition	3	
Process improvement	3	
Training	3	
Innovation	5	

Within each process area, the iCMM defines base practices it considers fundamental to performing that process. The base practices of the process areas and the generic practices of the capability levels have a useful synergy. Base practices provide guidance on the fundamental practices to accomplish the goals of a process area. The generic practices tell how to institutionalize and improve the capability of a sound process. Neither the base practices nor the generic practices will themselves insure the desired outcome from processes, but the iCMM requires the measurement of process performance, and the base and

generic practices are used to help identify shortcomings and develop corrective action.

Below is the definition of a specific process area, its goals, and the best practices for the process area "Design." The FAA looks at the definition and goals as being minimum requirements for compliance with the iCMM principles, whereas the best practices are those that most persons would find necessary to meet the definition and its goals. Other best practices may be used by a particular certificate holder as long as the definition and goals of all the process areas have been met.

PA 03 DESIGN: TO ESTABLISH AND MAINTAIN AN ARCHITECTURE AND DESIGN SOLUTION FOR THE NEEDS AND REQUIREMENTS OF THE CUSTOMER AND OTHER STAKEHOLDERS.

GOALS

1. A product or service design that will meet the defined requirements is established and maintained.
2. The established product or service design is based on an evaluation of alternatives against criteria that represent the requirements.
3. Allocations of requirements to the design elements are established and maintained.

BASE PRACTICES

BP 03.01 Identify and Prioritize Design Issues. Establish and use a mechanism to capture, prioritize, and resolve product and service design issues.

BP 03.02 Develop design structure. Evaluate alternatives against established criteria to select the architecture, structure, and elements for the product or service design.

BP 03.03 Develop Interface Specifications. Develop interface specifications for the selected product and service elements.

BP 03.04 Allocate requirements. Allocate product and derived requirements to the design elements and interfaces, and to personnel or processes where appropriate.

BP 03.05 Define Interactions among Design Elements. Define the dynamic interactions and operational sequences among design elements.

BP 03.06 Establish Component Specifications. Establish design specifications for each element of the product or service.

BP 03.07 Establish and Use a Strategy for Non-developmental Items. Establish and use a strategy for managing issues relating to the use of non-developmental item (NDI) product and service elements.

BP 03.08 Establish and maintain design description. Establish and maintain a complete description of the product and service design.

In order to achieve iCMM Maturity Level 3 the process area "Design" above must satisfy iCMM Capability Levels 1, 2, and 3; the other 19 process areas required for meeting Maturity Level 3 must also satisfy these same Capability Levels. Below are the iCMM defined Goals and Generic Practices associated with Capability Levels 1, 2, and 3:

CAPABILITY LEVEL 1: PERFORMED
GOAL: ***The process achieves the goals of the process area.***
GENERIC PRACTICES:
1.1 Identify Work Scope. Identify the scope of the work to be performed and work products or services to be produced, and communicate this information to those performing the work. **1.2 Perform the Process.** Perform a process that implements the base practices of the process area to provide work products and/or services to a customer.
CAPABILITY LEVEL 2: MANAGED: PLANNED AND TRACKED
GOAL: ***The process is institutionalized as a managed (planned and tracked) process.***
GENERIC PRACTICES:
2.1 Establish Organizational Policy. Establish and maintain an organizational policy for performing the process. **2.2 Document the Process.** Document the process for performing the practices of the process area. **2.3 Plan the Process.** Establish and maintain a plan to accomplish the objectives of the process. **2.4 Provide Adequate Resources.** Provide resources that are adequate for performing the process as planned. **2.5 Assign Responsibility.** Establish responsibility, authority, and commitment for performing the process. **2.6 Ensure Skill and Knowledge.** Ensure that the people performing the process have the needed skill and knowledge. **2.7 Establish Work Product Requirements.** Establish and maintain requirements on work products and services that result from the process.

2.8 Consistently Use and Manage the Process. Consistently use the documented plans, standards, processes, or procedures in implementing and managing (planning and tracking) the process.

2.9 Manage Work Products. Place identified work products of the process under appropriate levels of configuration management.

2.10 Objectively Assess Process Compliance. Objectively assess adherence of the performed process to the documented process.

2.11 Objectively Verify Work Products. Objectively verify adherence of work products and services to established requirements.

2.12 Measure Performance. Measure performance against the plan.

2.13 Review Performance with Higher-level Management. Review the activities, status, and results of the process with higher-level management.

2.14 Take Corrective Action. Take corrective actions to address problems.

2.15 Coordinate with Stakeholders. Coordinate and communicate among those performing the process and with appropriate stakeholders.

CAPABILITY LEVEL 3: DEFINED

GOAL: ***The process is institutionalized as a defined process.***

GENERIC PRACTICES:

3.1 Standardize the Process. Establish and maintain a set of standard processes for the organization, including tailoring guidelines.

3.2 Establish and Use a Defined Process. Establish and use a defined process, designed to meet specific business objectives, that is tailored from the organization's set of standard processes.

3.3 Improve Processes. Collect and use work products, measures, measurement results, and improvement information to improve the standard and defined processes.

When the applicant organization is creating, redesigning, or evaluating its business processes to show compliance to the requirements of subpart P, they should identify the process areas that each of their processes and procedures are addressing, in addition to the specific regulation in subpart P that it addresses. A single business process may address elements of several process areas, for example a drawing approval process may include base practices from the requirements, design, and configuration management process areas.

The capability maturity model also provides a method for evaluating the maturity of an organization's processes. This is not a measurement of their age

but of the number of processes that are performed at a defined capability level. The maturity staging in the process area reflects the process areas that should be performed at the corresponding capability level for each maturity level. For a given maturity level, all process areas staged at that level and below should be performed at that capability level. Hence there are 9 process areas to be performed at capability level 2 for maturity level 2, and 20 process areas to be performed at capability level 3 for maturity level 3 (9 staged at level 2, and 11 staged at level 3).

An applicant for a CDO or a certificate holder should be able to demonstrate a level 3 capability and maturity for the processes required of a CDO. This level was selected as the appropriate level for a process based certification organization based on the CDO objectives of repeatable and reliable certification processes.

One of the generic practices of level 3 is for the organization to standardize its procedures. This is described by the phrase, "establish and maintain a set of standard processes for the organization, including tailoring guidelines." Section 21.731(a) has language making it clear that, even within standard processes guidelines, individual processes may be created from standard processes. This is the tailoring referred to above. The objective of this requirement is to have standard processes where possible and where individual processes have been created, the basis of those processes and the relationship to the original process is understood so that problems detected within the tailored process or the original process can be traced to the other process, so that process improvements or corrections can be applied to all affected processes.

21. §21.733 What must be included in the procedures manual?

a. General contents – The CDO procedures manual contains the CDO organization's procedures for meeting its regulatory requirements. The manual must address all relevant CDO requirements. The first section should be labeled "Certificate" and address the scope of the certificate and its privileges. These constitute a part of the CDO certificate. Specific details of an acceptable procedures manual content are found in Appendix A of this AC.

b. Kinds of procedures – The manual should address compliance and process objectives, including those details necessary to ensure that the regulatory requirements are met. The process and procedures must be sufficient for the FAA to determine that they properly address regulatory compliance; they must be measurable. The manual is intended to be a top level document that will guide the development of lower level processes and work instructions that the CDO 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 top level processes and the procedures outlined in the FAA approved CDO procedures

manual. Compliance with these referenced procedures will be evaluated by the FAA as part of its certificate management.

The manual also must contain procedures or references to procedures that demonstrate how compliance to all of the requirements of 14 CFR part 21 subpart P will be made. It must be more than an index to procedures, it must provide the top level procedure to be followed; details may be in referenced documents but the CDO personnel must be able to follow the procedures contained or referenced in the manual to comply with the organizations obligations under the CDO certificate.

Internal company processes and procedures that are not related to the CDO requirements would not be tied to the procedures manual and would not be auditable by FAA as part of its CDO oversight.

22. §21.735 What records and reports must the certificate holder maintain?

a. Types of records – A CDO certificate holder produces two types of required records in the course of exercising the privileges of its certificate: (1) those related to the processes and procedures identified in the procedures manual that are necessary to comply with the requirements of subpart P; and (2) those required as part of making determinations of compliance associated with the issuance, amendment, or continued operational safety of type certificates, TSO authorizations, or PMA. The regulation addresses specific retention periods for both types of records.

b. Surrender or termination of the certificate – Should the CDO certificate be surrendered or terminated, the surrender of each of these two types of records would be dealt with differently. The records associated with the operation of the CDO with respect to the processes and procedures required by subpart P would be submitted to the FAA.

The records related to findings or determinations of compliance to airworthiness standards define the design (type design for products) and all of the compliance data used to demonstrate compliance; records related to production also capture all the compliance activity necessary to support the issuance of airworthiness certificates. These records are not specifically related to the CDO certificate, but are related to the efforts that are necessary for the issuance and retention of design and production approvals, and are irrespective of the process used to obtain them. These records must also be submitted to the FAA, but a copy of the records would be required to remain with the design and production approval holder after their CDO certificate is no longer valid, for as long as they hold those approvals. They are essential for the certificate or approval holder to continue to meet its regulatory responsibilities as a design or production approval holder. The continued retention and eventual surrendering of those records would be in accordance with other requirements contained in part 21.

c. Data provided to others – In accordance with §21.735(a)(4), the CDO would be required to maintain a record of all determinations of compliance and approved data to enable proper FAA oversight. If FAA-approved data is provided to others outside of the CDO system, in accordance with paragraph §21.735(a)(5) the certificate holder must maintain a record of who that data was initially sent to and what data was sent, in case there is a need to notify that party of continued airworthiness issues associated with the data.

d. Service difficulties – Section 21.735(b)(2) addresses service difficulties associated with approvals or certificates held by the certificate holder, even if they were issued prior to the person obtaining a CDO certificate. This is included because §21.723(f) would require that all compliance activities be conducted under its CDO certificate. That would include activities associated with legacy products, parts, and appliances.

23. §21.737 What FAA oversight is a certificate holder subject to?

a. The process – The FAA will use an integrated team to oversee the CDO, with all the disciplines necessary to address the scope of the certificate. This team may include a representative(s) from the policy office managing CDO (initially), the product directorate(s), the AEG(s), the geographic ACO and MIDO, and the FSDO. This FAA CDO oversight team will develop a coordinated FAA response to issues that arise with the operation of the CDO, ensure that adequate oversight is performed on the CDO operation, and provide an FAA response to issues that arise, so the certificate holder does not have to coordinate matters among the different FAA organizations involved in CDO oversight.

Participation of the representatives from the policy office managing CDO, the directorates, and AEG is intended to assure that policy standardization takes place for all CDOs, regardless of geographic locale. These representatives may not be involved in all matters of the CDO but would be involved with issues related to policy they are responsible for. FAA specialists from the geographic region that are not members of the CDO oversight team may participate in oversight of the CDO or be called in for their specific technical expertise, as requested by the oversight team. All contact with the certificate holder will be through the FAA CDO oversight team and they will provide the FAA response to any issues raised by the CDO or raised by FAA personnel involved in oversight of the CDO.

b. Routine surveillance – One type of FAA oversight is routine surveillance, which involves the regular oversight of the CDO organization during its normal operation. The objective is to see that the organization is following its procedures manual processes related to its CDO scope and to evaluate if these processes are effective in establishing appropriate regulatory compliance. This oversight may be performed by any member of the FAA CDO oversight team or may be performed by other FAA personnel with particular skills or expertise, as requested by the CDO oversight team. Records will be maintained to document all oversight and to record any findings. These records will identify the product being evaluated, the portion of

the CDO system being observed (procedure observed), and any particular observations of the person performing the oversight. The CDO oversight team will review the surveillance records and determine whether there are any compliance matters or concerns with the certificate holder not following its procedures manual. Persons performing surveillance will not discuss any findings with the CDO, but will document the observation and identify the concern to the FAA CDO oversight team who will formally communicate any concerns to the CDO. If a person performing oversight is asked about their observations, they may share them with the CDO, but they will not expect action by the CDO until the FAA CDO oversight team has reviewed and made a decision on the appropriateness of any concerns.

c. Audits – The CDO oversight team will conduct scheduled audits to assess specific portions of the CDO certificate procedures for compliance with the regulations, whether the procedures have been properly followed during the operation of the CDO, and whether the procedures resulted in appropriate compliance with FAA airworthiness standards or other requirements.

d. Appeals – The certificate holder is eligible to exercise any and all appeal avenues within the FAA should it disagree with an FAA position on a matter. It is preferred, but not required, that any issue be first worked with the CDO oversight team, and only then with appropriate management that is responsible for the policy or regulation related to the disagreement.

24. §21.739 FAA must determine no undue burden

If the location of the initial CDO suppliers or other aspects of its operations is outside of the U.S., the FAA will assess if the location of those activities places an undue burden on the FAA in conducting its certificate management responsibilities. In making that determination, the FAA will consider the availability of its bilateral partners to perform oversight of overseas CDO activities on its behalf, under an existing bilateral airworthiness agreement. The certificate holder is required to keep a current list of suppliers and it should notify the FAA of any new suppliers or other aspects of its operation that are outside of the U.S.

25. §21.741 What requirements of this subchapter have different applicability for a CDO?

a. The regulatory principal - The requirement in §21.723(a) is that the CDO must continue to meet all applicable requirements specified under this part and other parts in this subchapter that any other applicant for or holder of an FAA design or production approval would have to meet, unless otherwise specified. There are some regulations in this subchapter that have different applicability for a CDO than they do to other applicants and certificate holders. That different applicability stems primarily from the fact that the CDO makes all determinations of compliance and in doing so must operate in accordance with its FAA-approved CDO procedures manual. The discussions below describe why the different applicability exists and

how compliance with the part 21 or part 26 requirements may be shown by the certificate holder.

b. Section 21.21 Issue of type certificate – The presumption for delegated organizations is that all compliance records will be retained at the company, with FAA having access to those records when it desires. The records required by § 21.21 will be turned over to the FAA when the organizational delegation is terminated, or retained by the type certificate holder under an FAA records retention agreement. This same, long-standing principle is applied to a CDO certificate holder.

c. Section 21.33 Inspection and test – The CDO certificate holder makes all determinations of compliance, and the FAA may rely on those determinations when issuing a design approval. Current §21.33(a) requires the applicant to allow the FAA to make any inspections and tests "necessary to determine compliance." Under the CDO concept, the FAA will not be making detailed findings of compliance that would trigger the application of §21.33(a). The FAA may wish to confirm compliance determinations made by the certificate holder, as a part of its surveillance of that certificate. In exercising its authority to confirm compliance, the FAA would continue the practice of working with the applicant to witness testing it is planning to conduct, or to reach agreement with the applicant on additional testing that the FAA believes is necessary to exercise its oversight responsibilities.

d. Section 21.35(a)(4) – Even though the flight tests required under §21.35 will be a part of the CDO applicant's demonstration of compliance, the flight test report prepared in compliance with §21.35(a)(4) must include a flight test risk assessment, and the methodology found in FAA Order 4040.26 is acceptable. That is because an FAA flight test pilot must be able to conduct certificate oversight activities onboard the aircraft during the flight tests. The FAA policy does not allow its pilots to participate in or observe any flight testing unless a proper flight test risk assessment has been completed.

e. Section 21.53 – All compliance testing will be accomplished by the CDO, so there would be no need to submit a statement of conformity to the FAA. The FAA may observe any testing as part of its oversight of the certificate holder.

f. Sections 21.81, 21.83, and 21.85 – These three sections deal with the issuance of provisional type certificates. Since the CDO makes all determinations of compliance, the certificate holder need not submit the referenced reports to the FAA, but would need to make them available to the FAA upon its request. The certifying statements required in each of those sections would be made in accordance with §21.719(a), since those statements deal with the issuance of a type certificate. The FAA will rely on those certifying statements in the issuance of a provisional type certificate to the same degree it does under §21.719(c).

g. Sections 21.95 and 21.97(a) – The certificate holder makes all determinations of compliance in accordance with its CDO procedures manual, for all changes to a type design. Under §21.721(d) the substantiating data and type design data associated with those changes is FAA-approved. Thus the intent of these sections is met using the CDO procedures manual processes and the privileges afforded the CDO under its certificate.

h. Section 21.99 – When the FAA finds it necessary to correct an unsafe condition on an in-service product, the affected type certificate holder must develop appropriate design changes and submit them to the FAA for approval. The approved changes are then referenced in an FAA airworthiness directive. Under the CDO concept, the determination of compliance for any design change is made by the certificate holder, including those associated with an airworthiness directive. The FAA retains the responsibility for defining the unsafe condition, which forms the basis for determining what design changes are needed. The FAA also retains the responsibility for establishing the compliance times, inspection intervals, and other such parameters that address the timeliness of the corrective action. Additionally, the CDO certificate holder may make determinations of compliance for changes that it or the FAA finds will contribute to the safety of the product. The certificate holder would be required to make the compliance and type design data available to the FAA upon its request.

i. Section 21.113 – The CDO certificate holder may initiate projects and make major changes to its type design without notifying the FAA, except for those changes that would result in a certifying statement being made in accordance with §21.719(a). In accordance with section 21.723(i), the CDO certificate holder must maintain a record of all CDO project activity; this would enable the FAA to be aware of all projects and determine if there are any others it wishes to review as part of its certificate management responsibilities.

j. Section 21.143 – The production certificate quality control data requirements may be included or referenced in the CDO procedures manual and need not be submitted separately to the FAA for approval. When so including it in the CDO procedures manual, the scope of the procedures in §21.143(a)(1) through (a)(6) are required to be addressed. Inclusion of the supplier delegation information requirement of §21.143(b) is also required.

k. Section 21.147 – The CDO certificate holder would be allowed to make changes to its production quality control system using procedures defined or referenced in its procedures manual. Substantive changes would need to be approved by the FAA prior to their implementation. All other changes would be required to be tracked and provided to the FAA on a regular basis, either in a hard copy or electronically, so that the FAA can perform proper certificate management. Examples of substantive changes include: quality control systems associated with new materials and their associated processes; the use of new inspection tools or the application of old tools to new situations; and the use of substantially new processes and

procedures in the performance of quality assurance functions. While it is not possible for the FAA to define each substantive change, the objective is to allow the certificate holder to make all but the most significant changes to the quality control system without prior FAA approval.

l. Section 21.303 - Similar to §21.33, the requirements in §21.303(e) would also apply to situations where the FAA wishes to confirm compliance determinations made by the certificate holder, as a part of its surveillance of the CDO certificate. Also, since the certificate holder makes all determinations of compliance, the FAA makes no findings in accordance with sections §21.303(d)(1) or §21.303(e)(1). Since those findings the FAA normally makes would lead to the issuance of a PMA approval, the certificate holder must make a certifying statement under §21.719(a) and the FAA would rely on that statement as specified in §21.719(c).

m. Subpart L Export Airworthiness Approvals – These are not airworthiness certificates as defined within this part. The certificate holder is authorized to issue export airworthiness approvals for products, parts, or appliances within the scope of its certificate. The processes and procedures in subpart L must be adhered to in the issuance of those approvals.

n. Section 21.611(a) – This section requires the TSO authorization holder to forward data to the FAA that demonstrates compliance with §21.605(b). Since the CDO certificate holder makes all determinations of compliance, it is not required to submit that data, but must make it available to the FAA. This is consistent with the data retention requirements of proposed §21.735.

o. Sections 26.43, 26.45, and 26.47 – These three sections require that data and other information be submitted to the FAA oversight office for review and approval, or to a properly authorized designee for review and approval. Since the CDO certificate holder would make all determinations of compliance, there is no need to submit the data or other information for approval. The data and other materials would be required to be retained in accordance with §21.735 and made available to the FAA. The CDO certificate holder must comply with all other requirements in Part 26.

I. More Information

26. Are there any related documents I should look at?

a. Notice XXX

b. Final rule amendment 21-YY

c. Federal Aviation Regulations part 21, subpart P

d. FAA Integrated Capability Maturity Model Version 2.0

e. FAA appraisal methods (iCMM)

f. FAA iCMM Version 2.0 – Quick Reference Summary

g. AVS SMS Doctrine

h. ICAO Safety Management Manual

27. How can I get this and other FAA publications?

a. You may obtain the Federal Aviation Regulations and those ACs for which there is a fee from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. You may view a list of all ACs at http://www.faa.gov/achome.htm.

b. You may view the FEDERAL AVIATION REGULATION at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_14/14tab_00.html.

c. To request free advisory circulars, contact:

U.S. Department of Transportation
Utilization and Storage Section, M-443.2
Washington, D.C. 20590

d. To be placed on FAA's mailing list for free Advisory Circulars contact:

U.S. Department of Transportation
Distribution Requirements
Section, M-494.1
Washington, D.C. 20590

28. How can I request more information?

You may get more information on this program by contacting the Delegation and Airworthiness Programs Branch, AIR-140 at (405) 954-4103. They may be reached by e-mail at 9-AMC-AIR-140-Policy@faa.gov.

APPENDIX A

GUIDANCE FOR DEVELOPING A CDO PROCEDURES MANUAL

1. How should the procedures manual be formatted?

a. The **FAA has not dictated any specific manual format** but the manual should follow a format that allows the FAA and the CDO organization to easily find the requirements applicable to the subject in question and to assess or audit the CDO to insure that all regulatory requirements are being met by the CDO. The following is recommended:

(1) Cover page - The manual should have a cover page with document number, title, and the appropriate approval signatures of the ACO manager and CDO Executive.

(2) Revision history - The manual must include a revision history section identifying what changes have been made and where the changes are located in the manual.

(3) Table of contents - A table of contents that identifies each section and the contents of that section along with the page on which it can be found. The table of contents should be down to at least the first sub-section level of each section. Any additional sub-levels are at the discretion of the CDO.

(4) List of abbreviations and acronyms – A list of any abbreviations or acronyms unique to the CDO at the beginning of the document is desirable.

(5) List of tables and figures - While not required a list of tables and figures may be desirable and helpful.

(6) Scope- A separate scope section defining the scope of the CDO certificate.

(7) Organization structure - A section for identification of the CDO leadership and chain of command from the CDO Executive up to and including the CEO as required by §21.723(a) and §21.723(b).

(8) Communications process – A process describing how communications will be conducted between the FAA and CDO on all activities.

(9) Design organization staff – A section for identifying how the design organization staff is trained and qualified and how they will maintain their currency with the regulatory requirements. The staff of the CDO includes anybody who performs a compliance function within the CDO.

(10) Compliance assurance system (CAS) - A separate section to define the compliance assurance system requirements and how the process functions.

(11) Safety management system – A separate section to define the safety management system requirements and how the process functions.

(12) Quality management system – A separate section to define the quality management system and how the process functions.

b. **Manual content structure guidelines** - In creating the CDO manual the "what, how, who, and when" questions should be addressed when writing each section to help ensure that the procedure adequately defines both the requirement and the process for meeting the requirement. The "what" is the requirement, the "how" is the means of accomplishing the requirement, the "who" is the position responsible, and the "when" tells when in the requirement must be accomplished.

(1) What is the requirement or purpose - The requirement for the individual procedure may be summarized but there should be a reference to the regulatory requirement so that the reader can go directly to the actual requirement if necessary.

(2) How is the requirement satisfied – This should describe how the requirement is going to be satisfied. It should include appropriate steps and references to other procedures or requirements as necessary. The manual may have the high level procedures defined in the manual and other supporting procedures defined in other sub-tier procedures documents. When this occurs, the procedures must be cross referenced in both documents.

(3) Who is responsible – Define who, by position, is responsible for complying with the requirement. Individual names should not be imbedded in any procedures. Individual names responsible for any requirement will be included on the appropriate organization chart. 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 and explain what particular regulatory requirement is not being complied with. The CDO is obligated to respond to FAA's request within an agreed upon time frame.

(4) When is it accomplished – Each procedure should identify when something should occur if the sequence or timing of a requirement is important. If the sequence or timing is not important it should so indicate.

c. Functional organization charts without pictures. These should be kept current and available to the FAA and all CDO members. Note: The organizational chart is not part of the procedures manual but is essential to interpret many of the procedures and specifications in the procedures manual.

2. How does company management indicate its commitment to follow the procedures manual?

The procedures manual must contain a **statement signed by senior management of the company and the CDO Executive** affirming, on behalf of the company, the agreement to meet its responsibilities as outlined in the CDO regulations and the CDO procedures manual.

3. What organizational requirements must be addressed?

a. A **particular organizational structure is not required**; however, there are certain functional roles that must be defined.

b. The certificate holder must always have a **qualified management and technical staff** with the appropriate mix of knowledge, skills, and abilities (KSA) necessary to perform the functions of the CDO organization for the scope of the CDO certificate they hold and to enable the organization to make a statement of compliance upon completion of a project. The qualified staff must be able at all times to determine that the work performed by the CDO, including that accomplished by any augmented resources, is compliant with the requirements of their compliance assurance system. The process must explain how the CDO determines that individuals are qualified to support their responsibilities.

c. The procedures manual must include a process for determining what constitutes the qualified staff needed to maintain the authorized scope of the CDO organization. **If the qualified staff identified by the procedures manual is not maintained**, this must be reported to the FAA and the CDO procedures manual must include provisions to ensure that no determinations of compliance are made within the CDO and that no statements of compliance are made to the FAA in the affected areas.

d. In certain situations, the CDO may **need to rely on outside specialists** from its suppliers or other technical specialists, or from other divisions within its company. In all cases, the qualified management and technical staff must have the skills necessary to manage those activities and to determine that the work performed by any temporary resources utilized by the CDO is compliant with their certificate responsibilities. Procedures must be included in the procedures manual for making determinations on the acceptability of any outside specialists.

e. CDO Executive - The CDO Executive has the responsibility for ensuring all design, production, and airworthiness certification activities within the scope of the CDO certificate are accomplished in accordance with regulatory requirements. The manual must identify the organization structure by name from the CDO Executive to the CEO. It must identify the relationship of the CDO Executive with the management structure within the CDO, by position only. The procedures manual must define the qualification requirements and responsibilities of the CDO Executive. The CDO Executive may act as the point of contact for the CDO or may

delegate specific responsibilities to others as defined in the manual. The CDO Executive or a designee must always be available to address FAA inquiries in a timely manner.

f. Persons authorized to make statements of compliance – The procedures manual must identify by name and their accountability to the CDO Executive, the person(s) authorized to make the statement of compliance leading to the FAA issuance of a type certificate at the completion of a project. These individuals must have a thorough knowledge of the airworthiness standards and procedural regulations and be able to determine that the compliance plan has been followed. They must be capable of determining on behalf of the company that the CDO has found compliance with the appropriate airworthiness standards for the product identified and has done so following the procedures in the CDO manual. This is intended to allow a company to place the responsibility for compliance at the appropriate level of management. Because of the significance and potential consequences of this statement, these must be persons specifically designated by the company to sign the statement of compliance. The procedures manual must identify the qualification requirements and responsibilities for these positions.

g. Points of Contact (POC) – The CDO Executive may designate specific individuals to act for the CDO in formally coordinating and communicating official positions with the FAA. The CDO POC must have a thorough knowledge of CDO processes and the applicable FAA regulations consistent with their area of responsibility within the scope of the CDO certificate. The CDO POC must also have unencumbered, but not necessarily direct, access to the CDO executive. Any limitations on their responsibilities or authority must be identified in the manual. The line of accountability from the POC to the CDO Executive must be defined in the manual. These persons will be identified in the manual or by a means acceptable to the FAA that is readily available to both the FAA and the CDO organization. The procedures manual will identify the qualification requirements and responsibilities of these persons.

h. Persons authorized to make determinations of compliance – The procedures manual must identify the qualification requirements and responsibilities of the any persons uniquely authorized to make determinations of compliance. Compliance may also result from proper process execution with no one person identified as making the compliance determination. The CDO must maintain a list of those specifically identified persons, their qualifications, and authority. The list need not be in the manual but the process for determining and maintaining the qualifications must be in the manual. The process for managing these individuals must include:

(1) A process for determining the initial qualifications of the individual are appropriate to the tasks being performed,

(2) A process for maintaining the qualifications of the individual,

(3) A process for review of the work performed to ensure it is consistent with the compliance assurance system objectives, and

(4) A process for keeping records of the individual's accomplishment of the compliance activity.

i. Component suppliers authorized to make determinations of compliance – Component suppliers, both domestic and foreign, may be used to augment the CDO capabilities in specific areas as long as there is proper oversight by the CDO The procedures manual must define how the CDO will authorize its design suppliers to make determinations of compliance under the CDO. The CDO must maintain a list, with contact information, of all design suppliers authorized to make determinations of compliance and make that list available to the FAA. The process must define how the CDO will notify the FAA of changes to this list.

j. Design suppliers and technical specialists authorized to make determinations of compliance – Design suppliers and technical specialists may be hired by the CDO to enhance its technical capability in performing compliance functions as long as they have proper oversight by the CDO. The procedures manual must define how the CDO will authorize technical specialists to make determinations of compliance under the CDO.

4. What facility requirements must be addressed?

a. Company owned facilities - The procedures manual must provide the physical address and contact information for the main design facility as well as for all other company owned design and production facilities included in the scope of the CDO.

b. Design supplier facilities – The procedures manual must identify the physical address and contact information for any design supplier authorized to make a "determination of compliance." This does not preclude design suppliers located outside the United States provided that they are accessible to the FAA to conduct its oversight. The procedures manual will have procedures for FAA notification when the CDO adds/changes suppliers located in other countries.

5. What processes and procedures must be included in my procedures manual?

a. Authorized functions - The procedures manual must contain the scope and list of functions the CDO has been authorized to perform as listed on the CDO certificate.

b. Compliance determinations - The procedures manual must contain the process used by the CDO in making all compliance determinations to the airworthiness standards.

c. Statements of compliance - The procedures manual must contain the process used by the CDO to make statements of compliance to the FAA to obtain a design

approval within the scope of its certificate. The process shall identify directly or by reference the person(s) authorized to make the statements of compliance and how the statement will be presented to the FAA.

d. Use of existing design approvals - A CDO may use existing certificates and design approvals it holds or those obtained by third parties as part of its compliance process for new designs provided the CDO has determined the data are applicable and valid for integration into a CDO design. The CDO must identify in its procedures manual how it will determine applicability and validity of existing or previous design approvals for a particular project.

e. Previously approved data - The procedures manual must contain a process whereby the CDO determines the validity of previously approved data when it makes a compliance determination that the data are applicable and valid to a specific CDO design approval. Previously approved data must come from either the FAA or a CAA recognized through a bilateral agreement with the FAA.

f. Eligible data – The procedures manual must establish a process for controlling the creation and use of eligible data within the CDO if it desires to exercise this privilege. The process must document the assumed certification basis and any analyses and test results in a manner that will be acceptable for inclusion in later compliance documents. The process must define how the eligible data can be applied to a specific certification project and how it will be tracked and stored.

g. Approved data – The CDO must establish a process for the creation and identification of approved data in support of design approvals currently held by the company, as well as those design approvals that the company is seeking. The process must include how the data will be marked or identified for internal use and how it will be identified for use outside of the company.

h. Additional privileges granted by the FAA – The procedures manual must identify any additional privileges granted by the FAA and the procedures by which the CDO will satisfy the requirements of those privileges. This may include:

(1) Procedures for the use of FAA designees for issuance of design approvals and certificates including a list of authorized FAA designees or delegated organizations.

(2) Procedures for the use of FAA voluntary self-disclosure policy per FAA Order 8100.89 but not include any relief for regulatory reporting per 14 CFR §21.3, etc.

(3) Procedures for making compliance determinations and statements of compliance to CAA regulations.

6. What CDO Obligations should I address in my procedure manual?

a. Statement of compliance process – The procedures manual must establish a process for creating and submitting a statement of compliance to FAA for issuance of a certificate or other approval.

b. Staffing requirements – The procedures manual must establish a process for identifying what constitutes its qualified staff. It must have defined processes for:

(1) Determining the skills necessary for specific jobs within the CDO,

(2) Determining if its minimum technical and management staff has the skills necessary to meet the CDO requirements,

(3) Determining training needs and assuring that the training is provided to keep those skills current, including upgrading skills as the job or CDO scope changes, and

(4) Periodically reassessing the skills needed.

c. Establish processes defining its CAS, SMS, and QMS systems – The procedures manual must define the process by which the CDO will create and manage its CAS, SMS, and QMS systems. The requirements for each are separately defined in later sections of this appendix.

7. What does the manual need to address with respect to coordination and communication with the FAA?

a. Procedures manual changes – The procedures manual must define the process for submitting changes to the manual and having them approved by the FAA prior to implementation by the CDO. The process may allow temporary changes to be approved by the FAA and implemented prior to incorporation into the manual. Any temporary changes must be incorporated into the manual at the next manual revision. The procedures manual must identify how updated sections of the manual will be provided to the FAA.

The process must define how revisions will be provided to the FAA for review and approval. If the entire document is reprinted after a revision, a complete copy of each revision is required to be maintained and provided to the FAA in either paper or electronic form, or both. A log of revision pages is not required but the document must contain the following:

(1) A means of determining what changed,

(2) Where within the document either by page number or by section number that the change occurred, and

(3) The date of approval of each revision recorded with the revision description

b. FAA Requested manual changes - 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 CDO is obligated to respond to FAA's request within an agreed upon time frame.

c. Supporting procedures changes – CDO internal procedures that support the CDO procedures manual but are included in separate sub-tier procedures may be changed at the discretion of the CDO holder to incorporate new or revised process changes. These supporting procedures and changes to them must be identified in a list and made available to the FAA.

d. New certification project coordination - The procedures manual must define the process for application and approval of new designs. The procedure will include:

(1) A process for determining when a new project application is required,

(2) A process for briefing the FAA on new projects and ensuring that necessary FAA support will be available to assist as required,

(3) The process for coordinating the certification basis, special conditions, exemptions, and equivalent levels of safety,

(4) Process for addressing any specific oversight activity the FAA requests to be involved in,

(5) The process for identifying the methods of compliance that the CDO plans to use in determining compliance with the applicable airworthiness standards, and

(5) The process for submitting the statement of compliance to the FAA upon completion of the project.

e. Sustaining certification project coordination – The procedures manual must define the process by which the CDO will provide visibility to the FAA of all certification activity for changes to existing products, especially those that do not rise to the level needing an application submitted or formal notification.

f. Changing the scope of the CDO – The procedures manual must define the process by which the scope of the CDO will be changed. The process must define how the CDO will perform the self evaluation to determine if it is qualified and the requirements to be included in the letter to the FAA point of contact stating that the CDO is qualified for the expansion of scope requested.

g. Certification issues – The procedures manual will define the process it will use for addressing certification issues, much like the existing the FAA issue paper process does. It will also establish a process to ensure that formal project level guidance provided by FAA is properly addressed.

h. 14 CFR reporting requirements - The procedures manual will provide a process for how the CDO will meet all reporting requirements of 14 CFR part 21, including how it will address the failures, malfunctions, and defects reporting requirements of §21.3.

i. Information transmittal process - The procedure must define what information must be transmitted formally to the FAA and what may be transmitted informally. The procedure must define how that information will be transmitted. All formal communication will be in writing and through the FAA POC and CDO Executive.

j. FAA and CDO management coordination - The CDO Executive and the FAA POC will establish regularly scheduled meetings to review the operation of the CDO. The purpose of these meetings is to discuss operation of the CDO and any related FAA issues. The results of the meeting will be shared with the CDO management and the FAA management. All issues raised must be identified with a plan of action for resolution.

k. Changes affecting a CDO's ability to meet requirements of certificate – The procedures manual must define the process for notifying the FAA when the CDO is not able to meet any requirement of its certificate. The procedures manual must define how the FAA will be notified within 48 hours of any changes to company upper management that affect signatories to the CDO agreement or the CDO Executive position. The procedures manual must provide procedures for how the CDO will notify the FAA and execute its responsibilities for such things as required reporting under §21.3, supporting accident/incident investigations, and other required activities in the event of temporary disruptions in the CDO activities.

The procedures manual must define a process for notifying the FAA when it is unable to make compliance determinations within the scope of its certificate and how the CDO will address the issue. The CDO must not make any compliance determinations in that area until an acceptable alternative has been agreed to with the FAA.

l. Transfer of design approvals – The procedures manual must define how the CDO will make decisions on who will notify the FAA of plans to transfer a design approval either to or from the CDO, and how the activities will be planned and coordinated with the FAA. The plan must include how the CDO will manage the continued airworthiness responsibilities for products involved in the transfer.

m. Process for responding to FAA requests and inquiries – The procedures manual must have a procedure that defines how the CDO will respond to FAA requests and

inquiries. This will include FAA audits, letters of investigation, and other items that are part of the CDO responsibilities. The procedure should include the method for establishing the schedule for when responses must be provided to the FAA.

n. Process for FAA OMT oversight – The procedures manual must address the process by which the FAA OMT will conduct oversight, or shadow, the CDO during normal daily operation and participate in development of new materials or processes, or observe tests, etc. This is different than the OMT activities during an audit.

o. Coordination with FAA Boards – The procedures manual must address the process by which the CDO will work with the Flight Operations Evaluation Board (FOEB), the Flight Standards Board (FSB), and the Maintenance Review Board (MRB). It must also include the process for how the CDO will find compliance for all of the airworthiness standards associated with those boards.

p. Process for use of FAA Orders – Although a CDO is not required to follow most FAA orders, there are certain orders that remain pertinent to the CDO and the CDO needs to have procedures to address the use of those orders. When applicable, the procedures manual should also address the process for using other FAA orders that the CDO may wish to include as part of its CDO processes.

8. What should be included in my procedures manual to address the compliance assurance system requirements?

The manual is a means to provide the high degree of assurance that the design and design changes of the applicant's products, parts, and appliances comply with the applicable airworthiness requirements. The procedures must address requests for new design approvals as well as changes to existing design approvals including repairs. Consideration should be given to using processes similar to processes the FAA is familiar with in order to simplify coordination and communication with the FAA. The manual must describe safeguards and/or checking functions for the determinations 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 CDO as compliant with the regulatory requirements.

a. Compliance planning – The procedures manual must define the processes by which the CDO identifies the regulatory requirements and determines compliance. This includes the following:

(1) Defining compliance requirements,

(2) Continually reviewing and acquiring current FAA regulations and implementing policy that affects the scope of the CDO and updating the manual to meet applicable new requirements,

(3) Establishing acceptable methods of showing compliance,

(4) Establishing plan for access to facilities and equipment necessary for CDO activities,

(5) Establishing and maintaining design practices and standards as applicable,

(6) Establishing, approving, and revising project compliance plans throughout the project, and

(7) Reviewing and approving compliance project planning prior to compliance execution.

b. Compliance execution – The procedures manual must define the process by which the CDO executes compliance. This includes the following:

(1) A process that identifies how all of the determinations of compliance are made within the CDO,
(2) Creating and approving analytical reports to determine compliance,

(3) Defining test articles and documenting conformity,

(4) Conducting compliance testing, including appropriate risk assessments,

(5) Performing and documenting safety assessments (FHA, PSSA, SSA, CCA),

(6) Specific compliance processes for subjective regulatory standards,

(7) Process for generation and management of "eligible data" and previously approved data,

(8) Process for classifying repairs as major or minor if so authorized, conducting damage limit and damage tolerance evaluation, verifying compatibility with other repairs or alterations, and approving them,

(9) Process for alterations, including a process for determining when an STC rather than an alteration is appropriate, and the process for documentation and approval of either as appropriate for the scope of the CDO,

(10) Process for managing and approving all supplier parts and documents and changes to them,

(11) Function and reliability test requirements, objectives, and failure dispositions,

(12) Preparation and approval of required documents appropriate for the scope of the CDO,

(13) Creating or changing the recommended TCDS, the AFM, and airworthiness limitations,

(14) Developing instructions for continued airworthiness before the product is delivered to the customer or returned to service,

(15) Reviewing and approving compliance project execution prior to compliance verification, and

(16) Recording pertinent information related to compliance determinations including the regulations, document identification, person, or process used in the compliance determination, and the date.

c. Process for compliance verification – The procedures manual must define a process by which compliance verification is accomplished. This may be by process or by a qualified person. The process should include:

(1) Identify and define criteria for the transitions between the compliance planning phase, the compliance determination phase, and the compliance verification phase of projects as defined by these times,
(2) Develop and document product, component, part, article, and compliance data configuration management,
(3) Coordinate with the FAA in the establishment of certification requirements and acceptable methods of compliance, and in the performance of FAA surveillance and audits.

d. Continued airworthiness instructions – The procedures manual must contain a process for developing, approving, and disseminating required continued airworthiness instructions. The process must include compliance with XX.1529 and how the maintenance aspects of the ICA are addressed consistent with 14 CFR 21.59 and FAA Flight Standards regulatory guidance.

e. Statement of compliance – The procedures manual must have a process for determining that all compliance requirements have been met, and for completing and signing of the statement of compliance. The statement must state "CDO [name of the CDO holder] certifies that [description of design] meets the minimum airworthiness standards identified in [14 CFR part XX, or TSO XX] as established in the certification basis by the FAA, and that all determinations of compliance have been accomplished in accordance with the approved procedures manual. The CDO hereby requests FAA issuance of the [identify specific TC, STC, PMA, or TSO] design approval."

f. Issuance of design approvals – The procedures manual must define the process for obtaining the issuance of TCs, STCs, or PMA design approvals.

g. Compliance data management – The procedures manual must define the process for managing and controlling compliance data.

h. Management of compliance personnel - Where the compliance system is dependent on the qualifications of certain individuals, the processes for the qualification, selection, and management of those individuals is required.

i. Management of compliance tools - Where the compliance system is dependent on the qualifications of certain tools, the processes for the control and verification of those tools is required. The process must ensure:

(1) The tool performs its required function,

(2) The tool and its output are controlled under a configuration management program,

(3) The tool is periodically verified for its applicability with respect to the processes and methods for which it is intended to apply, and

(4) A record is kept of the use of the tool to accomplish the compliance activity.

j. Compliance supplier oversight – The procedures manual must define the process for oversight of suppliers, partners, and sub contractors engaged in compliance determinations and how the CDO will coordinate with the FAA in these situations.

k. Consortiums – If applicable, the procedures manual must define the process by which the CDO will coordinate and provide compliance determinations to a consortium that it is a member of.

l. Post TC design approval activities – The procedures manual must define the process to be used for:

(1) Classification and approval of major or minor design changes,

(2) Repairs to fielded products accomplished within the CDO scope,

(3) Notification to the field of required inspections or changes to the product,

(4) Coordination and approval of alternate means of compliance to ADs, and

(5) Obtaining feedback from the field and addressing service difficulties.

9. What should be included in my procedures manual to address the safety management system requirements?

The procedures manual must contain either the identification of the procedures to meet the requirements of the SMS rule or reference where those procedures are found. If the procedures necessary to comply with the SMS regulatory requirements are merely referenced within the procedures manual, those procedures must still be approved by the FAA. The procedures manual should contain specific references that may be used to show compliance with the various requirements of the SMS rule. The procedures manual must clarify that the SMS requirements apply to both the design process and the products that result, and provide unique processes for each where necessary. The process should review data from all available reporting sources and evaluate its impact on the safety of the product throughout the life of the product. The process must provide reports to the FAA in accordance with 14 CFR part 21 and it must provide required SMS results to the FAA in a manner acceptable to the FAA.

a. A safety policy – The procedures manual must describe or identify where the description is of the:

(1) SMS goals and objectives.

(2) Management actions demonstrating the management commitment to the safety management system.

(3) Processes and methods used to attain the SMS goals and objectives.

(4) Processes and methods used to measure the attainment of the SMS goals and objectives.

(5) Policies and procedures establishing the expectation of high safety performance by the organization.

(6) Processes and methods used to promote safety within the organization.

b. A formal safety risk management process – The procedures manual must describe or identify the processes and methods used to:

(1) Define the system being assessed by the safety risk management process.

(2) Identify the hazards associated with the system being assessed by the safety risk management process.

(3) Characterize the likelihood and severity of each of the hazards associated with the system being assessed by the safety risk management process.

(4) Incorporate the risk from the safety risk management process into the decision making processes.

(5) Decide whether to accept, control, mitigate, or eliminate the risk from the safety risk management process.

(6) Control, mitigate, or eliminate the risk associated with the system being assessed by the safety risk management process.

c. A safety assurance process – The procedures manual must define a process that continually assesses activity to identify new hazards and to ensure risk controls achieve their intended objectives throughout the product life cycle. The procedures manual must describe or identify where the description is of the process and methods used to:

(1) Monitor the safety risk control, mitigation, or elimination to determine that they are meeting their objective from (b) above.

(2) Assess the safety risk management process.

(3) Assess the safety impact of the changes to the compliance processes.

(4) Assess the safety impact of changes to the product, part, or appliance design.

(5) Assess the safety impact of in-service events.

(6) Analyze the assessments for common process shortcomings or systemic improvements.

(7) Form corrective actions for those items found not to be meeting their safety objectives.

d. Safety promotion – The procedures manual must describe or identify where the description is of the process and procedure used to:

(1) Create the environment where safety objectives can be achieved and maintained.

(2) Qualify people to perform the safety analysis required by the safety risk assessment process.

(3) Qualify people to use the SMS principles when making safety decisions.

(4) Definition the acceptable and unacceptable actions in the workplace with respect to reporting safety issues.

(5) Share safety information within the organization.

(6) Share lessons learned with others doing the same or similar tasks and how those individuals may access this information.

(7) Perform a periodic review of the safety management program. This should focus on whether the defined processes are achieving their desired outcomes.

10. What should be included in my procedures manual to address the quality management system requirement?

a. Procedures – The procedures manual must provide procedures for determining that the CDO continues to meet its qualification requirements as defined in the procedures manual through continual internal assessments and regular audits. This process must address both procedures and the technical data compliance determinations to ensure compliance with the regulations. The frequency of the assessments and audits may be based on a risk assessment that is defined in the procedures manual. The results of all assessments and audits must be documented and made available to the FAA upon request. Assessment and audit results must be retained for 5 years.

b. FAA audit requirements – The procedures manual must address how it will coordinate with the FAA on all FAA audits and the processes it will use to respond to the FAA on issues identified in the audit. The procedure must identify the time allowed for the response to the FAA unless deviations are agreed to for specific issues.

c. Operational or safety concerns – The procedures manual must have defined procedures for addressing any CDO operational or safety concerns raised by any member of the CDO staff or supplier network, and for documenting and resolving the issue. The objective is for the safety concern to be raised within the CDO so necessary changes may be made to its procedures. The procedure must also define how a concern will be addressed by the CDO with the FAA when required. This procedure is not intended to prohibit communication between FAA and company specialists, but is intended to ensure that safety matters and decisions are channeled through formal points of contact between the FAA and the CDO, and within the CDO. Safety concerns brought to the FAA will be redirected to the CDO Executive for proper assessment, with a copy of that assessment being provided to the FAA for their review.

d. High level management commitment – The procedures manual must define how the CDO management will meet the requirement to have a high commitment to well defined procedures through surveillance and regular audits, with a closed loop corrective action process to update and correct its procedures. The corrective action process must ensure that issues are resolved in a manner appropriate to the risk they present, or may have presented.

e. Procedures manual configuration control – The procedures manual must incorporate a configuration management process, including a change control process, to assure its approved procedures continue to meet their intended purpose.

f. Personnel review process – The procedures manual must include a process to verify that its personnel are qualified to understand and operate in accordance with applicable procedures.

g. Partner's, supplier's, or subcontractor's oversight – The procedures manual must include procedures for ensuring its processes and methods are adequate for proper supervision of partners, suppliers, or subcontractors in its supply chain.

11. What should be included in my procedures manual to address the production aspects of my CDO?

The production aspects may be included in the CDO manual or a separate referenced manual. As with the CDO manual, the production manual may recognize sub-tier procedures that do not require direct FAA approval. However, there must be a process for the FAA to approve some substantive changes in the sub-tier procedures when required.

a. Design only CDO – A CDO performing design functions only must establish processes for initial and ongoing conformity of experimental/prototype/pre-production products, articles, and parts used in the certification process for which they are seeking a final FAA design approval. The procedure manual must include a process:

(1) By which the configuration and changes to it are documented;

(2) By which any changes are properly classified and controlled,

(3) For determining conformity and ensuring that it is maintained;

(4) For review and proper disposition of non-conforming products, articles, and parts; and

(5) To the extent applicable, for flight, endurance testing, and teardown inspections.

b. Combined design and production CDO – A CDO with a certificate scope that include both design and production functions, in addition to the items in (a) above, must also have a quality system that ensures that each product, article, or part produced conforms to its approved design and is in a condition for safe operation. This quality system must include procedures for:

(1) Controlling design data and subsequent changes;

(2) Controlling quality system documents and data;

(3) Ensuring that each supplier furnished product or article conforms to its approved design;

(4) Controlling manufacturing processes to ensure conformity to its approved design;

(5) Inspections and tests;

(6) Ensuring calibration and control of all inspection, measuring, and test equipment;

(7) Documenting the inspection and test status of products and articles supplied or manufactured to the approved design;

(8) Ensuring that only products or articles that conform to their approved design are installed on a type-certificated product;

(9) Ensuring that discarded articles are rendered unusable;

(10) Implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design or noncompliance with the approved quality system;

(11) Preventing damage and deterioration of each product and article during handling, storage, preservation, packaging, and delivery;

(12) Identifying, storing, protecting, retrieving, and retaining quality records;

(13) Planning, conducting, and documenting internal audits to ensure compliance with the approved quality system;

(14) Receiving and processing feedback on in-service failures, malfunctions, and defects;

(15) Identifying, analyzing, and initiating appropriate corrective action for products or articles that have been released from the quality system and that do not conform to the applicable design data or quality system requirements;

(16) Issuance of airworthiness approvals and export approvals; and

(17) Applying for a production certificate and changes to the production limitation record.

12. What records retention requirements must be addressed in the procedures manual?

The CDO holder is responsible for permanent retention of all CDO specific active and inactive technical and compliance data files, and for making that information available to the FAA either upon request, or directly through a means agreed to between the FAA and the CDO, as long as the CDO holds the CDO certificate or the type certificate or design approval for the product. This includes records produced under a previously held delegation or records held through a record retention agreement with the FAA.

a. Project records - The CDO must have a process for maintaining a record of all certification projects. Items that must be included in the information are the certification basis for each project, the method of compliance, documentation of the compliance determinations to the airworthiness standards, and schedule information. For new design approvals this will include the statement of compliance.

b. Certification compliance records - The procedures manual must define the process for maintaining certification compliance records including all type design and compliance documents and supporting data created by both the CDO and its suppliers. It will also include any statements of compliance made in the pursuit of a design approval. The documents must be related to the project in a manner that allows documents specific to a project to be easily identified and located. It will include the compliance determinations, how they were made, and when. All records must be maintained and made available in a manner that allows the FAA to review them as needed and this process must be defined in the manual.

c. Service documents and field reports - The procedures manual must define the process by which the CDO will maintain a permanent record of all service letters, service bulletins, and other related publications for as long as the CDO holds the type certificate or design approval of the product. The procedure for retention of records of field difficulties for at least 5 years must be identified.

d. Safety management records – The procedures manual will define the process for the retention of safety management records.

e. Internal audit results – The procedures manual will define the procedures for maintaining the internal audit records for a minimum of 5 years.

f. Training records – The procedures manual will define the process for maintaining the training records of all persons qualified to make determinations of compliance and the determinations they are approved to make.

g. Storage media – The storage media for permanent records must be defined and agreed to by the FAA in the event that the FAA needs to review any data or the CDO certificate is surrendered and the FAA must assume responsibility for the data.

h. Data security – The security provisions and location of the data must be defined in the procedures manual.