

U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION

ORDER 8120.23A

National Policy

03/06/2017

SUBJ: Certificate Management of Production Approval Holders

This order provides guidance and assigns responsibility for the implementation of the Aircraft Certification Service (AIR) certificate management (CM) of production activities of manufacturers and their suppliers producing products and articles in accordance with Title 14 of the Code of Federal Regulations.

This order has been organized into three functional components. The first two chapters describe the CM process. Chapter 3 describes ongoing CM practices and includes Quality System Audits (QSA) and related activities. Chapters 4 and 5 describe additional CM activities, continuous improvement, and the Aircraft Certification Audit Information System's (ACAIS) role in CM.

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Chapter 1. General

- **1-1. Purpose of This Order.** This order explains the Aircraft Certification Service (AIR) certificate management (CM) program.
- **1-2. Audience.** All Federal Aviation Administration (FAA) employees who participate in CM activities conducted at a production approval holder (PAH) and its suppliers.

Note: As used in this order, the term PAH encompasses both a PAH and its associate facilities.

- **1-3. Where Can I Find This Order.** You can find this order on the Directives Management System website at https://employees.faa.gov/tools_resources/orders_notices/. This order is available to the public at http://www.faa.gov/regulations-policies/orders-notices/. This order is also available on the Regulatory and Guidance Library at http://rgl.faa.gov/.
- **1-4.** Cancellation. FAA Order 8120.23, *Certificate Management of Production Approval Holders*, dated February 25, 2013, and all associated changes are canceled.
- **1-5. Explanation of Changes.** This revision:
 - **a.** Updates the CM process and modifies the method by which risk assessments are conducted.
 - **b.** Introduces the point of manufacturing methodology for planning and conducting audits.
 - **c.** Requires all audits be conducted using the product-based system audit approach.
 - **d.** Replaces the Certificate Management Information System (CMIS) with the Aircraft Certification Audit Information System (ACAIS) as the CM automation tool.
 - e. Adds policy pertaining to determining undue burden or no undue burden.
 - **f.** Modifies the process for managing the Category Parts List (CPL).
 - **g.** Adds noncompliance codes for use in documenting a noncompliance on FAA Form 8100-6, Noncompliance Record.
 - **h.** Updates FAA Form 8120-14, Production Approval/Certificate Management Activity Report.
 - i. Clarifies that a product audit is no longer considered a separate audit, but rather it is conducted as a component of a PI audit, SCA, and QSA.
 - **j.** Deletes the random generator method of selecting suppliers for a supplier control audit (SCA) and replaces it with a risk assessment method of selecting suppliers for an SCA.

k. References the newly created CM website. https://my.faa.gov/org/linebusiness/avs/offices/air/div_dir/air100/cm.html

- **1-6.** Effective Date. This order is effective April 10, 2017, with the following exceptions:
 - **a.** The use of Table 3-1, Ongoing CM Audit Responsibilities (Minimum Requirements) is effective October 1, 2017.
 - **b.** The number and frequencies of all audits conducted prior to October 1, 2017, will be based on the CM Responsibilities (Ongoing) Minimum Requirements table, formerly located in FAA Order 8120.23, Change 3 (Figure 3-1) and currently located on the Certificate Management (CM) website.
 - **c.** Paragraph 3-5; Annual risk assessments (Level Determination and Risk-Based Resource Targeting (RBRT), will be conducted from the period of April 10, 2017 to May 5, 2017.
 - **d.** Paragraph 3-15; Facility selection and audit planning, via the use of the Aircraft Certification Audit Information System (ACAIS), will not commence until the release of ACAIS version 2.1, which is scheduled to be released May 1, 2017.

Chapter 2. Certificate Management Overview

- **2-1. Purpose of This Chapter.** This chapter provides an overview of the AIR CM program. It describes our statutory responsibilities to perform CM and explains how our policies fulfill those responsibilities.
- **2-2. FAA's Authority to Perform CM.** Title 49 of the United States Code (49 U.S.C.) subtitle VII provides the statutory authority for the AIR CM program and allows the FAA to perform oversight of PAHs at any time and take appropriate actions in the interest of safety. Title 14 of the Code of Federal Regulations (14 CFR) part 21 includes specific requirements for PAHs to produce duplicates. Specifically, 14 CFR §21.137 requires a PAH to describe in writing a quality system that ensures each product and article conforms to its approved design and is in a condition for safe operation. Holders of production certificates (PC), parts manufacturer approvals (PMA), and technical standard order (TSO) authorizations must meet the responsibilities of a holder as described in 14 CFR 21.146, 21.316, and 21.616, respectively.
- **2-3. CM Program Overview.** The CM program consists of the policies, procedures, and associated information technologies by which FAA fulfills its statutory responsibilities to ensure a PAH remains in compliance with those regulations that govern the manufacturing of its products or articles. It is a system approach to monitoring a PAH's compliance with regulations that ensures appropriate corrective actions are taken. The applicable FAA manufacturing managing office is responsible for all activities associated with the CM of PAHs. This program does not impose additional requirements on PAHs.
- **a. Ongoing CM.** Ongoing CM consists of a four-step closed-loop process that is consistent with safety management system best practices. Figure 2-1 below provides a flowchart of this process. The process consists of the following four steps:
- (1) Planning Audit Activities. Planning activities include conducting an annual indepth risk assessment of each PAH and scheduling the audit activities based on the results of that risk assessment. AIR's CM policy and its planning activities are designed to focus audits on the PAH and its points of manufacture that pose the greatest risk.

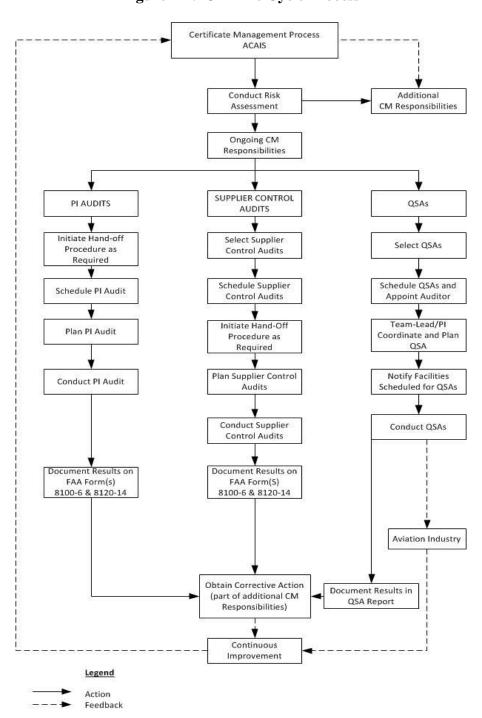
(2) Conducting Audits.

- (a) Auditing is the key component of the CM program. AIR employs a product-based system audit approach when conducting audits. A product-based system audit is a planned and recorded activity that relies on using selected products and articles to the maximum extent practical for determining—
 - 1 Whether that product or article conforms to approved data,
- 2 Whether a PAH complies with quality system requirements, including procedures and special processes established to meet those requirements, and
- 3 Whether a supplier is furnishing products, articles, or services that conform to the PAH's requirements.

- (b) Two types of audits are conducted:
- I Audits using the point of manufacturing methodology. This is a focused, data-driven audit of an article or process performed in the manufacture of a product or article, conducted at any location where the product or article is manufactured or where the process is being performed (that is, the PAH or supplier location). This methodology uses a *combination* of a product-based principal inspector (PI) audit and a product-based supplier control audit. The PI assigned CM responsibility normally performs this activity. These audits focus on areas of high risk within the PAH's or supplier's facilities.
- 2 Quality System Audits (QSA). A QSA is a comprehensive product-based system audit designed to ascertain whether a PAH meets the applicable requirements of 14 CFR and complies with the procedures established to meet those requirements. It applies standardized noncompliance codes that are described in appendix D to this order.
- (3) Documenting Audit Activities. All audit activities are documented and maintained in ACAIS. ACAIS contains all audit related forms and templates to be used by the manufacturing managing office when planning and conducting audits.
 - (4) Performing Post-Audit Activities. Post-audit activities are performed to:
 - (a) Validate the PAH's corrective actions.
 - (b) Update the PAH's profile.
- **b.** Additional CM Responsibilities. The following tasks are accomplished on an as-required basis by the manufacturing managing office responsible for a specific PAH within its geographical boundaries. Any tasks required to be scheduled and conducted at a PAH or supplier facility located in another geographical area should be handled in accordance with paragraph 3-52 of this order.
- (1) Audit/inspect changes to a PAH's quality system that may affect the inspection, conformity, or airworthiness of the product or article.
- (2) Investigate service difficulties that involve quality system problems. The Monitor Safety/Analyze Data (MSAD) process is one source that should be used to identify safety issues or potential safety problems in the in-service aircraft fleet and identifies corrective actions (including changes to quality systems) to mitigate safety risks.
 - (3) Investigate regulatory violations.
- (4) Ensure appropriate corrective actions have been proposed and taken for all noncompliances identified at a PAH.
- (5) Determine the need for unscheduled audits and other investigation activity (for example, suspected unapproved part (SUP) investigations) necessary to ensure continued compliance with applicable regulations.

- (6) Provide guidance and assistance to the PAH as necessary.
- (7) Determining undue burden or no undue burden.

Figure 2-1. CM Life Cycle Process



2-4. CM Website. The CM website is an informational site on which material can be added, deleted, or changed as required. The CM website provides both current and historical information related to all aspects of CM and includes the following:

- a. Discussions on CM responsibilities,
- **b.** Links to CM related:
 - (1) Data collection and analysis sites,
 - (2) Work tools,
 - (3) FAA publications, QMS documents, and correspondence,
 - (4) Briefings, presentations, and articles,
- c. Lessons learned, and
- **d.** Any other information to support the CM process.

Chapter 3. Ongoing CM Responsibilities

Section 1. Introduction

- **3-1. Purpose of This Chapter.** Sections 2 through 3 of this chapter provide detailed guidance for accomplishing ongoing CM responsibilities.
- **3-2. Assignment of CM Coordinator.** Many of the tasks identified in this chapter for the Manufacturing Inspection Office (MIO) and the manufacturing managing office are primarily administrative. A high degree of operational efficiency may be achieved by assigning many of these tasks to a designated CM coordinator. MIO managers should consider whether such an assignment would be beneficial for their organizations. The types of tasks that a CM coordinator could coordinate include:
 - **a.** QSA candidate and auditor appointment and training.
- **b.** Audit scheduling and QSA team selection; obtaining additional resources when required.
 - **c.** Maintaining a supplier control audit list.
 - **d.** Dissemination of general CM-related information.

Note: For the purposes of this order, the term "manufacturing managing office" will be used in lieu of Manufacturing Inspection District Office (MIDO), and Certificate Management Office (CMO).

- **3-3. Status of a PAH.** For purposes of CM, the status of a PAH and its applicable projects can be identified as one of the following:
- **a. Pending.** The FAA has received the production approval application and is in the approval process, but has not yet issued the production approval.
- **b. Active.** The FAA has issued a new production approval, or the PAH has produced and/or shipped products or articles within the past 12 months..
- **c. Inactive**. The FAA has determined that the PAH has not produced or shipped products or articles within the past 12 months. A PAH may remain in an inactive status for three risk assessment cycles (3 years).
- (1) If the PI makes a determination to keep the PAH inactive in the third year, it must be approved by the PI's office manager and noted in the PAH's ACAIS file.
- (2) If the PI makes a determination to keep the PAH inactive in the fourth year, it must be approved by the MIO and noted in ACAIS.
- (3) An inactive PAH's production approval will be cancelled in the fifth year unless approved by a deviation to the order signed by the AIR Design, Manufacturing, and Airworthiness Division, AIR-100.

d. Canceled. The FAA has completed action to revoke or otherwise terminate the PAH's production approval.

Note: If the determination is to cancel a PAH's production approval, the PI should contact the PAH and discuss whether it wishes to voluntarily surrender its production approval. If the PAH does not surrender its production approval and has no plans for future production, the PI may seek further guidance from the Office of Chief Council.

Section 2. CM Planning

Part 1. Risk Assessment

- **3-4. Overview.** To ensure resources are being applied to the appropriate areas of risk and the correct level of oversight is being conducted, each active PAH is subject to a risk assessment. Each assessment employs three pillars to provide a consistent and justifiable basis for effective use of FAA resources when performing CM:
 - a. Exposure within the National Airspace System (NAS),
 - b. Organizational Risk Assessment, and
 - **c.** Focusing of Oversight (Facility Selection)

Exposure
Within the
National
Airspace
System

Organizational
Risk
Assessment
(Facility
Selection)

Figure 3-1. Three Pillars of Risk Assessment

3-5. Risk Assessment Preparation. The manufacturing managing office must conduct a risk assessment of each PAH at a minimum of once every 12 months and not later than March 31 of each year. Delegated facilities, holders of a letter of TSO design approval, and PAHs in an inactive status are not subject to a risk assessment. The risk assessment must be conducted in accordance with the instruction provided in ACAIS and paragraphs 3-6 through 3-10 of this order. The PI must collect and verify all information needed to complete the risk assessment before entering the information into the system. When appropriate, the PI will contact each PAH

to obtain current or clarifying information relevant to the risk assessment. The PI must contact each PAH previously designated as inactive to determine whether the PAH's status has changed.

- **3-6. Exposure Within the National Airspace System (NAS).** The first pillar of the PAH's overall risk assessment determines the PAH's risk exposure in the NAS, using the Risk Level Determination Process, located in ACAIS. The Risk Level Determination Process places the PAH in one of three risk levels, based on a series of questions. Refer to Figure 3-2 of this order for the level determination decision flow.
 - **a.** PAH's with the highest risk exposure in the NAS are placed in level 1. These PAHs manufacture products, as defined by §21.1, at high production rates, with greater complexity, and significantly outsource production to its suppliers.
 - **b.** PAHs placed in level 2 manufacture either a product designated as a lesser risk than level 1 or a critical article..
 - **c.** PAHs designated Level 3 have the least risk exposure in the NAS. Unlike PAHs designated level 1 or level 2, these PAHs do not manufacture products or articles located on the CPL or designated as critical by the PAH.
 - **d.** The manufacturing managing office may change the level determination up to level 1 or down one level to level 2. If this type of change is made by the manufacturing managing office, the rationale must be documented in ACAIS.

Note: When using the Risk Level Determination Process, the PI may use the PAH's critical parts list in lieu of the AIR CPL, when approved by the assigned engineering office.

Figure 3-2. Risk Level Determination Process

Risk Level Determination

Level 1 Determination Decision

(Note: The applicant must meet all three of the question criteria or use the option listed below)

Ouestion #1:

Does PAH produce annually more than 100 Aircraft, 500 Engines (to include rebuilt engines), or 1500 Propellers?

Question #2:

Does the PAH have 2 or more models in production?

Question #3:

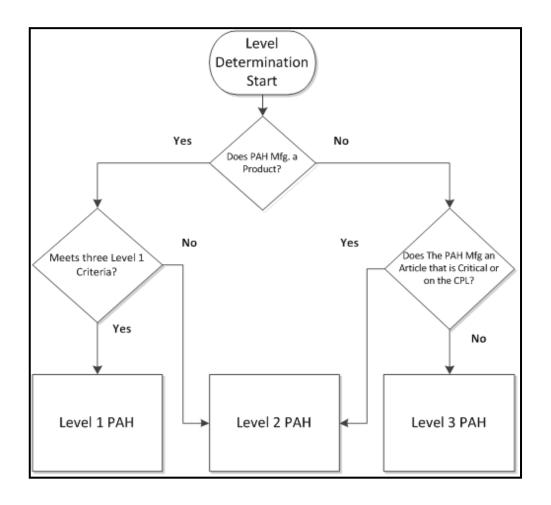
(a) Does the PAH have 20 or more external suppliers of critical parts/major assemblies

or

(b) Outsource 33% or more critical parts/major assemblies

[OR]

Option: The manager of the manufacturing managing office is empowered to move the status of a PAH to or from a LEVEL 1 or 2 with written rationale.



Note: In question #1of the Level 1 Determination Decision, the PI will include rebuilt engines in determining the response.

3-7. Organizational Risk Assessment. Subsequent to the results of the risk level determination, the second pillar of the PAH's overall risk assessment uses the RBRT assessment tool to determine the organizational risk. The tool includes several factors that result in the identification of quality systems and complexities according to their potential to produce nonconforming products or articles and the consequential results associated with introducing those products or articles into the system. As a result of the RBRT assessment, a PAH is assigned one of the following organizational risk levels:

- **a. High.** A PAH with the greatest potential to produce nonconforming products or articles.
- **b. Medium.** A PAH with a moderate potential to produce nonconforming products or articles.
 - **c.** Low. A PAH with low potential to produce nonconforming products or articles.

Note: The RBRT assessment questions and the guidance for completing the assessment are located in ACAIS.

- **3-8. Agreement of Risk Assessment.** The RBRT assessment tool requires an approving official, usually the manufacturing managing office manager or their delegate, to review the calculated risk level and the recommended CM requirements. To the greatest extent possible, the PI and manufacturing managing office manager or their delegate should agree on the final risk level. The manufacturing managing office manager or their delegate will indicate approval in accordance with the instructions provided in ACAIS.
- **3-9. Modification of Risk Assessment.** When any of the following conditions occur at a PAH subsequent to the final risk assessment, the PI should complete a new risk assessment using the risk assessment tools:
 - **a.** Changes in a product or article's criticality;
 - **b.** Significant quality system changes;
 - **c.** Significant quality system changes impacting inspection, conformity, or airworthiness;
 - **d.** Significant turnover of key staff;
 - e. Significant increases or reductions in workforce;
 - **f.** Deliberate non-responsiveness to corrective action requests;
 - **g.** Significant service difficulties attributed to manufacturing or quality system problems;
 - **h.** Addition of a complex manufacturing process;
 - **i.** Addition of a complex product, article, or part(s);
 - **j.** Significant changes in the use of suppliers/outsourcing;

- **k.** Significant increases in the use of international suppliers;
- 1. Movements or shifts of production locations or volumes; or
- m. Expiration of a labor contract or potential labor unrest.

Note: When the audit schedules, as established in the CM plan, are impacted by a change in the assigned risk level, the PI should adjust the CM plan accordingly.

3-10. Facility Selection. The third pillar of the PAH's overall risk assessment is the manufacturing managing office's determination of which of the PAH's manufacturing facilities should be audited. The facility selection determination is a risk-based decision that determines how the required number of FAA audits will be distributed among the PAH's manufacturing facilities. To aid in this decision, a facility selection process has been developed that prioritizes a PAH's manufacturing facilities based on risk. Refer to paragraph 3-15 of this order.

3-11. Periodic Review of Risk Assessment Tools.

- **a.** AIR-100 will review and analyze the risk assessment tools periodically to determine if changes are needed. This review is necessary to continually improve the risk assessment process and to keep up with changes in the industry.
- **b.** AIR-100 will coordinate the implementation of any changes to the risk assessment tools, including development and dissemination of revised program guidance, updated ACAIS programming, and associated training materials.

Part 2. Audit Requirements and CM Plan

3-12. Minimum Audit Requirements. The output of the PAH's risk assessment, specifically the risk level determination and the organizational RBRT designation, is used to define the manufacturing managing office's CM audit responsibilities. Table 3-1 provides the minimum of audits and corresponding frequencies associated with the ongoing CM of PAHs.

Table 3-1. Ongoing CM Audit Responsibilities (Minimum Requirements)

Level 3 Low	Level 3 Medium	Level 2 Low	Level 2 Medium	Level 2 High	Level 1 Low	Level 1 Medium	Level 1 High
1+ Audit within every 60 months	1+ Audit within every 48 months	1+ Audits within every 36 months	3+ Audits within every 24 months	4+ Audits within every 12 months	6+ Audits within every 12 months	12+ Audits within every 12 months	18+ Audits within every 12 months
		1 QSA NTE 48 months	1 QSA NTE 36 months	1 QSA NTE 24 months	1 QSA NTE 36 months	1 QSA NTE 24 months	1 QSA NTE 24 months

Note 1: All audits in the table above are only "minimum" audit requirements. The plus symbol (+) indicates that management of the manufacturing managing office may determine additional audits are required based on risk.

Note 2: Product Audits must be conducted during all audits.

3-13. CM Plan. A CM plan assists the manufacturing managing office in planning and tracking audits and the performance of PAHs and its applicable suppliers.

- **a.** After risk assessments have been completed, the manufacturing managing office will develop a CM plan annually for those PAHs that have oversight activities planned for upcoming fiscal year. The manufacturing managing office will adjust the CM plan when changes occur that affect any of the three pillars of risk.
 - **b.** As a minimum, the CM plan should include the following:
 - (1) The name of the PAH or applicable supplier subjected to an audit.
- (2) Prioritization of the locations to be audited based on risk assessment results. For the number of audits to be conducted at the PAH or supplier locations, refer to table 3-1 of this order. The objective is to conduct oversight at the manufacturing facilities with the greatest risk. Additional audits at a manufacturing facility may be warranted when the FAA's confidence in the PAH's quality system has diminished.
- (3) Schedules for the audits to be conducted by the manufacturing managing office. For audits at suppliers, include the names and locations of the suppliers.
- (4) A list of hand-offs or CAA requests sent, including, as a minimum, the name of the assigned office that has accepted the hand-off or the CAA that has accepted the oversight request from the manufacturing managing office. Also include the type of audit requested, the name of the manufacturing facility receiving the audit, and the name of the responsible PAH. Refer to paragraph 3-16 of this order for more information about hand-off procedures.

Note: Hand-off activity duration can be for any given period of time from a one-day event to multiple days/trip in a given fiscal year. Example: The hand-off manufacturing managing office can request the CAA or other assigned office to perform the audit once a year or once a quarter per year or multiple years until cancelled.

- (5) A list of hand-offs or CAA requests received, including, as a minimum, the name of the manufacturing managing office or CAA that has requested the hand-off, the type of audit or oversight requested, and the name of the applicable manufacturing facility.
- **c.** The scheduling function in ACAIS is intended to provide a starting point in the development of the CM plan. Should an inconsistency develop between the ACAIS-generated number, frequencies, or scheduled dates of CM activities and the requirements in table 3-1 of this order, table 3-1 will take precedence. Manufacturing locations to be audited should be prioritized based on the risk assessment results. If the number of audits exceeds the CM chart minimums, additional CM tasks should be considered at the discretion of the manufacturing managing office. For manufacturing locations not audited in one fiscal year, an audit should be planned for the next fiscal year based on the risk assessment results remaining the same.

Section 3. Product-Based System Audit Activities

Part 1. General

3-14. Audit Basics. An audit (PI audit., supplier control audit, or QSA) is a systematic, independent, and focused data-driven, product-based examination of an established PAH's manufacturing system based on the quality system elements as defined in §21.137 (refer to appendix D to this order). Its purpose is for the manufacturing managing office to validate that the PAH is effectively complying with regulations and to determine conformity to FAA-approved type design and applicable quality system requirements. An audit is conducted at the location of the PAH or its supplier. The audit should be conducted at the point of manufacturing, on areas with the highest risk.

Note: Although a PI audit, SCA, and QSA are product-based system audits, a product audit must still be conducted during all audits and whenever determined to be necessary by the manufacturing managing office.

- **3-15. Selection of a PAH and its Facilities for Audits.** Subsequent to determining the results of a PAH's risk assessment (i.e., the number and frequency of CM audits), the manufacturing managing office must select the point of manufacturing locations where the required CM audits will be conducted. The PI may begin the selection process by determining a PAH/supplier ratio that reflects where the PAH's manufacturing occurs. For example, a PAH that utilizes suppliers to perform most of its manufacturing, may have a ratio of 20% PAH facilities versus 80% suppliers. In this case, 20% of the required minimum number of audits would be conducted at the PAH's facilities, and 80% would be conducted at the PAH's suppliers. The selection of which specific facilities to audit should be based on a prioritization of the risk of the manufacturing activities performed at each facility. When a PAH has multiple facilities listed on the production approval and/or numerous suppliers producing critical articles, the manufacturing managing office will prioritize their audit locations by validating the following criteria:
- (a). Will the facility produce any aircraft, aircraft engine, propeller, or article thereof in the next twelve months?
- **(b).** Does the facility perform any final testing for an aircraft, aircraft engine, propeller, or critical article?
 - (c). Is the facility solely an assembler/integrator?
- (d). Are special processes being performed on a critical article (e.g., heat treat, welding, composite, friction stir welding, chemical etching, etc.)?
- (e). Have major inspections been delegated to this facility? (e.g., receiving inspection, supplier control, testing, in-process inspection, nondestructive inspection (NDI), final inspection, dock to stock, MRB, etc.)?

(f). Has the facility been added to the production approval or the supplier listing within the last 12 months?

- (g). Has the facility been relocated to a new address within the last 12 months?
- **(h).** Does evidence indicate that no on-site evaluations have been performed at this facility in the last 12 months?
- (i). Have any FAA documented noncompliances at the facility resulted in compliance and enforcement action within the last 2 years?
 - (i). Has the facility had any quality escapes events within the last 24 months?
- (k). Is the facility located in a non-bilateral country or a bilateral country where the foreign CAA cannot support the FAA?
 - (l). Is there new or novel manufacturing being implemented at the facility?
- **(m).** How many quality systems elements are applicable to the facility? (Refer to Appendix D to this order)?
 - (n). Other criteria as applicable.
 - **Note 1:** The manufacturing managing office may use a facility selection process other than the process described in paragraph 3-15, provided the alternate process is equivalent to or better than the facility selection process described in paragraph 3-15. Prior to its use, the manufacturing managing office will submit its alternative facility-selection process to AIR-100 for review and acceptance.
 - **Note 2:** The manufacturing managing office will not select a PAH for an SCA unless there is a special reason or if the supplied articles are not a part of the PAH's production approval. In cases where the supplied articles are listed on the PAH's production approval, the manufacturing managing office will conduct the audit as described in either paragraph 4-16 or paragraph 4-17 of this order.
- **3-16. Hand-off Procedures.** The following hand-off procedures are applicable to PI audits, SCAs, and product audits:
- **a.** The requesting manufacturing managing office will submit in ACAIS a memorandum to the assigned office no later than May 1 of each year. The memorandum will indicate the type of audit that should be conducted and will include all pertinent information regarding the audit including—
- (1) The name and address, including county, if applicable, of the PAH or supplier, the actual address where the audit will occur, as well as the PAH's project number;

(2) The name, title, and telephone number of the accountable manager at the PAH's facility or the person to contact at the supplier who can furnish purchase orders, quality system data, technical data, and other pertinent information;

- (3) In the case of an SCA:
- (a) A copy of the PAH's or supplier's quality system procedures that are required to be implemented at the particular supplier's facility, unless these documents are available to the FAA at the supplier's facility;
 - (b) Any delegation of MRB and/or technical data change control authority;
 - (c) Any authority permitting direct shipment;
- (4) Any other information regarding specific PAH or supplier activities that should be audited, such as a new process or new technology;
- (5) Information pertinent to a product or article to be audited, such as part number and description, next level of assembly, or service difficulty or warranty return history; and
- (6) The duration of the audit (for example, whether the audit is a single event or will be ongoing for the given fiscal year).
 - **b.** When an assigned office receives a request to conduct an audit, it will—
 - (1) Acknowledge the receipt of the request in ACAIS.
 - (2) Add the audit to its CM plan, if applicable.
- (3) In the case of an SCA, notify the responsible PAH in accordance with paragraph 3-53 of this order.
- **c.** At the completion of the audit, the assigned office will submit in ACAIS a memorandum to the requesting manufacturing managing office. This memorandum should summarize the results of the audit and include all applicable FAA Form(s) 8100-6, 8100-1, and 8120-14. All applicable objective evidence will be mailed to the requesting manufacturing managing office. The requesting manufacturing managing office will consider its hand-off request complete upon receipt of this memorandum and any objective evidence.
- **3-17. Recording Noncompliances.** The PI will record all noncompliances, including those reported by a civil aviation authority (CAA) while performing CM activities for the FAA, on FAA Form 8100-6, in accordance with the guidelines listed in appendix C to this order. The FAA will notify a PAH of noncompliances found at its supplier. For all other circumstances, the FAA will not reveal noncompliances to a manufacturer other than the particular manufacturer involved unless a formal request has been processed in accordance with the Freedom of Information Act (refer to FAA Order 1270.1, *Freedom of Information Act Program*).

Part 2. Quality System Audit

Subpart 1. Overview

- **3-18.** What is a QSA? A QSA is a comprehensive system audit program employing a product-based system audit approach. It is a vital element within the FAA's mission of continued operational safety. The QSA—
- **a.** Ascertains whether PAHs meet the applicable requirements of 14 CFR and comply with procedures established to meet those requirements.
 - **b.** Populates a database for analyzing audit results and reporting trends.
- **c.** Provides continuous improvement for the FAA by continually auditing stakeholder feedback reports and considering proposed improvements by FAA internal and external customers.
- **d.** Evaluates the continued integrity of the design data at PAHs after initial FAA approval. However, the QSA does not reevaluate the approval of previously approved data such as quality manuals or design data.

Subpart 2. QSA Auditor Appointment and Training

- **3-19. General.** The appointing officials designated in paragraph 3-20 of this order will select QSA auditor candidates who have attained a specified level of experience or a combination of experience and education, as engineers, flight test pilots, or aviation safety inspectors (ASI), and who have demonstrated technical knowledge and skills. A candidate will receive QSA training and serve as an auditor-in-training during QSAs under the direct supervision of an appointed QSA team leader before appointment as a QSA team member. Before appointment, a candidate for auditor team leader will have participated in QSAs as an appointed team member and will perform as a team leader-in-training under the direct supervision of an appointed QSA team leader.
- **3-20. Appointing Officials.** The following division/directorate, and headquarters managers are authorized to select QSA auditor candidates and to appoint qualified candidates as QSA team members or team leaders within their respective organizations:
 - **a.** Assigned engineering office managers and branch managers;
 - **b.** MIO and manufacturing managing office managers;
 - c. Division/directorate Standards Staff managers; and
 - **d.** AIR-100 managers.
- **3-21. Criteria for Candidate Selection.** The appointing official will select engineering, flight test or ASI candidates on the basis of the following criteria (refer to figure 3-3 of this order):

a. Candidates have attained at least one of the following specified levels of experience or a combination of experience and education in their specific disciplines:

- (1) At least 8 years of technical experience in aerospace manufacturing or design, or in the audit thereof;
- (2) A technical or trade school certificate with 6 years of technical experience in aerospace manufacturing or design, or in the audit thereof;
- (3) An associate's degree in engineering or science disciplines, with 5 years of technical experience in aerospace manufacturing or design, or in the audit thereof; or
- (4) A bachelor's degree or higher in engineering or science disciplines, with 3 years of technical experience in aerospace manufacturing or design, or in the audit thereof.
 - **b.** Candidates have demonstrated—
- (1) Technical knowledge in aerospace manufacturing or design and understanding of FAA goals and objectives, and
 - (2) Effective oral, written, communication, and interpersonal skills.

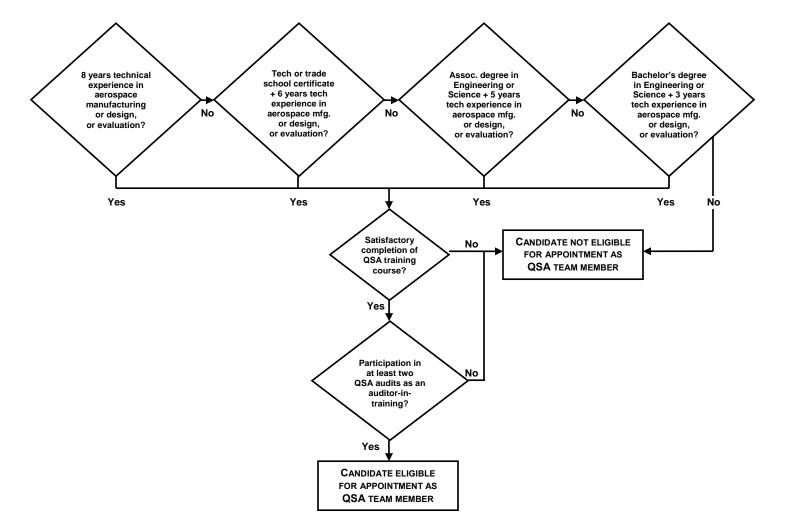


Figure 3-3. Criteria for Candidate Selection and Team Member Appointment

3-22. Criteria for Appointment. Appointment is the formal process of certifying a QSA candidate as a QSA team member or team leader on the basis of successful completion of all requirements (refer to figures 3-5 and 3-6 of this order).

- **a. Team Member.** Candidates must meet the following minimum requirements before appointment as a team member (refer to figure 3-3 of this order):
- (1) Satisfactory completion of the QSA training course and associated written examination. The course will provide training in the policy established in this order, including the techniques for applying the standardized noncompliance codes contained in appendix D to this order and in coordinating team member involvement.

Note: The AIR Planning and Program Management Division, AIR-500, will ensure classes are scheduled in accordance with AIR priorities as identified in the annual call for training.

(2) Participation of the candidate, and demonstration of the knowledge and skills acquired during QSA team training, in at least two QSAs as an auditor-in-training.

Note: The candidate's appointing official must schedule the candidate's participation as an auditor-in-training to be completed in as short a timeframe as possible to maximize the candidate's use and retention of acquired knowledge and experience.

- (3) The team member candidate's appointing official is responsible for performing the following in considering the qualifications of the candidate as a team member:
 - (a) Consider the candidate's previous experience and education.
- (b) Consider the product complexity, facility size, and complexity of quality system elements audited in QSAs in which the candidate participated. (Refer to appendix D to this order for information on quality system elements).
- (c) Discuss with team leaders audits in which the candidate participated to determine the candidate's QSA readiness.
 - (d) Review QSA reports for audits in which the candidate participated.
- (e) Review, when necessary, FAA Form(s) 8100-7, QSA Customer Feedback Report, for audits in which the candidate participated.
 - (f) Interview the candidate.
- (g) Discuss with the candidate any weaknesses or deficiencies in their audit readiness identified during the participation phase. Both parties will work to reduce or eliminate these weaknesses or deficiencies through additional training, additional QSAs, Air Transportation Oversight System/Air Carrier Evaluation Program audits, or other similar activities that will increase the candidate's audit readiness.

(4) On the basis of satisfactory results of the audit of the candidate as listed in paragraph 3-22a(3) of this order, the candidate's appointing official will appoint the candidate as a team member and add the individual to the auditor's module of the ACAIS program.

- **b. Team Leader.** Candidates must meet the following minimum requirements before appointment as a team leader (refer to figure 3-4 of this order):
 - (1) Current appointment as a QSA team member.
 - (2) Ability to mentor and instruct team members.
- (3) Participation in at least three audits as an appointed QSA team member. The candidate's appointing official may request reduction of the requirement by providing documented justification to the appointing official's manager. The responsibility for requesting any reduction of the requirement rests solely with the candidate's appointing official.
- (4) Participation as a team leader-in-training, and demonstration of knowledge and skills acquired during QSA team training in at least three QSAs under the direct supervision of an appointed QSA team leader. The candidate's appointing official may request reduction of the requirement by providing documented justification to the appointing official's supervisor. The responsibility for requesting any reduction of the requirement rests solely with the candidate's appointing official.

Note: The candidate's appointing official must schedule the candidate's participation as a team leader-in-training to be completed in as short a timeframe as possible to maximize the candidate's use and retention of acquired knowledge and experience.

- (5) The candidate's appointing official is responsible for performing the following activities in considering the qualifications of the candidate as a team leader:
 - (a) Consider the candidate's previous experience and education.
- (b) Consider the product complexity, facility size, and complexity of quality system elements audited in QSAs in which the candidate participated. (Refer to appendix D to this order for information on quality system elements).
- (c) Discuss with team leaders the audits in which the candidate participated to determine the candidate's team leadership abilities.
 - (d) Review QSA reports for audits in which the candidate participated.
- (e) Review, when necessary, FAA Form(s) 8100-7 for audits in which the candidate participated.
 - (f) Interview the candidate.

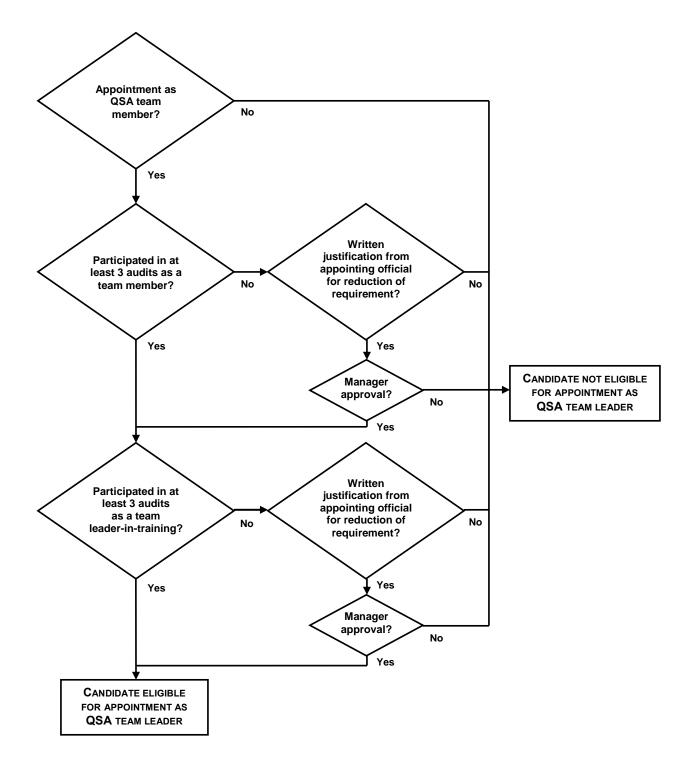


Figure 3-4. Criteria for Team Leader Appointment

(g) Discuss with the candidate any weaknesses or deficiencies in their team leadership abilities identified during the participation phase. Both parties will work to reduce or eliminate these weaknesses or deficiencies through additional training, additional QSAs, Air Transportation Oversight System/Air Carrier Evaluation Program audits, or other similar activities that will increase the candidate's leadership abilities.

- (6) On the basis of satisfactory results of the audit of the candidate as listed in paragraph 3-22b(5) of this order, the candidate's appointing official will appoint the candidate as a team leader and update the auditor's module of the ACAIS program.
- **c.** The candidate's appointing official will document and track the completion of the requirements in paragraphs 3-22a and 3-22b of this order for all QSA candidates. Upon successful completion of the requirements, the appointing official will appoint the candidate as a QSA team leader or team member and will formally notify the candidate of their appointment through issuance of a formal ACAIS-generated acknowledgement letter. The letter will include the individual's discipline and office identification.

Note: Provide notification of appointment before the auditor's first scheduled QSA as a team member or team leader.

- **3-23. Review of Appointment.** The cognizant appointing official (1) reviews the participation in QSAs by each auditor under their appointment authority, (2) notifies auditors in writing of decisions not to continue their appointment, and (3) determines the currency and continued validity of appointments as follows:
- **a. QSA Team Members.** Review QSA team members' participation annually. Ensure team members have accomplished the following requirements, as a minimum:
- (1) Participated at an interval of once or more every 2 fiscal years as a QSA team member or QSA team leader, or conducted audits in accordance with section 3, parts 3 and 4, of this chapter.
- (2) Demonstrated knowledge and skill in QSAs, as determined from sources such as the QSA report, team leaders, cognizant managers, and satisfactory corrective action for any shortcomings in knowledge or skills noted and discussed with the team member during the interim period.
- **b. QSA Team Leaders.** Review QSA team leaders' participation annually. Ensure team leaders have accomplished the following requirements, as a minimum:
- (1) Participated at an interval of once or more every 2 fiscal years as a QSA team leader or as a team leader for an audit with multiple team members in accordance with section 3, parts 3 and 4, of this chapter.
- (2) Demonstrated knowledge and skill in QSAs, as determined from sources such as the QSA report, cognizant managers, and satisfactory corrective action for any shortcomings in knowledge or skills noted and discussed with the team leader during the interim period.

3-24. Reinstatement of Auditors Failing to Meet Appointment Review Criteria. Under their appointment authority, appointing officials may reinstate auditors who have not met the appointment review criteria listed in paragraph 3-22 of this order. Use the following criteria to determine eligibility for reinstatement:

- **a.** Team members and leaders who have not met participation requirements may be reinstated after acceptable participation as an auditor-in-training or as a team leader-in-training, as applicable, in two QSAs.
- **b.** Team members who have not demonstrated QSA knowledge or skills may be considered for reinstatement by repeating the formal QSA team member appointment program listed in paragraph 3-22a of this order.
- **c.** Team leaders who have not demonstrated QSA knowledge or skills may be reinstated as a team member after acceptable participation as an auditor-in-training in two QSAs. Consideration for reinstatement as a team leader must then follow the formal QSA team leader appointment program listed in paragraph 3-22b of this order.

Subpart 3. Selection and Scheduling of QSAs

- **3-25. QSA Intervals.** Audit intervals for PAHs are identified in table 3-1 of this order.
- **3-26. Selection of Facilities to be Audited.** Procedures for selecting a PAH's facilities to be audited are identified in 3-15 of this order.
- **3-27.** Scheduling of QSAs. After all facilities have been selected for audit in accordance with Chapter 3 of this order, each division/directorate will be responsible for scheduling QSAs at the selected facilities. Use the following procedures:
- **a.** Estimate the onsite duration of each QSA according to the following information. Consider the quality and/or engineering procedures and processes required to be in place; the number of applicable quality system elements, when known (refer to appendix D to this order); the size and physical layout of the facility to be audited (single or multiple locations); and product complexity. Allow enough time to ensure compliance to the applicable 14 CFR and FAA-approved data will be fully audited. Use the following list as a guide for estimating, in terms of facility size only, the onsite duration of the QSA (excluding travel times):
- (1) Small facility with fewer than 100 total full-time persons: 1 to 5 working days onsite.
- (2) Medium facility with 100 to fewer than 400 total full-time persons: 3 to 5 working days onsite.
- (3) Large facility with 400 to fewer than 2,000 total full-time persons: 5 to 10 working days onsite.
- (4) Very large facility with 2,000 or more total full-time persons: 7 to 15 working days onsite.

Note: When estimating the onsite duration, include only those persons who are used to support the PAH activity.

b. Assign all scheduled audits a distinct QSA number, consisting of the fiscal year, division or directorate code (NE—Engine and Propeller Directorate, CE—Small Airplane Directorate, SW—Rotorcraft Directorate, or NM—Transport Airplane Directorate), and the audit order sequence. For example, "09CE123" represents the 123rd audit planned for completion by the Small Airplane Directorate during fiscal year 2009.

Note: Do not reassign QSA numbers from canceled audits. Each scheduled audit must be uniquely identified.

- **c.** Identify the lead audit office for each audit. That office is usually the one that performs CM responsibility at the facility to be audited. For an associate facility subject to CM under the hand-off procedure, the lead audit office is the manufacturing managing office receiving the hand-off. The lead audit office is responsible for—
 - (1) Coordinating the notification letter (refer to paragraph 3-29 of this order), and
- (2) Notifying the selected team leader and team members (refer to paragraph 3-31 of this order).
- **d.** Prepare an audit schedule for the current fiscal year based on the facility selection criteria in paragraph 3-15 of this order and the duration of each audit.
 - (1) Prepare the schedule using the following guidelines:
 - (a) QSA number.
 - (b) Scheduled start date of each audit.
 - (c) Duration of each audit.
 - (d) Facilities and types of approvals to be audited.
 - (e) Assigned risk level.
 - (f) Product lines or authorized functions at the facilities to be audited.
 - (g) Number and disciplines of auditors assigned to each audit.
 - (h) Additional auditors required beyond the division's/directorate's resources.
 - (i) Number and disciplines of auditors-in-training and team leaders-in-training.
 - (j) Total number of audits scheduled for the fiscal year.
 - (k) Applicable project numbers.

(2) All division /directorate QSA schedules will be entered into the schedule module of the ACAIS program.

- (3) The assigned engineering and managing manufacturing offices should schedule approval holders with multiple approvals, such as a PC and a PMA, so as to evaluate all approvals during one audit.
- (4) When an approval holder has multiple facilities that require significant resources and time to audit, the assigned engineering and managing manufacturing offices should consider scheduling the facilities individually.
- **e.** Designate an assigned engineer (AE). On the basis of the data collected for paragraphs 3-25 through 3-27d of this order, the managing manufacturing office will coordinate with the assigned engineering office to determine the need to assign an FAA engineer responsibility relating to a scheduled QSA at a particular design approval facility. The AE must answer questions from the auditors regarding the FAA-approved design or the design approval system in place. The AE also must coordinate any corrective action required regarding the FAA-approved design or the design approval system.
- **3-28. Selection of QSA Auditors.** The assigned engineering and managing manufacturing offices select appointed QSA auditors to perform each scheduled audit. To broaden expertise, whenever possible, managers are encouraged to permit auditors to participate in QSAs scheduled within the jurisdiction of other divisions/directorates. Determine the number and types of auditors required for each audit according to the following criteria:
- **a. Number of Auditors Required**. Determine the total number of auditors required to ensure compliance to the applicable 14 CFR and FAA-approved data.
- (1) Estimate the number of auditors required according to the following minimum criteria:
 - (a) PAH's assigned risk level;
- (b) Number and complexity of applicable quality, engineering, flight test, and facility procedures and processes in place;
- (c) Number of applicable quality system elements, when known (refer to appendix D to this order);
- (d) Number of PAH suppliers expected to receive an onsite visit as part of the PAH QSA supplier control system element, when known;
- (e) Size and physical layout of the facility to be audited (single or multiple locations); and
 - (f) Product or design approval system complexity.

(2) Use the following as a guide for estimating the number of QSA auditors required. Increase or decrease the number of estimated auditors shown below depending on your review of the criteria contained in paragraph 3-28a(1) of this order and your confidence that compliance to the applicable 14 CFR and FAA-approved data will be fully audited:

- (a) Small facility with fewer than 100 full-time persons: 1 to 3 auditors (including team leader).
- (b) Medium facility with 100 to fewer than 400 total full-time persons: 1 to 5 auditors (including team leader).
- (c) Large facility with 400 to fewer than 2,000 total full-time persons: team leader plus 5 to 10 auditors.
- (d) Very large facility with 2,000 or more total full-time persons: team leader plus up to 10 auditors.
 - **Note 1:** When estimating the number of auditors required, include only those full-time persons who are used to support the PAH facility activity.
 - **Note 2:** When necessary, the appropriate assigned engineering and managing manufacturing offices will assign additional auditors as needed.
- (3) If it is determined that one auditor is required, select an appointed team leader to perform the audit; this auditor is referred to as the principal auditor. If two or more auditors are selected for an audit, they will constitute a QSA team. Select an appointed team leader and the required number of appointed team members.
- **b.** Types of Auditors Required. Use the criteria identified in paragraph 3-28a(1) of this order and the following criteria to determine the types of auditors required. Select appointed QSA auditors who have appropriate knowledge of the noncompliance codes identified in appendix D to this order applicable to the facility to be audited and, as appropriate, to the products authorized by the approval (for example, select a propulsion engineer when an engine manufacturer is to be audited, and select a flight test pilot when a flight test program is to be audited). When making this determination, consider the following:
- (1) It is not necessary to select both engineers and inspectors for a small facility that does not have both engineering and manufacturing capabilities.
- (2) Select appointed QSA auditors, as appropriate, to maintain continued appointment in accordance with paragraph 3-23 of this order.
- (3) Do not include any appointed auditors who were previously employed by the facility to be audited within 2 years of the scheduled audit.
- (4) Determine whether auditors will be made available throughout the duration of the audit. Each auditor is expected to fully participate in each audit. Base any decision to limit

participation on the established AIR priorities. Notify the team leader of any limited participation by auditors.

c. Selection of PI and AE as Team Leaders or Auditors. To the greatest extent practicable, the PI and the AE will not be selected as team leaders on QSAs of facilities for which they have CM or oversight responsibilities. Use the guidelines in table 3-2 to select the PI and/or AE as auditors:

Number of Persons Performing the Audit	PAH Facility Procedure
One to four persons	Do not select the responsible certificate management PI as a team
	member. The AE may be selected as a team member.
Five persons or greater	The certificate management PI or the AE, or both, may be selected as
	team members

Table 3-2. Selecting a PI or AE as an Auditor

d. Selection of Auditors-in-Training and Team Leaders-in-Training.

- (1) Determine the number of appointed auditors required for the QSA before assigning auditors-in-training. Assign auditors-in-training only to audits for which a team is required. Do not assign auditors-in-training to a principal auditor. Auditors-in-training will supplement appointed auditors. Do not substitute auditors-in-training for appointed QSA auditors, or audit team leaders-in-training for appointed QSA team leaders.
- (2) Do not assign more than two auditors-in-training or more than one team leader-in-training to any one audit. Try to assign each auditor-in-training or team leader-in-training to different team leaders during the participation phase of the training.
- (3) In cases where auditors-in-training or team leaders-in-training from other divisions, directorates, or AIR-100 are proposed to be used in an audit, coordinate with the appointing managers to establish their eligibility.
- **e.** Additional Resource Requirements. Additional auditors beyond the division's/directorate's available resources may be required depending on the size of the facility; type and complexity of product, service, or design approval system; and overall audit objectives. Each division/directorate should identify the need for these additional resources before the release of the QSA master schedule for the next fiscal year and coordinate the auditors' participation with the appropriate division/directorate office and ACAIS coordinators. Additional support may also be available from AIR-100, if requested.
- **f. Scheduled Changes.** Each division/directorate must update schedule changes electronically in the ACAIS program at least quarterly. Audits added to the master schedule will be assigned a new QSA number in accordance with paragraph 3-27b of this order.

3-29. Notification of Facilities To Be Audited. The lead audit office identified in accordance with paragraph 3-27c of this order will notify facilities using the sample formats in appendix B to this order. Coordinate with the responsible PI to ensure the letter does not arrive during scheduled shutdown periods or during any other extended periods when the letter may not be acted upon. For notifications of first-time QSAs, inform the facility that QSA reference material is available on the FAA's website. If the facility cannot access the website, provide the reference material to the facility. Notify facilities as follows:

- **a. PAH.** The lead audit office will perform these tasks:
- (1) Prepare the notification letter and send it to the facility to be audited no later than 50 calendar days before the audit.
- (2) Provide a copy of the notification letter to the designated audit team leader or principal auditors, the PI, and the AE.
- **b.** Changes After Notification Letter Is Sent. As appropriate, notify the facility, responsible PAH, requesting manufacturing managing office, AIR-100, and team leader or principal auditor of any changes to the audit schedule or team composition after the notification letter has been sent.
- **3-30. Modifications to Scheduled Audits.** Every effort will be made to maintain established audit schedules. However, modifications to the audit schedule should be considered under special circumstances. The assigned engineering and managing manufacturing offices will jointly reschedule any affected audit in coordination with the PI, AE, and team leader or principal auditor, and update the schedule in the ACAIS program. Special circumstances that may warrant modifications to the audit schedule include
 - **a.** Risk to auditors' safety,
 - **b.** Change in a facility's production or delegation status from active to inactive,
 - c. Involvement of the FAA in a labor-management dispute at a facility, and
 - **d.** Reduction in the effectiveness of the audit.

Subpart 4. QSA Procedures

Subpart 4-1. QSA Preparation

- **3-31.** Lead Audit Office. Perform, as a minimum, the following QSA preparations:
- **a.** Notify, through ACAIS, the selected audit team leader and team members, or the principal auditor, at least 60 calendar days before each division/directorate QSA. A record of the notification does not need to be retained.
 - **b.** Ensure logistical support for an audit within the geographical area.
- **3-32.** Assigned Engineering and Manufacturing Managing Offices. At least 60 calendar days before each audit, notify through ACAIS all auditors within the division/directorate selected for AIR-100-led QSAs and QSAs in support of other divisions/directorates. A record of the notification does not need to be retained.
- **3-33. Audit Team Leader or Principal Auditor.** Coordinate QSA preparation to enable the audit team to make the most of limited time in the facility. The team leader provides orientation and assigns quality system elements to team members. These actions, as appropriate, require coordination with the PI, the AE, and the facility to be audited. The team leader or principal auditor will perform the following, as appropriate:
- **a.** Upon receipt of a copy of the notification letter, contact the lead audit office to identify the responsible PI and AE and obtain from the PI and AE items such as the following:
- (1) Applicable FAA-approved procedures, including engineering and quality manuals, procedures manuals, and handbooks, when practical. Obtain documentation in electronic format, if available, to simplify copying and distribution to team members. If applicable data are not available electronically, work with the PI or AE to identify relevant documents and to obtain printed copies of only those pages necessary to support the QSA.
 - (2) Current facility data available in ACAIS.
- (3) Known or suspected problem areas, including any areas the PI and AE would like special emphasis on during the QSA, such as requests to conduct a product audit. The team leader should also confer with the PI to identify and become familiar with the following quality system attributes as applicable:
 - (a) Critical processes (including special processes) and critical suppliers;
 - (b) Recent design changes;
 - (c) Significant changes in manufacturing personnel, procedures, or inspections;
 - (d) Rework and scrap data;

- (e) Material Review Board (MRB) history;
- (f) Quality escapes;
- (g) Any additional relevant correspondence or data pertaining to issues discovered in the course of new product deliveries or acceptance;
 - (h) Service difficulties;
 - (i) Airworthiness Directives (AD); and
 - (i) Relevant issues identified in the MSAD database.

Note: The team leader should contact the appropriate facility representative before the audit to arrange to have any information referenced in (a) through (j) above or other relevant quality data, procedures, or records available for the team at the in-briefing as referenced in the facility notification letter and deemed necessary by the team leader.

- (4) Recent self-disclosure items reported under FAA Order 2150.3, FAA Compliance and Enforcement Program.
- (5) Agreements made between the cognizant assigned engineering or manufacturing office and the facility to be audited.
 - (6) Facility access information, including badges and security clearances.
 - (7) Lodging information.
 - (8) Any other items necessary to prepare for the audit.
- **b.** Prepare a written audit plan, using the form found in the ACAIS program, for conducting the audit. The audit plan includes the following items:
 - (1) Name and address of the facility to be audited.
 - (2) Dates of the audit.
 - (3) Names of the team leader and members (when more than one auditor is selected).
- (4) Audit objectives. List the reason for the QSA and what information is expected to be obtained during the audit. For example: "Establish facility compliance with the procedures established to meet the applicable requirements of 14 CFR or establish cause of repetitive Service Difficulty Reports (SDR)."
 - (5) Types of approval.
 - (6) Type certificate (TC) or supplemental type certificate (STC) number, as applicable.

- (7) Current product line.
- (8) Number of employees associated directly with the production approval activity.
- (9) List of top-level FAA-approved procedures (for example, quality manual index of procedures, procedures manual, PMA approval letter, and TC data sheets).
- (10) FAA/facility agreements in effect; for example, agreement on frequency of submittal of minor design changes.
 - (11) Plant layout.
 - (12) Organizational chart.
 - (13) Major processes.
- (14) Unusual features of the product, manufacturing and inspection methods, or design approval system.
 - (15) Self-disclosure items under FAA Order 2150.3.
 - (16) Special emphasis items recommended by the PI and AE.
- (17) Quality system element, to include product audit, assignments (when more than one auditor is selected).
 - (18) Access information, including facility point of contact.
 - (19) Lodging information.
- (20) Equipment required (for example, notebook computer, safety shoes, and coveralls).
- **c.** Coordinate assignments, requirements, and arrangements with team members as far in advance of the audit as possible, but no later than 30 calendar days before the audit. The audit plan may be amended as necessary. Notify team members immediately of changes in schedule, assignments, requirements, and arrangements. Provide copies of all relevant facility documents to team members, when feasible.
 - **d.** Notify the lead audit office immediately of changes in team numbers or composition.
 - **e.** Coordinate with the applicable PI or AE, or geographic PI, as necessary.

3-34. Audit Team Member. Perform these tasks:

a. Upon notification by the team leader, confirm availability for the QSA, quality system elements assigned, and travel arrangements.

Note: Notify the team leader immediately if you become unavailable for the QSA.

b. Before the audit, review all material provided by the team leader, PI, or AE appropriate to the assigned quality system elements. When possible, make a preliminary selection of the procedures you plan to audit.

Subpart 4-2. Conduct of the Audit

- **3-35.** Team Leader or Principal Auditor Coordination With Facility Representative. The team leader or principal auditor will coordinate with the designated representative of the facility to be audited to ensure administrative arrangements for items such as team access, escorts, meeting rooms, and safety and security requirements are complete. The team leader should take this opportunity to review the special emphasis areas described in paragraph 3-33a(3) with the facility representative and arrange with the representative to have applicable information available to the FAA at the pre-audit team meeting.
- **3-36. Pre-Audit Team Meeting.** The team leader and all team members meet before starting the audit, usually at the facility to be audited. They review the following audit elements, as appropriate, for proper coordination and understanding:
- **a.** Current quality system or design approval system, and corrective action history of the facility to be audited in the selected areas;
 - **b.** Team functional assignments;
 - **c.** Audit plan;
 - **d.** Audit objectives;
 - e. Working relationship of the facility to be audited with the FAA;
 - **f.** Organizational structure of the facility to be audited;
- **g.** Approved quality system documents, including quality manuals and/or quality data submitted by PAHs to describe their quality systems;
- **h.** Approved design approval system documents, including any procedures manual or handbook; and
- **i.** Agreements made between the cognizant engineering or managing manufacturing offices and the facility to be audited.
- **3-37. Pre-Audit Conference.** Soon after arrival at the facility to be audited, the audit team leader or principal auditor conducts a pre-audit conference with appropriate senior management, cognizant supervisory personnel, and other appropriate personnel of the facility who will be associated with the audit, including escorts. The team leader or principal auditor must perform the following tasks, as appropriate:
 - **a.** Introduce team members.

b. Give a brief overview of QSA, highlighting the cooperative intention of the audit.

- **c.** Provide the audit's scope and objectives.
- **d.** Review details of the audit agenda, including the nonconformance codes and procedures to be used.
 - **e.** Review administrative arrangements for the post-audit conference.
- **f.** Discuss FAA Form 8100-7 sent with the notification letter to the facility being audited. Explain that this form is designed to obtain senior management assessment of the conduct of the QSA and is used by the FAA for continuous quality improvement of the CM program. Encourage senior management to complete the form and send it to the address on the form within 30 calendar days of the post-audit conference.
 - **g.** Allow time for a question-and-answer session.
- **3-38. Audit of Quality System Elements.** The QSA team audits all of the applicable quality system elements and conducts at least one product audit at the PAH. Each quality system element addresses a specific activity or function that may affect the maintenance of FAA-approved design or quality data. Each quality system element is listed in appendix D to this order. The QSA team will perform the following tasks, as appropriate:
- **a.** Review FAA-approved quality systems manuals or procedures manuals/handbooks to determine if current data ensure that regulatory requirements are met, if conforming products, articles, and parts are manufactured, and if design approval systems are maintained and controlled.
- **b.** Review design system, design approval system, and quality system data to determine if current data are FAA-approved.
- **c.** Review other facility procedures (related to the production approval facility) that are not part of the facility's FAA-approved data to determine if the current procedures impact any of the quality system elements.
- **d.** Review PAH supplier records by selecting a random sample of PAH supplier audit reports.
- (1) The reports may consist of onsite audits, mail-in surveys, third-party audits, or a combination of all three. The reports must be reviewed for compliance with the PAHs' quality system requirements. This may include, but is not limited to, the following conditions:
 - (a) Adherence to scheduled frequency of supplier control audits.
- (b) Appropriate documentation of audits. This includes a signature by an appropriate authority, and attachment of required certifications and test documents.

(c) Determination of whether noncompliances provide evidence of root cause, corrective action, follow up, and closure.

- (d) If a history of similar noncompliances is evident, determination of whether the PAH is appropriately conducting root cause analysis and applying corrective action.
- (2) FAA Form 8100-1, Conformity Inspection Record, will be used to record the following information. The completed record will be entered in ACAIS as part of the QSA report.
 - (a) Total number of audit reports reviewed.
 - (b) Identification of suppliers reviewed.
 - (c) Total number of noncompliances documented for all supplier reports reviewed.
- (3) The component page of the QSA report titled Special Emphasis Items may be used to record any additional or supplemental information pertaining to the supplier audit record review that the auditor considers important. Include this information as a note under the heading, "Note to MIO Manager and Cognizant Principal Inspector".

Note: The results will be used for two purposes: (1) to identify areas that may require more focused attention during audit of the supplier control system element and (2) as input into the following year's risk assessment of the PAH.

(4) Any noncompliance noted during the review of PAH supplier audit reports will be recorded under the supplier control quality system element. Noncompliance will also be documented in accordance with paragraph 3-39 of this order.

Note: Paragraph 3-38d and appendix D, of this order apply only to PAH facilities that use suppliers in the process of manufacturing FAA-approved products. Review of supplier records should be started early in the audit process to allow for additional time in case issues are noted.

e. Audit Compliance to Facility Procedures and Quality Requirements. Prioritize audits according to any special concerns raised by the PI or AE. Use the quality system elements in appendix D to this order to determine the depth of the audit in the subject area. Perform, as necessary, a combination of document and product reviews to determine if the quality system element meets applicable requirements.

Note: Standardized Noncompliance Codes. Auditors should use the noncompliance codes in appendix D to document the results of the audit of each quality system element in a standardized manner. The non-compliance codes are designed to cross all the functional areas within a facility's organization that have the greatest potential to impact the integrity of the FAA-approved design and product quality. All responses to the questions are direct inputs to the database from which trend analysis is accomplished. Each auditor should be knowledgeable of all the noncompliance codes applicable to the quality system element assigned to be audited and should strive to

audit as many of the procedures, requirements, and products related to the condition as time allows.

- **f.** Select at least one team member to conduct at least one product audit at a PAH of a manufactured product (for example, characteristic dimensioning, processing attributes, and physical examination) to determine compliance with current system procedures and quality requirements.
- **g.** On the basis of facility procedures or quality requirements, identify, and document other quality system elements and statement-of-condition practices and principles not contained in appendix D to this order that were required to document what was audited. Write or type additional criteria and statement-of-condition practices and principles, and include the appropriate reference to the facility procedures or quality requirements and the auditor's recommendation of the quality system element to which the criteria and statement of condition apply. Team members must present new criteria and statement-of-condition practices and principles to the team leader as soon as they are completed.
- **h.** Detect and report noncompliances and areas that may require additional audit by the PI or AE.
- **i.** If an QSA discloses a noncompliance that may involve other PAHs, the team leader and PI must consider the gravity and potential systemic impact of the noncompliance, and accordingly identify those additional PAHs also affected. The PI will follow up to verify the affected PAHs and notify and apprise the appropriate PIs of the encountered concern.
- **3-39. Recording Noncompliances.** Auditors will record all noncompliances on FAA Form 8100-6, or electronic equivalent, according to the guidelines in appendix C to this order.

Note: Record as a certification-related noncompliance any condition that questions the certification basis. Address the noncompliance on the QSA Executive Summary (refer to paragraphs 3-40b(2)(c) and 3-42b, and appendix E, to this order) and as a special emphasis item in the audit report (refer to paragraphs 3-40b(2)(d) and 3-41c, and appendix F to this order).

3-40. Audit Meetings.

- **a. Daily Meeting.** The team leader or principal auditor holds the following daily meetings, as appropriate:
- (1) Meeting With Audit Team Members. The team leader will review and discuss the following with team members:
 - (a) Status of the audit,
 - (b) Problems encountered,
 - (c) Plan of the next day's audit, and

(d) All FAA Form(s) 8100-6, or electronic equivalent, prepared during the day to ensure correctness, adequacy, and completeness.

- (2) Meeting/Communication With PI and AE. The team leader or principal auditor ensures the certificate management PI and AE, and the geographic PI, as applicable, are informed of all discussions concerning the status of the audit. This meeting should occur daily when the PI and AE are part of the audit team. Otherwise, coordinate with the PI and AE to establish the method and frequency at which these discussions should occur.
- (3) Meeting With the Audited Facility's Designated Representative. The team leader or principal auditor holds a brief meeting daily with the audited facility's designated representative to discuss the progress of the audit, including problems encountered, the status of actions requested by the team, schedule changes, and the coordination of further audit activities.
- **b. Final Critique Meeting/Audit Wrap-Up.** At the conclusion of the audit, the team leader holds a final critique meeting. The principal auditor allows time to finalize the details of the audit. The team leader and members or the principal auditor do the following, as appropriate:
 - (1) Team Members or Principal Auditor.
- (a) Complete all required FAA Form(s) 8100-6, or electronic equivalent. When using an electronic equivalent, print to paper when all information has been entered. Team members discuss FAA Form(s) 8100-6 with the team leader to determine if there are any possible violations of the applicable requirements of 14 CFR. The team leader must resolve any disagreement regarding noncompliances. The lead audit office, or requesting manufacturing managing office, as applicable, must determine the level of corrective action required (refer to paragraph 3-45 of this order).
- (b) Ensure all true copies of objective evidence are included to support the appropriate FAA Form(s) 8100-6, or electronic equivalent, appropriately referenced, and clearly identified in accordance with FAA Order 2150.3.
 - (2) Team Leader or Principal Auditor.
 - (a) Resolve team disagreements on specific noncompliances.
- (b) Discuss all noncompliances with the certificate management PI or AE, delegated facility AE, and geographic PI, as applicable.
- (c) Prepare the QSA Executive Summary (refer to appendix E to this order). Prepare original forms within ACAIS as follows:
 - 1 PAH. Prepare one original summary.
- 2 Facility With Multiple Production Approvals. Prepare one original summary. For example, if a facility has a PMA and a TSO authorization, prepare one original summary.

(d) Identify and record specific problems or concerns that the QSA team believes require further action and that should be brought to the attention of the assigned engineering or managing manufacturing offices, the geographic PI, the AE, and the Flight Standards principal maintenance inspector (as appropriate). Use the instructions in appendix F to this order to record these special emphasis items. Prepare original documents or electronic equivalents as follows:

- 1 PAH. Prepare one original or electronic document.
- 2 Facility With Multiple Production Approvals. Prepare only one original or electronic document. For example, if a facility has a PMA and a TSO authorization, prepare one original document.
- (e) Verify that signed original FAA Form(s) 8100-6 or electronic equivalents have been prepared for inclusion, as applicable, in each QSA report to be sent to the responsible manufacturing managing office, or assigned engineering office having delegation oversight (refer to paragraph 3-42d of this order). Each report to be sent must include all applicable FAA Form(s) 8100-6. When a signed original FAA Form 8100-6 is applicable to two or more reports, do the following:
- I Reproduce the signed original FAA Form(s) 8100-6 as required for inclusion in the applicable QSA reports to be sent to the responsible manufacturing management office with oversight.
- 2 Identify all true copies of the signed form in accordance with FAA Order 2150.3.
- (f) Provide a copy of the completed final draft FAA Form(s) 8100-6 to the certificate management PI or AE, and the geographic PI, as applicable, when they are present.
- (g) Verify that the required number of true copies of objective evidence has been prepared for inclusion, as applicable, in each QSA report to be sent to the responsible manufacturing management office having oversight responsibilities.
- (h) Provide all true copies of objective evidence to the certificate management PI or AE, when present. When the PI or AE is not present, forward the copies in accordance with the applicable instructions in paragraph 3-44a of this order. If the objective evidence will be necessary as a reference during preparation of the audit report, make a separate copy and identify each page as "For Reference Only."
- (3) Certificate Management PI or AE, or Geographic PI (When Present). As appropriate, consider providing a copy of the completed final draft FAA Form(s) 8100-6 to the facility's management. Clearly mark each copy as "DRAFT" before release.
- **3-41. Post-Audit Conference.** The team leader or principal auditor must conduct a post-audit conference with appropriate senior management and cognizant supervisory personnel of the audited facility. The team leader or principal auditor must, as appropriate, do the following:
 - **a.** Introduce FAA personnel not previously introduced at the pre-audit conference.

b. Give a brief presentation of the overall results of the audit, using each completed QSA Executive Summary as a reference:

- (1) Provide a completed and signed QSA Executive Summary to the audited facility's designated representative.
- (2) Summarize all noncompliances. Mention only noncompliances previously discussed with the certificate management PI and AE, the geographic PI, as applicable, and facility personnel.
 - **c.** Explain the purpose and use of ACAIS as it relates to QSA data.
 - **d.** Explain corrective action and follow-up procedures.

Note: Emphasize that the PI or AE may conduct additional investigations into noncompliances reported in the QSA report. The results of these investigations may be included with the letter requesting corrective action for the QSA noncompliances.

- **e.** Remind senior management about FAA Form 8100-7 and encourage them to complete the form and send it to the address on the form within 30 calendar days of the post-audit conference.
- **f.** Request final comments. Clarify any misunderstandings or disagreements before departure.
 - g. Adjourn the QSA.

Subpart 4-3. Post-Audit Activities

- **3-42. Preparing the QSA Report.** The team leader or principal auditor must prepare the QSA report. When a facility has one or more production approvals, prepare one audit report. Format and compile each audit report in the ACAIS program. The report will consist of the following:
- **a.** FAA Form 8100-3, Quality System Audit Report, or printed copy of electronic equivalent (appendix G to this order). Each completed electronic form or printed copy must be electronically or physically signed. Prepare an original electronic form or printed copy for each PAH affected.
- **b.** QSA Executive Summary or printed copy of electronic equivalent (appendix E to this order). Each electronic copy of the summary must be electronically signed. The printed copy presented to the PAH representative must be physically signed. All other information on electronic copies must be identical to the signed copy as presented to the PAH. Prepare an original summary or printed copy for each PAH affected.
- **c.** QSA Special Emphasis Items or printed copy of electronic equivalent (appendix F to this order). Prepare an electronic listing of special emphasis items or printed copy for each PAH affected.
- **d.** FAA Form 8100-6 or printed copy of electronic equivalent (appendix C to this order). Each report must include all applicable FAA Form(s) 8100-6.
- **e.** FAA Form 8100-1 or printed copy of electronic equivalent. Each report must include documentation of product audits (including onsite QSA supplier audits if applicable), and supplier audit record reviews as applicable.
- **f.** FAA Form 8120-14, Production Approval/Certificate Management Activity Report, or printed copy of electronic equivalent. FAA Form 8120-14 is only used when onsite supplier audits take place.
 - **Note 1:** Ensure the QSA report identifies only noncompliances presented at the post-audit conference.
 - **Note 2:** Do not include reproductions of true copies of objective evidence in an original audit report. Objective evidence must be a true copy signed and dated in accordance with FAA Order 2150.3.
- **3-43. Quality Review of the QSA Report.** The QSA report contains the data that forms the basis of corrective action requests (refer to paragraph 3-45 of this order) and the QSA national database. To this end, the audit report must be accurate and complete. Division/directorate managers (or delegated individuals) must establish a review process within their divisions/directorates that ensures accuracy and completion of the QSA report before distribution.

3-44. Sending the QSA Report. Using ACAIS, the team leader or principal auditor and the responsible assigned engineering and manufacturing managing office managers (or delegated individuals) will process the QSA report as follows:

a. Team Leader or Principal Auditor.

- (1) Make the audit report available to the responsible manufacturing office manager or delegate within 15 working days of the post-audit conference. The manager or delegate must return the report to the team leader or principal auditor for correction and/or continued processing within 5 working days of receipt.
- (2) Make the audit report available to the responsible certificate management MIO manager within 5 working days of receipt of the manufacturing managing office manager's or delegate's comments. Do not send copies of objective evidence to the MIO manager. Send or deliver all true copies of any objective evidence to the attention of the certificate management PI.
- (3) Make the audit report available to the cognizant assigned engineering office manager and to AIR-100. The copy for the assigned engineering office manager may be tailored according to the needs of that manager. Include copies of any objective evidence that the assigned engineering office manager may require to investigate identified special emphasis items. These copies must be sent or delivered to the attention of the assigned engineering office manager. Do not send copies of objective evidence to AIR-100.
- (4) Make the audit report available to the immediate supervisor of any auditors-in-training assigned to the team.

b. Certificate Management MIO Manager.

- (1) Make the audit report available to the certificate management PI within 3 working days of receipt of the report from the QSA team leader.
 - (2) Include any additional audit documents that the team leader provides.

c. Responsible Assigned Engineering Office Manager.

- (1) Make the QSA report available to the AE within 3 working days of receipt of the report from the QSA team leader.
- (2) Send or deliver all copies of any objective evidence to the attention of the AE, as applicable; send the true copies of the objective evidence under separate cover.

Note: Assigned engineering office investigations of special emphasis items identified during the conduct of a QSA should be coordinated with the responsible manufacturing managing office.

3-45. Requesting Corrective Action. The PI must request corrective action in accordance with paragraph 4-14 of this order.

Part 3. Supplier Control Audit

Subpart 1. Overview

- **3-46.** What Is a Supplier Control Audit? A supplier control audit is a systematic and independent examination, employing a product-based system audit approach, to determine compliance of an established supplier system or inspected products, articles, or parts with the PAH's requirements, technical data, or specifications. A supplier control audit is conducted to evaluate the PAH's established system to control the articles, materials, supplies, and services provided by outside sources. This audit is conducted by the manufacturing managing office assigned CM responsibility for the PAH. A supplier control audit is applicable to suppliers of a PAH as determined by the selection process identified in paragraph 3-15 of this order.
- **3-47. Purpose of a Supplier Control Audit.** The purpose of the supplier control audit is to determine whether a PAH is satisfactorily controlling its suppliers. The supplier control audit will determine whether the supplier complies with PAH's requirements, including any statistical sampling that may be used. A supplier control audit is not conducted to audit the performance of the suppliers. However, specific supplier issues or corrective action implementation should be audited when identified.
- **3-48. General PAH Supplier Control Responsibilities.** A PAH may use suppliers when it has established an FAA-approved quality system that provides assurance that all articles or services furnished by its suppliers are in compliance with its particular production approval and 14 CFR. The PAH must ensure each supplier-provided product, article, or service conforms to the PAH's requirements.
 - **a.** This responsibility is applicable regardless of:
 - (1) Where the suppliers may be located;
 - (2) Whether the parts received by the PAH are also FAA-approved (PMA or TSO);
- (3) Whether materials are accompanied by airworthiness approval tags, or their equivalent, issued by the CAA of a bilateral country;
- (4) Whether materials or equipment are supplied by the end product purchaser (customer-furnished equipment, buyer-furnished equipment, or government-furnished equipment);
 - (5) Whether the FAA performs an audit at the supplier;
 - (6) Whether the articles received by the PAH are commercial or standard parts;
 - (7) Whether the supplier has been delegated major inspection authority; or
 - (8) Whether the quality system data received from the supplier are in English.

b. Place special emphasis on controlling those suppliers that the PAH has authorized to ship directly to a user/operator. Suppliers may ship replacement and modification articles directly to the user/operator without the articles first being processed through the PAH's receiving inspection facilities only if the PAH—

- (1) Authorizes to the supplier, in writing, the authority to ship directly to a user/operator. An individual written authorization is not required for each direct shipment. The authorization may include limitations such as specific part numbers, time periods, or particular user/operators. This authorization will be maintained by the PAH for review by the cognizant manufacturing managing office.
- (2) Includes, in its FAA-approved quality system, controls to compensate for the absence of inspection normally conducted at the PAH's location, for example, receiving inspection and test. Compensating factors should include onsite audits of the supplier and the inspection of the article at the supplier by—
 - (a) The PAH, or
 - (b) The supplier under a delegated inspection authority from the PAH.
- (3) Ensures each article so shipped is accompanied by a shipping ticket, invoice, or other document containing a declaration that the individual article was produced under the terms of the production approval, and that inspection/acceptance has been accomplished by either the PAH or by delegated inspection authority. The shipping document for subcomponents manufactured for TSO articles should contain the TSO number. When FAA Form 8130-3, Authorized Release Certificate, is used for this purpose, the direct-ship authorization will be annotated in accordance with FAA Order 8130.21, *Procedures for Completion and Use of the Authorized Release Certificate, FAA Form 8130-3, Airworthiness Approval Tag.*
 - (4) Provides the appropriate article marking information to the supplier.
- (5) Advises its cognizant manufacturing managing office of each direct-ship authorization.
- **c.** Take measures to prevent suppliers from manufacturing articles without proper authority. For example, the PAH could limit projected overruns and request, in its contract with the supplier, that any unnecessary overrun articles be scrapped. The PAH may also include a clause in its contract that no articles are to be sold under any circumstances other than those described in the contract.
 - **d.** Make available to the FAA a current list of its suppliers.
 - e. Notify its suppliers that its facilities are subject to FAA CM.

3-49. CM Activity at Suppliers. The PAH is solely responsible for all supplier-furnished articles and services, therefore CM activity will focus on how well the PAH controls its suppliers. The FAA does not approve suppliers. However, the PI should review a PAH's list of suppliers to verify that any suppliers outside the United States have been previously evaluated for undue burden determination as required by FAA Order 8100.11, *Requirements for Finding Undue Burden and No Undue Burden Under 14 CFR Part 21*. Refer to chapter 4, section 7 of this order for more information on undue burden determinations.

3-50. Coordination of Requests for Supplier Oversight Assistance With Other CAAs. When a supplier to a U.S. PAH is located in a country or jurisdiction having an applicable bilateral agreement with the United States, the FAA may seek supplier oversight assistance from the bilateral CAA. Such assistance requests may take various forms at the PAH's supplier (for example, ongoing oversight, supplier control audits, or product audits), and may or may not be agreed to by the CAA, depending on factors such as its availability of resources and common production approval facilities. Requests for one-time or ongoing supplier oversight assistance should be transmitted from the MIO manager of the division/directorate in which the PAH is located to a counterpart CAA production contact. If the CAA agrees to the request and the assistance is recurring, a management plan must be formulated between the FAA and the supporting CAA. The management plan must outline information such as the details of the type of audit/inspection support requested, the methodology by which it will be performed (this is usually the normal audit/inspection procedures, and documentation of the local CAA), the frequency of the audit/inspection activity, and documentation expectations (that is, data and evidence that is useful to the compliance and enforcement program).

Note: Most of the FAA's bilateral agreements include provisions for technical assistance between authorities. Certain CAAs may charge a fee for oversight activities performed on behalf of the FAA at a PAH's facility located in its country or jurisdiction. A PAH should be aware that, although CAA fees may not have been charged in the past, fees may be incurred in the future. This change in the charging of fees for oversight activities is partly due to the scarcity of resources brought about by the globalization of aircraft manufacturing. In any case, any CAA oversight activity fees incurred are solely the responsibility of the PAH.

- **a.** AIR-100 has established management plans with certain European CAAs that permit those CAAs to conduct supplier oversight activity on the FAA's behalf, in accordance with FAA Order 8120.13, *International Cooperative Supplier Surveillance Program Procedures*. The management plans with the current International Cooperative Supplier Surveillance Program participants are located at the AIR Work Tools page on the FAA Employees' website, https://my.faa.gov/org/linebusiness/avs/offices/air/tools/tools_list.html. Supplier oversight activity conducted outside the United States will be handled in accordance with FAA Order 8120.13 when the local authority is a program participant.
- **b.** If the FAA must conduct the supplier oversight activity itself in another country or jurisdiction, for any reason, the PI will perform the following activities:
- (1) Notify the responsible CAA and invite CAA participation as an observer through a formal letter signed by the division/directorate MIO manager or delegated signatory. The letter

should be addressed to the production contact for the CAA. A list of CAAs and respective contacts is available from the International Division, AIR-400. Send an electronic facsimile (fax), scanned copy, or email of the letter at least 50 days before the audit, followed by mailing the formal letter. Notify the CAA of any changes in the audit's schedule. The CAA's participation in the audit is not mandatory, and the choice to provide an observer is at its discretion. The letter should, as a minimum, include the following information:

- (a) Identity of the supplier facility to be audited.
- (b) Type of supplier oversight activity to be conducted (such as a supplier control audit, a product audit, or ongoing oversight). Provide a general outline of what will be included in the scheduled activity.
 - (c) Dates of the scheduled activity.
 - (d) Number of FAA auditors participating in the scheduled activity.
 - (e) Name, address, telephone number, and email address of the responsible PI.
 - (2) Provide the PAH's manufacturing managing office with details of any noncompliance encountered during the oversight activity. For example, if there is a trend showing recurring test failures or nonconforming articles, it may be evidence of a system breakdown or a compliance problem at that facility. The PAH's manufacturing managing office will determine if there are any system issues or major problems that should be forwarded to the applicable CAA for its consideration because the PAH's supplier may coincidentally hold a local production approval.

Subpart 2. Scheduling of Supplier Control Audits

- **3-51. Division/Directorate Supplier Control Audit Schedule.** Subsequent to the supplier selection process described in paragraph 3-15 of this order, each manufacturing managing office will develop a division/directorate supplier control audit schedule annually.
- **a.** The division/directorate supplier control audit schedule will include the name of the selected supplier, the name of the responsible PAH, the scheduled date of supplier control audits to be conducted by the manufacturing managing office, and identification of any supplier control audits that may be handed off to other divisions/directorates or may require the assistance of a CAA in a bilateral country.

Note: When feasible, the manufacturing managing office should schedule the division/directorate supplier control audit for a time when the supplier has an active purchase order from the PAH or for articles produced within the last 12 months before the current fiscal year. The PI should consider reviewing future delivery of products/articles to ensure only current active suppliers are selected for a division/directorate supplier control audit. Such an audit may be scheduled in conjunction with a QSA, provided the audit (1) occurs in the same fiscal year,

(2) does not divert resources, and (3) is conducted and reported separately from the OSA.

- **b.** Each manufacturing managing office will maintain supplier control audit data in accordance with the instructions provided in ACAIS. This data will be used to plan resource allocation in the next fiscal year. The MIO manager will ensure the data submitted by each manufacturing managing office are reviewed for completeness and for identification of duplicate suppliers. When the same supplier is selected by different manufacturing managing offices, the MIO manager should ensure only one audit is scheduled at that supplier; however, compliance to the requirements of all applicable PAHs must be audited at that supplier. The MIO manager should also determine which manufacturing managing office will conduct the audit, and whether representation from other manufacturing managing offices is required. When all potential discrepancies with the data are resolved, the MIO manager will ensure the consolidated division/directorate supplier control audit data is prepared and made available in ACAIS in the applicable PAHs' files.
- **c.** The completed division/directorate data, described in paragraph 3-51b of this order, must be available in ACAIS to all other MIO managers. All MIO managers should ensure supplier control audit data received from other divisions/directorates are reviewed to identify duplicate suppliers, potential hand-offs that affect their offices, and supplier control audits to be conducted by the FAA at multiple international suppliers in the same country.
- **3-52.** Coordination of Supplier Control Audits. Coordination between assigned offices and manufacturing managing offices should ensure only one audit is scheduled at a supplier and that all affected PAHs will be audited as part of the audit, as well as to identify audit participants. During the audit, the PAHs with the higher risk assessment results will have priority over PAHs with lower risk assessment results.
- **a. Hand-offs.** If a supplier control audit is required in another manufacturing managing office, the PI will comply with the hand-off procedures in paragraph 3-16 of this order. MIO managers will accept and support hand-offs of supplier control audits that are scheduled within the requirements of paragraph 3-52 of this order. MIO managers will ensure supplier control audits that are handed off to their divisions/directorates are added to their division/directorate supplier control audit lists and scheduled. Updated audit lists should be provided to the other MIO managers. Contentious hand-offs, such as those that have significant resource implications, should not be scheduled at this time. Participants should discuss contentious hand-offs and agree on an appropriate solution.
- **b.** Supplier Control Audits To Be Conducted by the FAA at International Suppliers. MIO managers should identify one FAA office as a lead office to coordinate all international audit activities, which includes notifying the responsible CAA and inviting its participation.
- **c.** Corrective Action Validation. Occasionally, it may be necessary to validate corrective actions at a supplier facility located outside of the geographical boundary of the responsible CM office. When a hand-off to the manufacturing managing office is appropriate for this purpose, the following hand-off procedures will be used:

(1) The manufacturing managing office will forward a memorandum to the assigned office having geographical responsibility of the area in which the supplier is located. The memorandum will identify whether the corrective action to be validated is a short-term or long-term action, and will include all pertinent information regarding the corrective action to be validated. The memorandum also will specify a date for responding to the corrective action validation request. The memorandum should include, as a minimum:

- (a) The name and address of the supplier and the responsible PAH, including the PAH's project number;
- (b) The name, title, and telephone number of the person to contact at the supplier and accountable managers at PAH facilities that can furnish purchase orders, quality system data, technical data, or other pertinent information;
- (c) A copy of the PAH's or supplier's quality system procedures that are required to be implemented at the particular supplier's facility, unless these documents are available to the FAA at the supplier's facility;
 - (d) A copy of the noncompliance;
 - (e) A copy of the PAH's corrective action response; and
 - (f) A copy of the supplier's corrective action response to the PAH.
- (2) When a manufacturing managing office receives a request for a corrective action validation at a facility located within its geographical boundaries, it will—
- (a) Advise the requesting manufacturing managing office of receipt of the request within 30 days.
- (b) Submit a memorandum to the requesting manufacturing managing office upon completion of the corrective action validation. This memorandum should summarize the results of the validation and include all applicable FAA Form(s) 8100-6 or 8100-1, as well as all true copies of supporting objective evidence. The requesting manufacturing managing office will consider its hand-off request complete upon receipt of this memorandum.

3-53. Notifying a PAH.

- **a.** Before conducting a supplier control audit, the assigned office that will be conducting the audit will notify the responsible PAH. The assigned office will prepare a notification letter and send it to the PAH no later than 30 days before the audit.
- **b.** The PAH is responsible for notifying the supplier of the scheduled supplier control audit. If changes occur after the notification letter has been sent, notify the PAH by letter or other appropriate means. If a supplier control audit has been handed off as described in paragraph 3-16 of this order, the PAH will be advised accordingly, and the requesting office will be provided a copy of the notification through ACAIS. Figure 3-5 of this order contains a sample notification letter.

Figure 3-5. Sample Supplier Control Audit Notification Letter



U.S. Department of Transportation

Federal Aviation Administration

July 13, 2016

Molly Brown c/o Tight Weave Manufacturing 1600 Lind Ave SW Fort Worth, TX 76137

Dear Ms. Brown:

Transport Airplane Directorate Aircraft Certification Service Seattle MIDO 2500 East Valley Road, Ste C2 Renton, Washington 98055

The Federal Aviation Administration (FAA), in accordance with its responsibilities under Title 49 of the United States Code, Subtitle VII, part A, and applicable regulations, has selected Structural Components located in Seattle, Washington, for a supplier control audit. The audit is scheduled to be conducted on November 12, 2016, by an FAA representative from the Seattle Manufacturing Inspection District Office MIDO). This audit will determine that your supplier complies with purchase order and/or quality requirements, including any statistical sampling that may be used.

The FAA requests that you inform a representative at Structural Components of this audit. Also, please inform the Scattle MIDO at (425) 227-2170 of any security requirements so that we may obtain the appropriate clearance. In addition, please provide the name, title, address, and telephone number of an individual at Structural Components who will serve as the company point of contact for this audit.

If you have any questions concerning the scheduling or conducting of this audit, please contact the undersigned at the above telephone number.

Sincerely,

Julia Golla

Julia Gotta
Seattle Manufacturing Inspection
District Office

cc: Fort Worth MIDO

Subpart 3. Conducting a Supplier Control Audit

- **3-54. Audit Criteria.** Every effort should be made to conduct a supplier control audit when the supplier has an active purchase order or working agreement from the PAH. The supplier control audit will be conducted using the PAH's quality flow-down requirements noted on the applicable purchase order or working agreement. Quality flow-down requirements may include, but are not limited to, the control of raw and nonconforming materials, records, sample plans, inspection systems, calibration systems, certificates of conformance, software, age-controlled products, special processes, first article inspections (FAI), subtier suppliers, and design data.
- **a.** If circumstances arise and an active purchase order or working agreement is not available, a supplier control audit still may be accomplished using historical records that are traceable to the PAH's quality flow-down requirements noted on an applicable purchase order or working agreement.

Note: The noncompliance codes in the supplier control audit section of appendix D to this order should not be used as a checklist during supplier control audits. However, for data collection and analysis purposes, the PI must select the most appropriate noncompliance codes when documenting noncompliances on FAA Form 8100-6.

- **b.** If specific expertise is required during this audit, the PI should advise the manufacturing managing office manager. The PI should prepare an audit checklist for each supplier to be audited based on the applicable purchase order and/or quality requirements from the PAH.
- **3-55. Recording a Supplier Control Audit.** A supplier control audit must be recorded on FAA Form 8120-14. One form will be completed for each supplier control audit conducted. Each hand-off is considered a separate supplier control audit. Prepare the form in accordance with appendix H to this order. Document noncompliances on FAA Form 8100-6 (refer to appendix C to this order).
- **a.** If a supplier control audit discloses a noncompliance that may involve other PAHs, the team leader and PI must consider the gravity and potential systemic impact of the noncompliance, and accordingly, identify those additional PAHs also affected. The PI will follow up to verify the affected PAHs and notify and apprise the appropriate PIs of the encountered concern.
- **b.** If an applicable product or article is available at the supplier, a product audit will be conducted in accordance with section 3, part 5, of this chapter and recorded on FAA Form 8100-1.

Subpart 4. Determining a PAH's Control of its Suppliers

3-56. Determination of Supplier Control. The PI may determine whether a PAH is controlling its suppliers by reviewing the results of the PI audit at the PAH, when applicable, and the results of the supplier control audits at the selected PAH suppliers, including the results of all applicable CAA audits. This review should be accomplished annually, immediately following the last scheduled supplier control audit, PI audit, or CAA audit, whichever occurs last. During the review, the PI should look for evidence that may indicate a system breakdown in supplier control by the PAH. When a systemic noncompliance is identified, the PI will prepare FAA Form 8100-6 and retain all applicable objective evidence in accordance with Manual FAA-IR-04-01, *AIR Records Management Requirements Manual*. The PI will request corrective action for a system breakdown in accordance with chapter 4, section 4, of this order.

Part 4. Principal Inspector Audit

- **3-57. What Is a PI Audit?** A PI audit employs a product-based system approach to evaluate whether a PAH is complying with its approved quality procedures. It is conducted at a PAH's manufacturing location by the manufacturing managing office having the assigned CM responsibility for that PAH. During the PI audit, the manufacturing managing office will evaluate quality system elements as defined in §21.137 as follows (refer to appendix D to this order):
 - **a.** PAHs designated Levels 1 and 2 should receive an audit of as many of the quality system elements as possible, in the interval between QSAs.
 - **b.** PAHs designated Level 3 should, at a minimum, receive an audit of the top five noncompliant quality system elements applicable at the facility, as identified annually by each division/directorate through an analysis of ACAIS data. This audit requirement will be completed at least once within its applicable 48- or 60-month period.
- **3-58. Scheduling a PI Audit.** The PI audit will be scheduled by the manufacturing managing office based on the PAH's risk assessment and subsequent risk prioritization. A manufacturing managing office may schedule additional PI audits at specific facilities when required to ensure continued operational safety. The duration of the PI audit may be one day or multiple days, depending on factors such as the PAH's size, location, production lines, buildings, etc. If specific expertise is required during a PI audit, the PI should advise the manager of the manufacturing managing office.
- **3-59. Hand-offs of PI Audits.** If a PI audit is required in another manufacturing managing office, the PI will comply with the hand-off procedures in paragraph 3-16 of this order.
- **3-60. Recording a PI Audit.** Record a PI audit on FAA Form 8120-14 (refer to appendix H to this order). Complete one form for each PI audit conducted. Prepare this form in accordance with appendix H to this order. Document noncompliances on FAA Form 8100-6 (refer to appendix C to this order).

Note: When performing a PI audit that includes a review of a PAH's supplier records, the PI will record the information required in paragraph 3-38d(2)(a) through (c) of this order on FAA Form 8100-1.

Part 5. Product Audit

- **3-61. What Is a Product Audit?** A product audit evaluates the effectiveness of the PAH's quality system and the airworthiness of products using critical and certain non-critical characteristics and/or processing attributes generated during the manufacturing process. A product audit is required to be conducted during all audits and whenever determined to be necessary by the PI or manufacturing managing office, and may be initiated at any point in the manufacturing process after inspections have been completed. The product audit is conducted at a PAH, but may also be conducted at a supplier facility where a product or article is manufactured. If specific expertise is required during this audit, the PI should advise the manufacturing managing office manager. If a product audit is required in another manufacturing managing office, the manufacturing managing office will comply with the hand-off procedures in paragraph 3-16 of this order.
- **3-62. Selection of Product Audit Characteristics.** The product audit will be conducted using critical characteristics and/or critical processing attributes generated during the manufacturing process, as well as certain non-critical characteristics and/or non-critical processing attributes. These characteristics and attributes are defined as follows:
- **a.** Critical characteristics are those where failure to maintain conformity could cause loss of function and create an unsafe condition. Critical process attributes are those where lack of conformity directly affects the product, article, or part(s) and could cause failure or create an unsafe condition. The selection of the critical characteristics and/or critical process attributes is determined by reviewing the following (this review does not need to be documented):
 - (1) Known service problem areas.
- (2) Characteristics/attributes that are operator controlled. Operator-controlled characteristics/attributes are controlled by people rather than machines or computers.
- (3) Characteristics/attributes classified as critical as defined by the PAH's engineering drawings, process specifications, test specifications, and quality system procedures.
- (4) Service difficulty reports. Information related to SDRs can be found on the Flight Standards Service Aviation Information website located at http://av-info.faa.gov/sdrx/.
- **b.** In addition to critical characteristics and/or critical processing attributes, the PI may select certain non-critical characteristics and/or non-critical processing attributes, such as radiuses, surface finishes, machine to cast features, cad plating, or nondestructive inspection.

3-63. Product Audit Areas. The product audit may be divided into one or more of the following:

- **a.** Final product,
- **b.** Article,
- c. Subassembly,
- **d.** Detail parts, or
- e. Raw material.
- **3-64. Product Audit Criteria.** The audit criteria used in the performance of a product audit to establish conformity to approved type design are listed below. This audit criteria is a minimum and not all-inclusive. Table 3-3 indicates which criteria are applicable to each product audit area, as a minimum.

Note: A product audit is not a re-inspection by the FAA representative. Rather, it is the FAA representative witnessing the re-inspection by the PAH or applicable supplier. The PAH's or applicable supplier's personnel are responsible for the handling of the articles during the product audit.

- **a. Operational/functional.** Verify that the subassembly or final product conforms to the functional/operational test criteria (for example, revalidating test results, test setup, software revision, software checksum, rig approval, certified equipment, use of approved procedures, certified test parameters, use of required rig, and calibration).
- **b. Dimensional.** Compare actual recorded measurements of the selected characteristic with the approved design data. Verify that characteristics are inspected using the correct calibrated tooling, gauging, fixtures, etc., surface finish dimensions and radius meet drawing tolerances, inspections are performed in proper sequence (following work instructions); for example, review or revalidate inspection records.
- **c. Visual.** Inspect articles for obvious external defects; for example, corrosion, burrs, handling damage, and scratches.
- **d. Identification.** Compare actual identification plates, tags, markings, etc., with approved design data or purchase order requirements and verify that identification is maintained throughout the product line; for example, part numbers, serial numbers, lot numbers for raw material, and inspection stamps. For software revision verification, verify that the software number can be displayed on screen or software load verified by documentation review.
- **e. Documentation.** Verify the latest revision level or changes, proper work instructions, completed operations, and proper authorizations. Also verify proper use of statistical sampling; for example, certificate of conformance, work travelers, blueprints, specifications, and FAI records.

f. Special Processes. Verify that special processes are in accordance with approved process specifications. Verify operator qualification/certification; for example, test coupons, training requirements for operators, test set-ups, and documentation. Verify oven surveys/calibration. For a chemical process such as plating, verify that control has been established over tank cleanliness and chemical concentration.

g. Material. Verify that the PAH has verified that incoming raw material meets its specification requirements.

Table 3-3. Applicability of Product Audit Criteria to Product Audit Areas (Minimum)

Product Audit Areas					
Product Audit Criteria	Final Product	Article	Subassembly	Detail Parts	Raw Materials
Operational/functional	X	X	X		
Dimensional	X	X	X	X	X
Visual	X	X	X	X	X
Identification	X	X	X	X	X
Documentation	X	X	X	X	X
Special processes		X	X	X	X
Material		X	X	X	

- **3-65. Recording Product Audit Results.** All product audit results will be recorded on FAA Form 8100-1. When unsatisfactory conditions are identified, prepare FAA Form(s) 8100-6 (refer to appendix C to this order). The PI will retain all applicable objective evidence to support unsatisfactory conditions until corrective action is deemed acceptable and any related noncompliances are closed.
- **3-66. Recording Completion of a Product Audit.** The completion of a product audit will be recorded on FAA Form 8120-14 by the person conducting the audit (refer to appendix I to this order). However, FAA Form 8120-14 is not required for a QSA unless an onsite supplier audit is done as a part of the QSA. When a product audit is conducted in conjunction with a PI audit or supplier control audit, one form should be completed for each product audit completed. Prepare this form in accordance with appendix H to this order. The PI will retain all applicable objective evidence to support any noncompliances until closure. Any corrective action required should be accomplished in accordance with chapter 4, section 4, of this order.

Chapter 4. Additional Oversight Responsibilities

Section 1. Introduction

4-1. Purpose of This Chapter. Sections 2 through 7 of this chapter provide guidance for accomplishing additional CM responsibilities. The tasks discussed below are accomplished on an as-required basis.

Section 2. Audit of Changes to a PAH's Quality System

4-2. General Manufacturing Managing Office Responsibilities. The manufacturing managing office must thoroughly review applicable changes to the quality system required for the applicable production approval that may affect the inspection, conformity, or airworthiness of the product or article. Any inadequacies in the quality system must be identified to the PAH for corrective action.

Note: The review of changes at an associate facility will remain with the office having CM responsibility for the original PAH. If the original PAH has delegated responsibility to approve changes to the associate facility, the CM office of the associate facility will review the changes.

- **4-3. Prioritization of Review.** Review of a facility's changes to its quality system should be prioritized according to its risk assessment level. For example, the changes at a facility rated as "High Risk" will be reviewed before the changes for a facility rated as "Medium Risk." Reviews of changes from facilities rated the same risk assessment level will be prioritized by date of notification or receipt of applicable data.
- **4-4. Review of Changes.** The manufacturing managing office should review changes to the quality system to ensure—
- **a.** The quality system will continue to adequately provide for the consistent acceptance of only those products, articles, or parts which are in conformity with the approved design data and in a condition for safe operation.
- **b.** The quality system will continue to meet the intent of the pertinent rules and can be realistically implemented.

Note: The conditions identified in paragraphs 4-4a and 4-4b of this order may often be verified through data review alone. In some instances, however, onsite inspection or review may be required.

4-5. Post-Review Actions. The manufacturing managing office will—

- **a.** Identify any inadequacies found in the changed quality system and request corrective action from the PAH.
 - **b.** After any required corrective actions have been taken, process the changes as follows:
- (1) For changes to a quality system at a PAH, forward a letter to the PAH approving the quality system changes, including applicable changes submitted to the FAA-approved inspection and test procedures. Refer to the sample letter in figure 4-1 of this order.
- (2) The PI will update the ACAIS project folder to reflect the current quality system and include a copy of the FAA letter that acknowledges the approval of the applicable PAH quality system.

Figure 4-1. Sample Letter of Approval for Quality System Changes



U.S. Department of Transportation

Federal Aviation Administration 1601 Lind Avenue SW. Renton, WA 98055-4056

August 10, 2015

Mr. Michael D. Dorsey, President ABC Aircraft Company 4954 Airport Drive Renton, Washington 12345

Notification of Quality System Change Status

Dear Mr. Dorsey:

We have completed our review and audit of the quality system changes documented in your Quality Management Manual. Your submitted data neets specify applicable CFR.] The Federal Aviation Administration (FAA) approves the submitted data. The FAA reserves the right to require changes, additions, and clarifications that may be come necessary as a result of subsequent inspections and/or audits.

This notification should remain on file as will be of FAA review of your quality system document.

Document Name: Quality Management Manual.

Document Number: 101248

Revision Number: C

Date: June 30, 2015

Sincerely,

Dewey Revn

Dewey Revu Principal Inspector

Section 3. Investigation of Service Difficulties

- **4-6. General Service Difficulties Information.** This section provides guidance for conducting and participating in service difficulty investigations.
- **a. Source.** There are various means by which the FAA obtains information regarding service difficulties in TC products; for example—
- (1) Manufacturer's notification of failures, malfunctions, and defects (refer to § 21.3 and Advisory Circular (AC) 21-9, *Manufacturer's Reporting Failures, Malfunctions, or Defects*);
 - (2) SDR (refer to §§ 121.703, 125.409, and 135.415);
- (3) Mechanical Interruption Summary (MIS) Report (refer to §§ 121.705 and 135.417);
 - (4) Repair station reports of unairworthy conditions;
- (5) Accident and Incident Report (refer to 49 U.S.C., subtitle II, chapter 11, subchapter III, sections 1131 through 1136);
 - (6) User complaints (general public, military, and foreign governments);
 - (7) Reports and information received from other FAA and government offices;
 - (8) FAA website for submission and review of SDRs: http://av-info.faa.gov/sdrx/; and
 - (9) MSAD database.
- **b.** Assigned Engineering and Manufacturing Managing Offices Investigation. Upon receipt of an SDR, the manufacturing managing office having CM responsibilities over the manufacturer of the identified product, article, or part(s) will investigate the information and determine if design or production deficiencies are involved. The assigned engineering office is responsible for overseeing the certificate holder's corrective action to any design deficiencies.
- **c. Manufacturing Managing Office Responsibility.** The manufacturing managing office will assign a high priority to service difficulty investigations, which must be completed as expeditiously as possible. The identity of a firm or private person reporting service difficulties to the FAA will not be revealed to the manufacturer. The FAA must witness any tear-down inspections or testing to be performed on defective products, articles, or parts when such products, articles, or parts are flagged (by FAA tags or forms) as requiring the presence of an FAA inspector during the tear-down, inspection, or test, as applicable.
- **4-7. Investigation.** The assigned ASI will conduct an investigation, independent of that performed by the manufacturer, of reported service difficulties, in accordance with the criteria contained in this order. The ASI will also investigate and include in the report the results of any investigation conducted by the manufacturer.

4-8. Corrective Action. The manufacturing managing office will formally request the manufacturer to take corrective action when the investigation discloses unsatisfactory conditions in conformity, quality system, or workmanship. In such cases, particular emphasis must be placed on determining by examination or reexamination of all related quality system practices, data, records, etc., whether the discrepancy may also involve products, articles, and parts in service, in the manufacturing process, or spares, either in storage or shipped to users. If justified, AD action should be recommended to the responsible assigned engineering office.

4-9. Reporting a Service Difficulty Investigation.

- **a. Service Difficulty Investigation Report.** The manufacturing managing office will prepare and process a report of service difficulty investigation in accordance with this order and FAA Order 2150.3. The report may be in the form of a memorandum or any other acceptable manner and will include, as a minimum, the following information:
 - (1) Name and address of manufacturer;
 - (2) Type and number of certificates or approvals held;
- (3) Make, model, and part number, as appropriate, to positively identify the defective product, article, or part(s);
- (4) Inspector's statement of findings, including an audit of any investigation conducted by the manufacturer;
 - (5) Inspector's conclusion as to the cause of the service difficulty;
- (6) All corrective actions requested by the manufacturing managing office and/or taken by the manufacturer including a copy of the manufacturing managing office letter to the manufacturer and the manufacturer's reply;
 - (7) Effect on products in service; and
 - (8) Recommendations and/or further actions required.
- **b. Interim Report.** In the event that the investigation is delayed for any reason, and if requested by the MIO, the manufacturing managing office will prepare an interim report of the service difficulty investigation outlining the progress of the investigation.
- **c. Violations.** When the SDR and the subsequent investigation indicate that a violation exists, the investigating and reporting procedures in FAA Order 2150.3 will also be followed.
- **d. ODA Reports.** Upon notification by the FAA, ODA holders are required by § 183.63 to investigate and report to the FAA the results of their investigation and any action taken or proposed. These reports should be forwarded to the assigned engineering and the managing manufacturing offices, which should initiate any actions deemed appropriate for the particular service difficulty involved.

4-10. Foreign Manufacturers. Foreign manufacturers are exempted from the reporting requirements of § 21.3. When foreign manufactured products, articles, or parts approved pursuant to § 21.29, § 21.500, § 21.502, or § 21.621 are involved in service difficulties, the MIO in the division/directorate where the service difficulty occurred will initiate an investigation. A complete report will be provided to the MIO and Standards Staff of the division/directorate having geographical responsibility over the particular country where the product, article, or part manufacturer is located. Upon receipt and audit of the report, the MIO having geographical responsibility will bring the matter to the attention of the CAA for further investigation and corrective action as necessary. If critical articles, processes, or methods are involved, ADs or alert bulletin action should be considered. If the condition is serious and affects safety and if adequate corrective action is not immediately forthcoming from the foreign manufacturer or CAA, action pursuant to § 13.19 would also be necessary. Coordinate such enforcement action through the Assistant Chief Counsel, Enforcement Division, AGC-300, AIR-400, and the State Department.

Section 4. PAH Noncompliances and Corrective Action

- **4-11. PAH Noncompliances.** FAA CM responsibilities often result in identifying PAH noncompliances. All identified noncompliances must be processed in accordance with FAA Order 2150.3 and the AIR Compliance and Enforcement Process, as described in Technical Business Process AIR-002-035.
- **4-12. Documenting Noncompliances.** As indicated in paragraph 3-17 of this order, noncompliances are recorded on FAA Form 8100-6. The PI must review each item on FAA Form 8100-6 to determine if the noncompliance is substantiated. If a noncompliance is substantiated, the PI must process the noncompliance in accordance with FAA Order 2150.3 and the AIR Compliance and Enforcement Process, as described in Technical Business Process AIR-002-035.
- **4-13. Processing Noncompliances.** The following are additional considerations when determining the proper means to document a noncompliance.
- **a.** If a facility provides objective evidence subsequent to the issuance of an FAA Form 8100-6 that justifiably negates the basis of the reported noncompliance, a request for corrective action of that noncompliance will not be required. The PI must retain the FAA Form 8100-6 and all applicable evidence in accordance with Manual FAA-IR-04-01.
- **b.** If the noncompliance meets the definition of a SUP, as described in FAA Order 8120.16, *Processing Reports of Suspected Unapproved Parts*, the PI must report the SUP in accordance with FAA Order 8120.16.
- **c.** If the noncompliances identified on FAA Form(s) 8100-6 are found during a supplier control audit or product audit conducted as the result of a hand-off, the FAA Form 8100-6 must be transmitted to the requesting manufacturing managing office for action.

d. If the PI determines, after the audit is finalized, that the noncompliance recorded on FAA Form 8100-6 is incorrect and should be changed, the PI must—

- (1) Prepare a memorandum providing justification for changing the type of noncompliance.
 - (2) Obtain written concurrence (signature) on the memorandum from their manager.
 - (3) Inform the team leader or principal auditor of the change, if applicable.
- (4) Complete a revised FAA Form 8100-6, corresponding to the changed type of noncompliance.
- (5) Retain the original FAA Form 8100-6, the signed justification memorandum, the revised FAA Form 8100-6, and any applicable objective evidence, in the office project folder or official files list.
- **4-14. Obtaining Corrective Action.** Corrective action for all noncompliances must be performed in accordance with FAA Order 2150.3 and the AIR Compliance and Enforcement Process, as described in Technical Business Process AIR-002-035.

Section 5. Unscheduled Audits or Investigations

- **4-15. General Unscheduled Audit Information.** Chapter 3 of this order addresses scheduled product-based system audits. However, any one of these audits may be performed on a non-scheduled basis at the discretion of the manufacturing managing office whenever necessary to ensure continued operational safety. Other investigations may arise for purposes such as SUP or whistleblower allegations.
- **4-16. Non-Scheduled CM Audits.** The manufacturing managing office will determine the type of audit that will provide the best assessment of the applicable situation. A non-scheduled CM audit will be planned, conducted, and reported in accordance with chapter 3 of this order to the greatest extent practicable. Appropriate emphasis on planning the audit should be provided despite the reduced time that may be available between the decision to conduct the audit and the actual conduct of the audit. Notification of the unscheduled audit to the PAH or supplier should be provided as soon as practicable. For a PAH or supplier facility located outside the United States, the responsible CAA also should be provided notification as soon as practicable. Situations that may warrant an unscheduled audit may include
 - a. Accidents and incidents;
 - **b.** Deliberate violations:
 - **c.** Repetitive notices of quality escapes, ADs, and SDRs;
 - **d.** SUP investigations;
 - e. Excessive owner/operator complaints;

- **f.** PAH's refusal/failure to take appropriate corrective action;
- **g.** PAH's inability to control suppliers;
- h. Renewal of a PAH's production activity after a prolonged period of inactivity; and
- **i.** Relocation/addition of a production facility or supplier that produces articles listed on the CPL.
- **j.** Oversight Requests From CAAs. A U.S. manufacturer that has entered into a supplier, subcontractor, or other similar relationship with a foreign manufacturing entity (for example, a manufacturer of aircraft, aircraft engines, or propellers; a repair station; or an air carrier) may produce, identify and deliver civil aeronautical products, articles, and parts to that entity without obtaining an FAA design and production approval under part 21. The purchase order or similar contract/procurement agreement, from the foreign manufacturer to the supplier manufacturer should provide any evidence of the sales relationship to the FAA as needed. These products, articles, or parts are to be produced in support of a design approval issued by a CAA, to include modifications made to a type design by repair stations or air carriers (for example, TC, STC, or CAA-approved modification). The regulatory responsibility for control or oversight of a U.S. manufacturer acting strictly as a supplier to a foreign manufacturing entity resides with the CAA having oversight of that design and/or production approval. The FAA assumes no regulatory responsibilities for these programs and will provide assistance only in oversight of the U.S. supplier through a special written arrangement with the CAA under the provisions of the bilateral agreement.
- (1) A CAA's request should include clear, concise, and specific instructions to the FAA that includes the following: company name, address, phone number, and point of contact; details concerning the extent of oversight to be conducted on behalf of the CAA; and documentation to be submitted to the CAA. The responsible geographic MIO will ensure the request is complete before assigning it to a manufacturing managing office.
- (2) The responsible manufacturing managing office will review all completed documentation being submitted to the CAA to ensure the requirement of the CAA's request have been met. On completion of the review, and incorporation of any applicable corrections, the responsible manufacturing managing office will prepare a cover letter to accompany the documentation and forward it to AIR-400 for review and comment. After incorporating any applicable corrections to the cover letter, the completed documentation and cover letter will be forwarded to the MIO manager for signature. The MIO manager will forward all documentation to the requesting CAA.
- (3) When the CAA conducts its own oversight activities at a U.S. manufacturer, the FAA may be invited to observe or participate. The responsible manufacturing managing office should consider accepting the CAA invitation only when there is no impact on scheduled ongoing CM activities or other special CM activities with higher priority.
 - **k.** Any other situation as deemed necessary in the interest of safety.

4-17. Special Audit Item (SAI). An SAI is an item, process, or area that senior management has determined requires specific focus during audits. The MIMT, AIR-100, or senior management has authority to declare an SAI based on a perceived need. The scope of the SAI, such as what is to be audited, when it is to be audited, and how results are documented, will be included in the SAI instructions that are sent to the ASI.

Note: An SAI is different from a special emphasis item, in that the SAI is an audit directed by senior management for a specific issue, whereas a special emphasis item is a concern, determined by a QSA result, that may require further attention.

Section 6. Providing Guidance to a PAH

- **4-18. Guidance.** The PI should provide guidance to a PAH as necessary for the manufacturing of products and articles produced under the approved quality system. The guidance provided by the PI may include, but is not limited to, the following:
 - a. Quality system changes;
 - **b.** Facility changes;
 - c. Technical assistance;
 - **d.** Updating supplier lists;
 - e. Service difficulty and corrective action review;
 - **f.** Support of QSAs;
 - g. Regulatory requirements, changes to guidance materials, or industry best practices;
 - h. Understanding of applicable regulations; and
- **i.** Undue Burden or No Undue Burden Determinations in accordance to FAA Order 8100.11 and AC 21-55, *Process to Support FAA Findings of Undue Burden or No Undue Burden for PAHs Requesting to Use a Manufacturing Facility Located Outside of the United States.*

Section 7. Determining Undue Burden or No Undue Burden

4-19. PAH's Requirements. Sections 21.122(a), 21.139(a), 21.309(a), and 21.609(a) of 14 CFR state that the FAA does not issue production approvals if the manufacturing facilities are located outside the United States unless the FAA finds the location of the manufacturer's facilities places no undue burden on the FAA. The PAH must demonstrate to the FAA that its request to use a manufacturing facility outside of the United States would prove no undue burden to the FAA. The PAH should provide this information by following the procedures described in AC 21-55. However, the PAH may provide the necessary information by other means. Should that occur, the manufacturing managing office will ensure the information provided by the PAH is commensurate with the information requested in AC 21-55's appendix A, PAH Project Initiation Plan. In

addition, the manufacturing managing office should inform the PAH that, should it provide the information to the FAA in a manner other than that described in AC 21-55, the decision-making process may be prolonged. Using manufacturing facilities located outside of the United States before FAA approval could result in compliance and enforcement action.

4-20. Undue Burden Determination. Following the guidance in FAA Order 8100.11, the manufacturing managing office will determine whether the information provided by the PAH sufficiently demonstrates that the proposed activity will cause no undue burden to the FAA. It is the PI's responsibility to work with their office manager, MIO manager, division/directorate manager, and, if applicable, AIR-400 to obtain their concurrence with the review and validation of the information provided by the PAH. Once the undue burden determination is complete, the manufacturing managing office will notify the PAH of the FAA's finding.

Chapter 5. ACAIS

- **5-1. Purpose.** Audit data resulting from PAH CM activities is stored in ACAIS. Upon extraction from ACAIS, this data can be manipulated using Microsoft Excel or other software with statistics capabilities. The software will be used to detect shifts in performance and statistically significant trends within the manufacturing industry, by division/directorate, by production approval type, or by other categories as supported by the data available within ACAIS. ACAIS data may also be used to study various aspects of the performance of QSAs on an as-required basis.
- **5-2. Initial Activation of a New PAH in ACAIS.** The information related to the PAH that is initially entered into ACAIS is divided into two parts:
 - **1. Quality System Information.** In ACAIS, the entity that applies for a production approval is called a "Quality System." The Quality System contains the name and main address of the entity as well as the name of the accountable manager, as required per 14 CFR 21.135, 21.305, and 21.605.
 - **2. Project Information**. In ACAIS, the additional information needed by the FAA to effectively manage the production approval from the time of application until its cancellation is called a "Project." The Project contains information such as the type of production approval, the current status of the production approval, the facility location, personnel assigned to manage the production approval (both at the facility and the FAA), as well as information about the products or articles the facility manufactures.
- **5-3. Forms.** ACAIS contains all CM forms, including, FAA Form 8100-1, FAA Form 8100-3, FAA Form 8100-6, FAA Form 8100-7, and FAA Form 8120-14.
- **5-4. Database Management.** AIR-100 is responsible for monitoring ACAIS and will, as appropriate, do the following:
 - **a.** Review the database as follows:
 - (1) Enter into ACAIS any completed FAA Form 8100-7 as returned by the facility.
 - (2) Highlight noncompliance trends with respect to the quality system elements.
 - (3) Analyze noncompliance trends with respect to the quality system elements.
 - (4) Highlight trends emerging in the performance of QSAs.
 - **b.** Provide selected data and reports.
 - **Note 1:** All recipients of ACAIS audit data will use the information internally only and will not release results outside of AIR (refer to appendix L, paragraph 8, to this order).

- **5-5.** Use of the Database. Divisions/directorates may use ACAIS to—
- **a.** Obtain reports on noncompliances, frequently used 14 CFR references, and PAH compliance.
- **b.** Detect shifts in performance and statistically significant trends for different segments of the industry.
 - **c.** Assist in scheduling.

Appendix A. Category Parts List

1. Purpose. This appendix describes the Category Parts List (CPL), which may be used by the manufacturing managing office when conducting a risk assessment of a PAH.

2. Category Parts List. The CPL contains:

a. A list of systems, assemblies, and part(s) that have been assigned a category rating of 1 or 2. To receive a category rating of 1, a system, assembly, or part must be one whose failure could prevent continued safe flight and landing, and resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations. To receive a category rating of 2, a system, assembly, or part must be one whose failure would not prevent continued safe flight and landing, but whose resulting consequences may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.

Note: For ACAIS purposes only, a category rating of 3 is assigned to a system, assembly, or part whose failure would have no effect on continued safe flight and landing of the aircraft.

- **b.** A list of special processes that may be considered critical to the manufacturing of a part or assembly listed on the CPL (e.g., heat treating, cadmium plating, additive manufacturing, welding). A special process is considered critical if:
 - (1) It could degrade the performance of the assembly or part or the consequences of a failure may reduce the capability of the aircraft.
 - (2) It adds value to a part that cannot be validated by nondestructive testing techniques, such as visual inspection or measurement by complex means.
- **c.** A list of special conditions and equivalent levels of safety associated with an applicable system, assembly, or part.
- **3. Structure of the CPL.** The CPL is grouped by regulatory basis (i.e., 14 CFR parts 23, 25, 27, 29, and 33). The regulatory basis is further delineated by the Joint Aircraft System/Component (JASC)/Air Transport Association (ATA) codes, which have been assigned a rating of either a category (CAT) 1 or 2 or N/A.
- **4. Review of the CPL.** AIR-100 will review the CPL every 12 months from the date of the last change or review. This review will be documented on a revision/review tracking log that is attached to the CPL. The CPL, with the attached revision/review tracking log, will be posted on the FAA Employees' website.
- **5. CPL Revision Process.** A request to add, remove, or change the category rating of a system, assembly, or part to the CPL may be generated from any source (e.g., PI or assigned engineering office). The following procedure is used to revise the CPL:

Note: A request to change the category of an existing CPL system, assembly, or part may be justified based on a specific application. For example, a windshield may appear on the CPL as Category 1 for a part 23 aircraft. Based on the application (e.g., unpressurized vs. pressurized), a request to change the category rating for a specific part 23 aircraft may be warranted if the category rating of 1 is not appropriate.

- **a.** The requester should prepare a Part Categorization memo and include the following as a minimum (refer to sample memo in figure A-1):
 - (1) Identify and fully describe the applicable system, assembly or part.
 - (2) Identify the applicable 14 CFR part (i.e., part 23, 25, 27, 29, or 33).
- (3) Describe the reason for adding, removing, or changing the category rating of the system, assembly, or part.
- (4) Provide all applicable supporting data. This may include service difficulty information, ADs, or any other data to support the request.
- (5) Identify where on the CPL a new system, assembly, or part should be added. Omit this data for a change or removal request.
- (6) When requesting a change to the category rating of an existing system, assembly, or part, or requesting removal of an existing system, assembly, or part, include its current category rating. Omit this data for an add request.
- **b.** The manufacturing managing office manager reviews the memo to verify that it contains the minimum required information and coordinates with the requester, if necessary. The manufacturing managing office will then send the Part Categorization memo to its respective MIO manager.
- **c.** The MIO manager retains a copy of the request and forwards the memo to AIR-100.
- **d.** AIR-100 will investigate and coordinate the data described in the memo with the appropriate division/directorate standards group. AIR-100 will then complete the "Coordination" section of the Part Categorization memo as follows:
 - (1) Indicate whether the action taken is to "Accept" or "Deny" the request.
- (2) If the action is to accept either a request to add a system, assembly, or part or to change an existing category rating, assigns the appropriate category to the system, assembly, or part.
- (3) If the action is to accept a request to remove an assembly or part from the CPL, indicate the concurrence.

- (4) If the action is to deny the request, indicates the reason it was denied.
- **e.** On completion of the actions in paragraph 5d of this appendix, the AIR-100 will sign the completed memo and forward it to the requesting MIO manager.
- **f.** AIR-100 updates the CPL, documents the new revision date in the CPL revision/review/tracking log, and disseminates the revised CPL to all MIO managers.
 - g. AIR-100 will post the updated CPL on the FAA Employees' website.

Figure A-1. Sample Part Categorization Memo for Requesting a Change to the CPL



Memorandum

Date: March 26, 2016

To: Manager, AIR-100

From: Dewey Revu, Manager, Seattle MIDO

Kathleen Beall, Manufacturing Inspection Manager, ANM-100

Prepared by: Ronald Reynolds

Subject: <u>ACTION:</u> Remove [Add/Change Category] Part from CPL

We request to remove [add/Change Category] the following part from the Category Parts List (CPL):

1. Part name: Brake deboost valve.

- 2. 14 CFR part affected: 25.
- 3. Reason for removing [adding/Changing Category] part: The only PAH manufacturing brake deboost valves is no longer in business.
- 4. The following applicable supporting data are attached: Letter from ASW MIDO-42 canceling project. Cover letter from PAH containing the returned PMA letter.
- 5. Placement of part on CPL:
- 6. Current Category: 1

Attachment

Letter from ASW MIDO-42 Letter from Poland Valve Co.

COORDINATION

Date: April 23, 2016

Action on request: Accept removal

Category Assigned: N/A

V. Small

Small, AIR-100 CPL Specialist

Appendix B. Preparation of the QSA Notification Letter to a PAH

- **1. Purpose.** This appendix provides instructions and sample paragraphs for preparing a notification letter to a PAH for a scheduled audit.
- **2. Information to Include in the Notification Letter.** Figure B-1 provides sample paragraphs with the minimum information to include in a notification letter to a PAH. Additional paragraphs may be added as necessary to provide specific division/directorate or AIR-100 information.
- **a. First Paragraph.** The first paragraph is introductory and serves to establish the regulatory basis for the audit and to identify the facility and type of approval being audited. This paragraph applies to all approval types.
- **b. Second Paragraph.** The second paragraph identifies the dates of the audit and provides a general outline of the functions to be audited.
- **c. Third Paragraph.** The third paragraph identifies the approximate number of auditors who will be participating in the audit and the team leader or principal auditor, as applicable.
- **d. Fourth Paragraph.** The fourth paragraph requests appropriate senior management attendance at pre-audit and post-audit conferences, as well as cognizant technical and supervisory personnel. It also requests assignment of knowledgeable escorts. This paragraph also requests that the facility make available at the opening briefing any information the team leader deems relevant for review by the team. Refer to paragraphs 3-33a(1), (2), and (3) of this order.
- **e. Fifth Paragraph.** The fifth paragraph requests senior management feedback on the conduct of the QSA through FAA Form 8100-7 to be sent to the cognizant engineering or managing manufacturing office. This form should be prepared electronically and may be provided to the facility to be audited in either electronic or printed format. Prepare FAA Form 8100-7 (figure B-2) by typing in the following:
 - (1) Block 1. The QSA number.
 - (2) Block 2. The name of the audited facility.
 - (3) Block 3. The start and end dates of the audit.
- (4) Block 4. The address of the cognizant engineering or the managing manufacturing office. Enclose a prepaid self-addressed envelope in which the facility may return the form.
- **f. Final Paragraph.** The final paragraph is a closing paragraph indicating to whom specific questions concerning the audit should be addressed. It directs that questions relative to scheduling be addressed to the lead audit office or requesting manufacturing managing office and that questions relative to the conduct of the audit be addressed to the team leader or principal auditor.

Figure B-1. Sample Paragraphs for the Notification Letter

The Federal Aviation Administration (FAA), in accordance with its responsibilities under the recodified Federal Aviation Act of 1958 (as amended) and applicable requirements of Title 14 of the Code of Federal Regulations, has selected (name of PAH), located in (city, state), for the conduct of an audit. Your certification as a (type of approval holder) has been approved by the FAA contingent upon the Administrator's right to audit and inspect your organization, facilities, product, and records. This includes your entire network of suppliers and approval extensions, as appropriate.

The audit of your facility is scheduled to be conducted from (<u>start date</u>) to (<u>end date</u>) under the FAA's Quality System Audit (QSA) program. This audit will be broad-based in nature and will encompass elements such as design control, manufacturing processes and controls, and supplier control. Procedures and records will be examined in addition to a "hands-on" witnessing of relevant system processes.

(The FAA audit team will consist of approximately (total number) members.) The (FAA team leader designated/principal auditor) for this audit is (Mr. Ms.) who may be reached at (telephone number). (His/Her) address is (office address).

Attendance by a representative of senior manager and responsible for the facility to be audited, as well as cognizant technical and supervisory personnel, is requested during the pre-audit and post-audit conferences. We further suggest that exports who are knowledgeable of the various areas to be visited be provided to ensure the audit is conducted smoothly and with minimal disruption to your staff. Please have available at the time of the facility in-briefing any specific information, data, or records perturning to your FAA-approved quality system that was previously requested by the team leader.

One of the primary features of the OSA is continuous quality improvement. As part of this process, it is important for us to how what your senior management thought about the conduct of the QSA. We therefore encourage senior management to complete the attached FAA Form 8100-7, QSA Justomer Feedback Report, and return it in the enclosed prepaid self-addressed enveloped within 30 calendar days of the post-audit conference.

Please be advised that FAA QSA reference material is available on the FAA website.

If you have any questions concerning the scheduling of this audit, please feel free to contact me. If you have any questions concerning the conduct of the audit, please contact the (team leader/principal auditor) (Mr./Ms.) (name of team leader/principal auditor), at the above address and telephone number.

Figure B-2. Sample FAA Form 8100-7, QSA Customer Feedback Report

Department of Transportation Ideral Aviation Administration QUALITY SYSTEM AUDIT QSA No. (1) Name of Audited Facility: (2) Dates Audited: (3) Part of the Federal Aviation Administration (FAA) and lity System Audit (QSA), this form is provided for you right the conduct of the audit recently conducted at you we did, and thank you for the time you will take to support to the appropriate rating in each of the tables be an appropriate. Pre-audit arrangements Unsatisfactor Timeliness Coordination/Planning Imments/recommendations for improvements	ndustry confi use in furnis r facility. W port our quali	in tous in proven shing the EAA we destruct try encl ity improvement	ment efforts with comme urage you t and custon	nts to tell us mer service
QSA No	ndustry confi use in furnis r facility. W port our quali	in tous in proven shing the EAA we destruct try encl ity improvement	ment efforts with comme urage you t and custon	nts to tell us mer service
Dates Audited: Dates Audited: (3) Part of the Federal Aviation Administration (FAA) and lity System Audit (QSA), this form is provided for you rding the conduct of the audit recently conducted at yo we did, and thank you for the time you will take to superives. See Check the appropriate rating in each of the tables be appropriate. Pre-audit arrangements Unsatisfactor Timeliness	use in furnis r facility. W port our quali	shing the EAA we since rely enclity improvement	vith comme ourage you t and custor	nts to tell us mer service
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part of the Federal Aviation Administration (FAA) and lity System Audit (QSA), this form is provided for you reding the conduct of the audit recently conducted at yo we did, and thank you for the time you will take to sujctives. se check the appropriate rating in each of the tables be appropriate. Pre-audit arrangements Unsuis actor Timeliness Coordination/Planning	use in furnis r facility. W port our quali	shing the EAA we since rely enclity improvement	vith comme ourage you t and custor	nts to tell us mer service
part of the Federal Aviation Administration (FAA) and lity System Audit (QSA), this form is provided for you reding the conduct of the audit recently conducted at yo we did, and thank you for the time you will take to supctives. se check the appropriate rating in each of the tables be appropriate. Pre-audit arrangements Unsatisfactor Timeliness	use in furnis r facility. W port our quali	shing the EAA we since rely enclity improvement	vith comme ourage you t and custor	nts to tell us mer service
	y Poor	Satisfactory	Good	Excellen
Pre-audit conference Unsatisfacto	v Poor	Satisfactory	Good	Excellent
Communication				
Presentation			П	
Purpose of audit explained				

FAA Form 8100-7 (09/12)

Figure B-2. Sample FAA Form 8100-7, QSA Customer Feedback Report (Continued)

QUALITY SYSTEM AUDIT FEEDBACK REPORT, con't

3. Daily meetings	Unsatisfactory	Poor	Satisfactory	Good	Excellent
Explanation of noncompliances					
Resolution of issues					

Comments/recommendations for improvement:

		•	II			
4. Post-audit conference	Unsatisfactory	Poor	Sp	tistactory	Good	Excellent
Communication			II			
Explanation of executive summary		T T	$\overline{}$			
Explanation of follow-up actions		/\\\\	\Box			

Comments/recommendations for improvement:

	// \\ \\ /\ /\					
5. Conduct of the audit		Unsatisfactory	Poor	Satisfactory	Good	Excellent
 Team profession 	di sm	7 -				
Overall conduct of	the OSA team					

Comments/recommendations for improvement:

Signature (optional) Date

Please return completed form to:

(4)

FAA Form 8100-7 (09/12)

Appendix C. Preparation Instructions for FAA Form 8100-6, Noncompliance Record

- **1. Purpose.** This appendix provides instructions for completing FAA Form 8100-6 for all audit activities.
- **2. Specific Guidance.** Figure C-1 shows FAA Form 8100-6 with numbered blocks. The form will be prepared as a stand-alone document. Write the noncompliance against the responsible PAH. Prepare the form by inserting in:
- **a. Block 1.** When the activity is a QSA, enter the QSA Number/Audit Number. For all other activity, enter an appropriate Audit/Report Number or "N/A" as applicable.
 - **b.** Block 2. Enter the project number(s) applicable to the production approval(s) activity.
 - **c. Block 3.** Number the noncompliance sequentially beginning with the number "1."
- **d. Block 4.** Insert a checkmark in the appropriate box to indicate the type of audit that was conducted.
- **e. Block 5.** Under "System Element Audited," enter the name of the quality system element in appendix D to this order to which the noncompliance is relevant. Under "Noncompliance Code," enter the audit noncompliance code number from appendix D to this order. The systems elements and noncompliance codes are available in ACAIS. Under "Process Code," when the type of noncompliance identified in block 10 is a "Product Nonconformity," enter the process that deviated to cause the noncompliance. The process codes are available in ACAIS, as well as in table 1 of the latest revision of SAE Aerospace Standard AS9131. Do *not* insert more than one number.

Note: More than one noncompliance may be recorded for an audit criteria number. When an audit criteria contains several statements of condition, it is possible to find noncompliances to some or all of those conditions. When multiple statements of conditions under one criterion are affected, complete an FAA Form 8100-6 for each condition. When recording noncompliances for a common condition, complete only one FAA Form 8100-6.

f. Block 6. The controlling document is defined as the FAA-approved data, purchase order/quality requirements from a PAH, or internal procedures used in producing the product, article, or part(s). Enter the complete reference number, or, as a minimum, the document title and effective date. (e.g., ABC Company Quality Manual dated March 5, 2005; XYZ QOI 32-6 dated June 23, 2007; BCD Drawing No. 9825333-2 dated May 20, 2009.) Insert a check in the "Yes" or "No" block, as appropriate, to indicate whether the controlling document is FAA-approved.

Note: Purchase orders and/or quality requirements flowed down to a supplier by a PAH are generally not considered to be FAA-approved data. In some cases,

quality requirements for use at a supplier facility are specifically approved by the FAA before use. Determine the approval status of any referenced PAH supplier quality requirement before checking the "Yes" or "No" block.

g. Block 7. Enter the applicable 14 CFR part, section, or subsection that establishes the responsibility of the PAH (for example, § 21.316 or § 21.146(b)). If the observed condition is not directly traceable to one of these requirements, then leave the block blank. Insert the applicable 14 CFR reference for each approval type affected.

Note: When a facility holds multiple production approvals, and a noncompliance is found that applies to more than one of those approvals, use the highest level quality requirement. For the purposes of this order, the quality levels, from highest to lowest, are PC, TSO authorization, and PMA.

- **h. Block 8.** Insert a check mark in the appropriate box to indicate the scope of the noncompliance:
- (1) Systemic: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is systemic in nature; (i.e., is pervasive, repeatable, and represents a breakdown in the quality system).
- (2) Isolated: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is isolated or nonsystemic in nature; (i.e., is not pervasive or repeatable, and does not represent a breakdown in the quality system).
- **i. Block 9.** Insert a checkmark in the appropriate box to indicate whether the origin of the noncompliance can be traced back to the PAH or the PAH's supplier.
- **j. Block 10.** Insert a checkmark in the appropriate box to indicate whether the noncompliance was the result of a nonconformity in a product or a noncompliance in a procedure. If the noncompliance is the result of a product nonconformity, then enter a process code in block 5 and complete blocks 13 and 14.
- **k. Block 11.** Insert a checkmark in the "Yes" or "No" block, as appropriate, to indicate whether it is a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that compromises immediate continued operational safety and requires immediate corrective action.
- **l. Block 12.** Insert a checkmark in the "Yes" or "No" block, as appropriate, to indicate whether it is a noncompliance to 14 CFR that is discovered in FAA-approved data.
- **m. Block 13.** Enter the applicable JASC system code when the type of noncompliance identified in block 10 is a "Product Nonconformity." The system codes are available in ACAIS, as well as in the latest version of the Federal Aviation Administration Joint Aircraft System/Component Code Table and Definitions document.
- **n. Block 14.** Enter the applicable JASC component code when the type of noncompliance identified in block 10 is a "Product Nonconformity." The component codes are available in

ACAIS, as well as in the latest version of the Federal Aviation Administration Joint Aircraft System/Component Code Table and Definitions document.

- **o. Block 15.** Enter the condition required by the controlling document, applicable supporting documents, or the applicable 14 CFR part or section. Use the same wording as the controlling document, the applicable supporting document, or the applicable 14 CFR part or section, whenever possible. List all documents that demonstrate the link back to the controlling document or 14 CFR.
 - **p. Block 16.** Enter a detailed explanation of the encountered condition.
 - (1) Explain why the encountered condition differs from the required condition.
 - (2) Identify where the encountered condition was found.
- (3) Identify the total number of items checked and the total number of items found to be in noncompliance.
- (4) List the items found to be in noncompliance, using identification numbers or other specific identifiers whenever possible.
- (5) Record any evidence that the facility provided during the audit to show that corrective action was taken or initiated.
- (6) When the encountered condition finds FAA-approved data to be in noncompliance with an applicable 14 CFR part or section, include a note that further investigation by the assigned engineering or managing manufacturing office may be required.
 - (7) List all objective evidence obtained that describes the encountered condition.
 - **q. Block 17.** Enter the name of the team member who discovered the noncompliance.
 - **r. Block 18.** Enter the routing symbol of the person listed in block 17.
- **s. Block 19.** Enter the typed or printed name and signature of the person recording the noncompliance. If the form is completed within ACAIS, the signature is not required.
 - **t. Block 20.** Enter the routing office symbol of the person listed in block 19.
 - **u. Block 21.** Enter the date the form is completed.

Figure C-1. Sample FAA Form 8100-6

		No	ncompliance Re	cord	QSA	A No./Audit No. (1)
					Proj	ect No. (2)
					Non	compliance No. (3)
Type of Audit: ☐ MII	OO 🗆 PI	□ QSA	□ SCA □ Product	: 0	ther <i>(4)</i>	
System Element Audi	ted: (5)	Contro	olling Document: (6)		Applicable C	FR Section: (7)
Noncompliance Code:						
Process Code:		FAA-a □ Yes	pproved data? [Select one □ No	2]		
			compliance Character	ristics	I	
Scope: [select one] Systemic Isolated (8) JASC System Code: Required Condition	: (15)		Type: [select one] Product (10) Nonconformity Procedural Noncompliance JASC Component Code	Impact one] Yes [No [Certification Related? (12) [select one] Yes No
inconnected Condition. (19)						
Team Member Discove	ring Noncompliar	ice: (17)	!			Office Symbol (18)
Name and Signature of	Recorder: (19)				ice Symbol	Date (21)

FAA Form 8100-6 (06-14)

FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

Appendix D. Standardized Noncompliance Codes for PAHs

This appendix provides noncompliance codes, their associated CFR references, and quality system elements to be used when documenting noncompliances to the PAH's FAA-approved data and/or procedures on FAA Form 8100-6.

Note: An "N/A" in the associated CFR references column indicates not applicable.

Table D-1. Quality System Elements

Section No.	Quality System Element	Appendix D Page No.
(a)	Design data control	D-2
(b)	Document control	D-3
(c)	Supplier control	D-3
(d)	Manufacturing process control	D-5
(e)	Inspection and testing	D-6
(f)	Inspection, measuring, and test equipment control	D-7
(g)	Inspection and test status	D-8
(h)	Nonconforming product and article control	D-8
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Table D-2. Noncompliance Codes

Note: The tables below list the compliance codes for each type of Quality System Element.

	Section (a) Design Data Control						
Code	Description of Noncompliance	PC	PMA	TSOA			
001	The audited facility did not have written procedures for controlling design data and subsequent changes to ensure that only current, correct, and approved data are used.	§ 21.137(a)	§ 21.307	§ 21.607			
002	The audited facility did not follow procedures for controlling design data or subsequent changes to ensure that only current, correct, and approved data are used.	§ 21.146(b)	§ 21.316(b)	§ 21.616			
003	The approval holder did not approve minor design changes under a method acceptable to the FAA.	§ 21.95	§ 21.319	§ 21.619			
004	The approval holder did not submit major design changes, including process specification changes, to the FAA for approval.	§ 21.97 § 21.99	§ 21.319	§ 21.619			
005	The approval holder did not submit appropriate design changes for approval to correct unsafe conditions under an AD.	§ 21.99(a)(1)	§ 21.307	§ 21.607			
006	The approval holder did not make available to a user descriptive data and information on FAA-approved design changes resulting from ADs.	§ 21.99(a)(2)	§ 21.99(a)(2)	§ 21.99(a)(2)			
007	The approval holder did not keep an ICA current with design changes or make it available to appropriate persons.	§ 21.50	§ 21.50	§ 21.50			
008	The approval holder did not provide the FAA all required information to support inclusion of a commercial parts list in an ICA.	§ 21.50	§ 21.50	*N/A			
009	The audited facility did not follow approved procedures to coordinate and obtain approval from authorized personnel, including engineering, for a service bulletin or maintenance manual.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
010	The audited facility did not follow approved procedures to include a manufacturing, quality, or service/support organization in the review of design and technical data changes.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
011	Electronically stored or transmitted technical design or quality data were not adequately controlled or distributed to a supplier.	§ 21.146(a) and (b)	§ 21.316(a) and (b)	§ 21.616(a) and (b)			

	Section (b) Document Control						
Code	Description of Noncompliance	PC	PMA	TSOA			
012	The audited facility did not have written procedures for controlling quality system documents and subsequent changes to ensure that only current, correct, and approved data are used.	§ 21.137(b)	§ 21. 307	§ 21.607			
013	The audited facility did not follow procedures for controlling quality system documents or subsequent changes to ensure that only current, correct, and approved data are used.	§ 21.146(b)	§ 21.316(b)	§ 21.616			
014	The audited facility did not properly establish, maintain, or control a test procedure or subsequent change.	§ 21.137(b)	§ 21.307	§ 21.607			

Section (c) Supplier Control PC Code **Description of Noncompliance PMA TSOA** The audited facility did not have approved written 015 procedures to ensure that each supplier-furnished product, \{\} 21.137(c)(1) § 21.307 § 21.607 article, or service conforms to the PAH's requirements. The audited facility did not follow approved written 016 procedures to ensure that each supplier-furnished product, § 21.146(b) § 21.316(b) § 21.616(b) article, or service conforms to the PAH's requirements. The audited facility did not conduct a receiving inspection 017 of a supplied article or service to verify conformity to the § 21.146(b) § 21.316(b) § 21.616(b) PAH's requirements. The audited facility did not verify that specification 018 requirements were met for a purchased product or § 21.146(b) § 21.316(b) § 21.616(b) material with a shelf-life. The audited facility did not follow approved procedures 019 to flow-down applicable technical and quality § 21.146(b) § 21.316(b) § 21.616(b) requirements to a domestic or international supplier. The audited facility did not follow procedures for design § 21.146(b) § 21.95 data control with its supplier, including changes. 020 § 21.316(b) § 21.616(b) § 21.97 § 21.99 The PAH did not have written procedures to require suppliers of any level to report quality escapes to their 021 next level, and/or did not have written procedures to § 21.137(c)(2) § 21.307 § 21.607 require first-level suppliers to report quality escapes to the PAH. The PAH did not follow the approved supplier-reporting 022 process and/or procedures which require a supplier to § 21.146(b) § 21.316(b) § 21.616 report quality escapes to the next level or PAH.

Code	Description of Noncompliance	PC	PMA	TSOA
023	A supplier did not follow PAH procedures to report a quality escape to the PAH.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
024	The PAH did not take corrective action in response to a report of a quality escape from a supplier.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
025	The audited facility did not follow approved procedures for using only approved suppliers.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
026	The audited facility did not follow approved procedures in conducting a required supplier evaluation or in taking necessary corrective actions related to that evaluation.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
027	The PAH did not approve a supplier's quality manual as required by approved procedures.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
028	The PAH uses other parties to perform supplier surveillance or assessments on its behalf, but does not have procedures for using these other parties.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
029	The PAH uses other parties to perform supplier surveillance or assessments on its behalf, but does not follow procedures for using these other parties.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
030	The audited facility did not follow approved procedures for requiring suppliers to notify the audited facility in writing of significant facility or organizational changes such as changes in company name, company location, or senior quality management.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
031	A supplier with direct shipment authority was not controlled to ensure that only conforming parts were released.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
032	The audited facility did not follow approved procedures to require approved suppliers to have a supplier control program in place for their suppliers.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
033	The quality organization of the audited facility did not follow approved procedures in reviewing a purchase document before issuance.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
034	The audited facility did not follow approved procedures to require suppliers to have a program to ensure the proper operation of manufacturing software or inspection/test equipment.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
035	The PAH did not follow approved procedures for notifying the FAA of a new supplier in another country or receipt of a first article produced by that supplier.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
036	The audited facility did not follow approved procedures for preparing an interface quality document for consortium manufacturing activities.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (d) Manufacturing Process Control							
Code	Description of Noncompliance	PC	PMA	TSOA				
037	The PAH did not properly identify or define a special process within FAA-approved design data or in detailed process specifications.	§ 21.31	§ 21.303	§ 21.601				
038	The audited facility did not have written procedures for controlling manufacturing processes.	§ 21.137(d)	§ 21.307	§ 21.607				
039	The audited facility did not follow an approved manufacturing process, procedure, or instruction.	§ 21.146(b)	§ 21.316(b)	§ 21.616				
040	The audited facility did not generate or maintain a record to reflect compliance with an approved procedure, process, or instruction.	§ 21.146(b)	§ 21.316(b)	§ 21.616				
041	The audited facility did not follow approved procedures to use an environmental control in a manufacturing or assembly area.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
042	The audited facility did not identify or control an age-sensitive product, article, or material.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
043	The audited facility did not segregate a material or article awaiting acceptance.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
044	The audited facility did not identify a traceable component in assembly records.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
045	The audited facility did not provide or maintain traceability of a completed article to raw materials.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
046	The audited facility did not provide traceability or accountability for the completion of all manufacturing and inspection operations for a split lot.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
047	The audited facility did not provide controls for an article introduced into production before full acceptance.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
048	The audited facility did not follow approved procedures for segregating or identifying products or articles in a storage or manufacturing area.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
049	The audited facility did not control a product or article from an associate facility.	§ 21. 146(b)	§ 21.316(b)	§ 21.616(b)				
050	The audited facility did not follow approved procedures for using a properly qualified/approved special process operator.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				
051	The audited facility did not follow approved procedures in establishing a statistical sampling plan for acceptance of product characteristics at receiving inspection or during manufacture.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)				

Code	Description of Noncompliance	PC	PMA	TSOA
052	The audited facility did not follow approved procedures by excluding engineering and manufacturing organizations from the statistical quality control (SQC) program.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
053	The audited facility did not follow approved procedures in establishing a statistical process control (SPC) method for acceptance of specific product characteristics.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
054	The audited facility did not follow approved procedures in using or maintaining appropriate SPC control limits or subgroup selection.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
055	The audited facility did not follow approved procedures in establishing a satisfactory PRE-control method for the acceptance of specific product characteristics.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
056	The audited facility did not follow approved procedures for training personnel in statistical techniques.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
057	The audited facility did not follow approved procedures to retest a product or article that had been adjusted or reworked after test acceptance.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (e) Inspection and Testing						
Code	Description of Noncompliance	PC	PMA	TSOA			
058	An audited facility did not have a written procedure for inspection or test to ensure a product or article conforms to its approved design.	§ 21.137(e)	§ 21.307	§ 21.607			
059	An audited facility did not follow a procedure for inspection and test to ensure a product or article conforms to its approved design.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
060	The audited facility used an inspection method which did not ensure a product or article conforms to FAA-approved design data.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
061	The audited facility did not follow approved procedures to ensure proper control of inspection marking devices/stamps.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
062	The audited facility did not follow approved procedures to issue inspection marking devices/stamps to authorized persons only.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			
063	The audited facility does not have approved procedures to ensure records are generated and maintained for completed tests of aircraft, engines, or propellers.	§ 21.137(e)(2)	N/A	N/A			
064	Applicable procedures or process specifications were not readily available to or used by inspection personnel.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)			

Code	Description of Noncompliance	PC	PMA	TSOA
065	NDI processes, including changes, were not properly documented, controlled, or reviewed for conformance with FAA-approved design data.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
066	Critical NDI process parameters were not identified or controlled.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
067	Flight test procedures or changes were not submitted to and approved by the FAA.	§ 21.146(b)	N/A	N/A
068	The audited facility did not follow approved procedures in qualifying a test pilot or in using a flight test pilot without proper qualifications.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
069	The audited facility did not follow approved procedures in ensuring an NDI operator was performing within the limits of their authorization/certification.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
070	The audited facility uses NDI to make conformity determinations, but its procedures do not address NDI acceptance and rejection criteria.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
071	The audited facility did not follow approved procedures for identifying an NDI test piece or known defect sample.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
072	The audited facility did not follow approved procedures to check NDI tanks or solutions for compliance with specifications.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (f) Inspection, Measuring, and Test Equipment Control				
Code	Description of Noncompliance	PC	PMA	TSOA	
073	The audited facility did not have a procedure for inspection, measuring, and test equipment control to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of a product or article to its approved design.	§ 21.137(f)	§ 21.307	§ 21.607	
074	The audited facility did not follow a procedure for inspection, measuring, and test equipment control to ensure calibration and control of all inspection, measuring, and test equipment used in determining conformity of a product or article to its approved design.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
075	Equipment required for special processing is not available or calibrated as necessary.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
076	A tool, gauge, or equipment was not initially approved, periodically inspected, or calibrated.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
077	A calibration standard did not have adequate accuracy or was not traceable to a standard acceptable to the FAA.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Code	Description of Noncompliance	PC	PMA	TSOA
078	A tool, gauge, or equipment was not protected, maintained, or used in an acceptable environment to ensure product conformity.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
079	The audited facility did not properly control NDI equipment.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (g) Inspection and Test Status				
Code	Description of Noncompliance	PC	PMA	TSOA	
080	The audited facility did not have a procedure for documenting the inspection and test status of products and articles supplied or manufactured to the approved design.	§ 21.137(g)	§ 21.307	§ 21.607	
081	The audited facility did not follow a procedure for documenting the inspection or test status of a product or article manufactured to the approved design.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
082	The flight check-off form was not properly completed for an aircraft flight test.	§ 21.146(b)	N/A	N/A	

	Section (h) Nonconforming Product and Article Control				
Code	Description of Noncompliance	PC	PMA	TSOA	
083	The audited facility did not have a procedure for the identification, documentation, evaluation, segregation, and disposition by authorized individuals of nonconforming products and articles.	§ 21.137(h)	§ 21.307	§ 21.607	
084	The audited facility did not follow a procedure for the identification, documentation, evaluation, segregation, and disposition by authorized individuals of nonconforming products and articles.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
085	The audited facility did not have a procedure to ensure discarded articles are rendered unusable.	§ 21.137(h)	§ 21.316(b)	§ 21.616(b)	
086	The audited facility did not follow a procedure to ensure discarded articles are rendered unusable.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
087	An unauthorized person dispositioned a nonconforming product or article.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
088	A nonconforming product or article was not properly identified, documented, evaluated, segregated, or dispositioned.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
089	A nonconforming product or article was placed in storage.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Code	Description of Noncompliance	PC	PMA	TSOA
090	A disposition determination for a nonconforming product or article resulted in a major design change that was not approved by the FAA through its design approval process.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
091	Upper management did not follow approved procedures for reviewing and analyzing nonconforming material data to detect adverse trends.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
092	Engineering did not follow approved procedures for reviewing nonconforming material to determine if a nonconformance constituted a major or minor change to FAA-approved type design.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (i) Corrective and Preventative Actions				
Code	Description of Noncompliance	PC	PMA	TSOA	
093	The audited facility does not have written procedures for implementing corrective and preventative actions to eliminate the causes of an actual or potential nonconformity or noncompliance.	§ 21.137(i)	§ 21.307	§ 21.607	
094	The audited facility did not follow procedures for implementing corrective and preventative actions to eliminate the causes of an actual or potential nonconformity or noncompliance.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
095	The audited facility does not monitor corrective actions for response, implementation, and effectiveness.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
096	The audited facility did not take corrective action after finding an out-of-control NDI process.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
097	The audited facility did not evaluate the need for corrective action after accepting a product or article with a significantly out-of-tolerance gauge.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
098	The audited facility did not take corrective action to correct a manufacturing/special process which was found to be out of control.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Handling and Storage

	Section (j) Handling and Storage				
Code	Description of Noncompliance	PC	PMA	TSOA	
099	The audited facility did not have a procedure to prevent damage and deterioration of each product and article during handling, storage, preservation, and packaging.	§ 21.137(j)	§ 21.307	§ 21.607	
100	The audited facility did not follow a procedure to prevent the damage or deterioration of a product or article during handling, storage, preservation, or packaging.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
101	The audited facility did not control removal or issuance of a product or article from storage.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
102	The audited facility did not adequately identify or control a cleaner, solvent, degreaser, etc., to prevent potential product damage from misapplication.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

	Section (k) Control of Quality Records				
Code	Description of Noncompliance	PC	PMA	TSOA	
103	The audited facility did not have a written procedure for identifying, storing, protecting, and retrieving quality records.	§ 21.137(k)	§ 21.307	§ 21.607	
104	The audited facility did not have a written procedure for the retention of quality records for at least 5 years for products/articles manufactured under its approval and 10 years for critical components pursuant to § 45.15(c).	§ 21.137(k)	§ 21.307	§ 21.607	
105	The audited facility did not follow a procedure for identifying, storing, protecting, retaining, or retrieving quality records.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

	Section (l) Internal Audits				
Code	Description of Noncompliance	PC	PMA	TSOA	
106	The audited facility did not have written procedures for planning, conducting, and documenting internal audits to ensure compliance with the approved quality system.	§ 21.137(l)	§ 21.307	§ 21.607	
107	The audited facility did not follow approved procedures for planning, conducting, or documenting internal audits.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
108	The audited facility did not have written procedures to report results of an internal audit to the manager responsible for implementing corrective and preventative actions.	§ 21.137(1)	§ 21.307	§ 21.607	

Code	Description of Noncompliance	PC	PMA	TSOA
109	The audited facility did not follow a procedure to report results of an internal audit to the manager responsible for implementing corrective and preventative actions.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

	Section (m) In-Service Feedback				
Code	Description of Noncompliance	PC	PMA	TSOA	
110	The audited facility does not have an approved procedure for receiving and processing feedback on in-service failures, malfunctions, and defects.	§ 21.137(m)	§ 21.307	§ 21.607	
111	The audited facility did not follow approved procedures for receiving and processing feedback on in-service failures, malfunctions, and defects.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
112	The audited facility did not follow approved procedures for informing a user of its product/article with service information, including field purges.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Section (n) Quality Escapes					
Code	Description of Noncompliance	PC PMA		TSOA	
113	The audited facility does not have an approved procedure for identifying, analyzing, and initiating appropriate corrective action for quality escapes.	§ 21.137(n)	§ 21.307	§ 21.607	
114	The audited facility is not following approved procedures for identifying, analyzing, and initiating appropriate corrective action for quality escapes.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
115	Approved procedures do not provide a method to notify users and recall products, when necessary, when nonconformances are suspected or known to exist in products in service.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
116	A nonconforming product or article was released from the quality system.	§ 21.146(c)	§ 21.316(c)	§ 21.616(c)	
117	A required design change was not incorporated into a product or article before its release for installation/shipment.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Section (o) Issuing Authorized Release Documents				
Code	Description of Noncompliance	PC	PMA	TSOA
118	The PAH has issued authorized release documents that were not in accordance with approved written procedures.	§ 21.137(o)	§ 21.307	§ 21.607
119	The PAH is issuing authorized release documents outside of the scope of its approved procedures.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

Section (p) Other					
Code	Description of Noncompliance	PC PMA		TSOA	
120	The PAH did not report a failure, malfunction, or defect pursuant to § 21.3.	§ 21.3	§ 21.3	§ 21.3	
121	The PAH did not comply with the § 21.3(f) requirements related to investigation of and corrective action for products or articles deemed unsafe due to a manufacturing or design data defect.	§ 21.3(f)	§ 21.3(f)	§ 21.3(f)	
122	The applicant/PAH has not provided the FAA a document describing how its organization will ensure compliance pursuant to subpart G, K, or O as applicable.	§ 21.135	§ 21.305	§ 21.605	
123	The PAH did not amend the organization document required pursuant to § 21.135 to reflect changes in the organization or provide these amendments to the FAA.	§ 21.146(a)	§ 21.316(a)	§ 21.616(a)	
124	The applicant/PAH has not provided the FAA with a quality manual which describes its quality system.	§ 21.138	§ 21.308	§ 21.608	
125	The quality manual was not prepared in the English language or is not retrievable in a form acceptable to the FAA.	§ 21.138	§ 21.308	§ 21.608	
126	The quality manual has not been maintained to reflect changes in the quality system.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
127	The PAH did not obtain FAA approval before making a change to the location of one of its manufacturing facilities.	§ 21.139(b)	§ 21.309(b)	§ 21.609(b)	
128	The PAH did not immediately notify the FAA in writing of a change to the manufacturing facility that affects the inspection, conformity, or airworthiness of its product or article.	§ 21.139(c)	§ 21.309(c)	§ 21.609(c)	
129	The audited facility is not operating within the limitations of its production approval.	§ 21.146(b)	§21.316(c)	§ 21.616(c)	
130	A Software Configuration Management Plan did not meet approved requirements.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	
131	A Configuration Index Document did not meet approved requirements.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)	

Code	Description of Noncompliance	PC	PMA	TSOA
132	The audited facility did not follow approved procedures for software problem reporting and tracking.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
133	The audited facility did not follow approved procedures for recalling/purging obsolete software.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
134	The audited facility did not follow approved procedures for software security.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
135	A Software Development Environment did not meet approved requirements.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
136	The audited facility did not follow approved procedures for software identification.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
137	The audited facility did not follow approved procedures for programmed media handling/storage.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
138	The audited facility did not meet approved requirements for establishing build and load instructions.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
139				
140	The audited facility did not follow approved procedures for documenting and approving changes.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
141	The audited facility did not follow approved procedures for software problem reporting.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
142	The audited facility did not meet approved requirements for software security.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
143	The audited facility did not follow approved procedures for verifying software before use.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
144	The audited facility did not follow approved procedures for build and load instructions.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
145	A completed product or article did not have proper identification markings.	§ 21.146(d) § 45.11	§ 21.316(d) § 45.15	§ 21.616(d) § 45.15
146	An aircraft was not properly identified with nationality and registration marks before airworthiness certification.	§ 21.146(d) § 45.21	N/A	N/A
147	The PAH did not identify a portion of a product or article that left the manufacturer's facility as FAA-approved with the manufacturer's part number and name, trademark, symbol, or other FAA-approved manufacturer's identification.	\$ 21.146(e) \$ 21.137	§ 21.316(e)	§ 21.616(e)
148	The PAH did not have access to design data necessary to determine conformity for each product or article produced under its production approval.	§ 21.146(f)	§ 21.316(f)	§ 21.616(f)
149	The production approval/authorization is not available at the facility.	§ 21.146(g)	§ 21.316(g)	§ 21.616(g)

Code	Description of Noncompliance	PC	PMA	TSOA
150	The evaluated facility did not make information regarding all delegation of authority to suppliers available to the FAA.	§ 21.146(h)	§ 21.316(h)	§ 21.616(h)
151	The PAH did not follow approved procedures in notifying the FAA of suppliers with direct shipment authorization.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
152	The PAH did not notify the FAA of a change to its quality system that affected the inspection, conformity, or airworthiness of its product or article.	§ 21.150	§ 21.320	§ 21.620
153	A completed aircraft was not registered before airworthiness certification.	§ 47.3 § 21.173	N/A	N/A
154	The applicable airworthiness certificate or special flight permit was not obtained for an aircraft.	Part 21 Subparts H, I	N/A	N/A
155	A flight manual, supplement, or current weight and balance information was not furnished with an aircraft.	\$ 23.1581 \$ 25.1581 \$ 27.1581 \$ 29.1581 \$ 31.81	N/A	N/A
156	An unauthorized person issued an airworthiness approval (FAA Form 8130-4 or 8130-3).	§ 21.329 § 21.331	§ 21.331	§ 21.331
157	An export airworthiness approval was issued, but the necessary documents and instructions have not been forwarded to the aviation authority of the importing country as specified in AC 21-2.	§ 21.335(a)	§ 21.335(a)	§ 21.335(a)
158	A registration or airworthiness certificate was not cancelled for an aircraft whose title has passed to an importing country.	§ 21.335	N/A	N/A
159	The audited facility did not follow approved procedures for obtaining an export airworthiness approval for a product/article that left the PAH's quality system.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
160	The PAH does not have procedures that establish and identify a single point of contact or accountable manager for maintaining the organization's FAA-approved production operations.	§ 21.135	§ 21.305	§ 21.605
161	The PAH did not follow procedures that empower or authorize the point of contact to exercise their established authority pursuant to part 21.	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)
162	The PAH was manufacturing and installing an interface component that was not identified on the production limitation record (PLR).	§ 21.146(b)	§ 21.316(b)	§ 21.616(b)

^{*}Note: "N/A" in the associated CFR references column indicates "not applicable."

Appendix E. Preparation Instructions for FAA Quality System Audit Executive Summary

- **1. Purpose.** This appendix provides instructions for preparing the FAA QSA Executive Summary. This summary provides the status of each quality system element audited and a narrative of noncompliances. The completed summary will be the only record of noncompliances that the team leader provides at the post-audit conference to the audited facility.
- **2. Specific Guidance.** Figures E-1 and E-2 show sample executive summaries with numbered blocks. Prepare the summary as follows:
 - **a. Block 1.** Insert the QSA number/report number.
- **b. Block 2.** Insert the project number(s) assigned to the production approval activity being audited.
 - **c. Block 3.** Insert the name of the facility audited.
 - **d.** Block 4. Insert the date(s) of the audit.
- **e. Block 5.** Insert brief statements outlining the noncompliances for each of the applicable quality system elements. Format the summary as follows:
- (1) State the total number of noncompliances identified for the entire audit, even if there were none.
- (2) Discuss only those quality system elements that have noncompliances recorded. Do not list quality system elements that have no noncompliances recorded.
 - (a) State the number of noncompliances identified for each system element discussed.
 - (b) Summarize the noncompliances for each quality system element discussed.
- **f. Block 6.** For paper versions of this form, have the team leader sign in this block. This block may be signed by a team leader-in-training but must also be countersigned by the team leader. When an electronic version of the executive summary is used, ensure all required names are listed.
 - **g.** Block 7. Insert the date of the post-audit conference.

Figure E-1. Sample Executive Summary for Facilities with Noncompliances

FEDERAL AVIATION ADMINISTRATION QUALITY SYSTEM AUDIT (QSA) EXECUTIVE SUMMARY

(1)

QSA NO./REPORT NO.: 98NE278/1-1 **PROJECT NO.:** PE9999NE

(3) **FACILITY:** Cape Cod Aircraft Engine Co. (4) **DATE OF AUDIT:** August 6–15, 2011

(5) SYSTEM ELEMENT NONCOMPLIANCES

During this audit, the team documented 10 noncompliances.

<u>Design Control System Element</u>: Four noncompliances were recorded for this system element. One noncompliance was recorded for a breakdown in the approved procedure for determining major or minor design changes. A second noncompliance was recorded for a breakdown in the approved procedure for processing minor design changes. Two additional noncompliances were recorded for a breakdown in the approved procedures for submitting major design changes and process specification changes to the FAA.

Software Quality Assurance System Element: One noncompliance was recorded for this system element. It was recorded for an isolated incident of observe software media not being properly controlled.

Manufacturing Processes System Element: Four noncompliances were recorded for this system element. A noncompliance was recorded for a breakdown in the job order manufacturing sequence for the main housing, part Non 23–666 and 123–667. Another noncompliance was recorded for an isolated incident of changes to work instructions not being properly controlled. One noncompliance was recorded for an isolated incident of a change to a special process not being properly controlled. One noncompliance was recorded for a breakdown in the approved procedures for handling parts sensitive to electrostatic discharge.

Supplier Control System Element: One noncompliance was recorded for this system element. It was recorded for a breakdown in the approved procedure to make information available to the FAA regarding all delegation of authority to suppliers to make major inspection of any products/parts thereof.

(6) (7) J.J. Gem August 15, 2011

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Figure E-2. Sample Executive Summary for Facilities With No Noncompliances

FEDERAL AVIATION ADMINISTRATION QUALITY SYSTEM AUDIT (QSA) EXECUTIVE SUMMARY

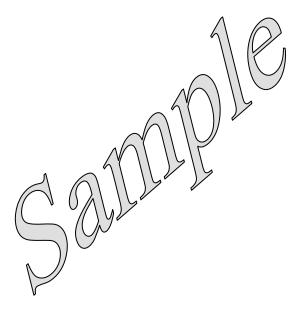
(1) (2) SW334/1-1 **PROJECT NO.:** PP0000SW

QSA NO./REPORT NO.: 01SW334/1-1

(3) FACILITY: Excellent Metal Components Inc.(4) DATE OF AUDIT: April 1, 2011

(5) SYSTEM ELEMENT NONCOMPLIANCES

During this audit, the team documented no noncompliances.



(**6**) J.M. Tired (**7**) April 1, 2011

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Appendix F. Preparation Instructions for Quality System Audit Special Emphasis Items

- **1. Purpose.** This appendix provides instructions for preparing QSA special emphasis items. These items are intended to bring to the attention of the assigned engineering and managing manufacturing offices and the flight standards district office (FSDO) principal maintenance inspector (as appropriate) specific problems or concerns the QSA team believes require further action.
- **2. Specific Guidance.** Figure F-1 shows a sample special emphasis items form with numbered blocks. Prepare the special emphasis items by inserting in the following:
 - **a. Block 1.** The QSA number/report number.
- **b. Block 2.** The project number(s) assigned to the production approval activity being audited.
- **c. Block 3.** A brief statement summarizing the problem or concern, identifying the relevant quality system element and referencing the relevant noncompliances. Provide a recommendation for further action required, as appropriate.

Figure F-1. Sample Quality System Audit Special Emphasis Items for PAHs

QUALITY SYSTEM AUDIT SPECIAL EMPHASIS ITEMS

(1) (2) **QSA NO. /REPORT NO.:** 98SW314/1-2 **PROJECT NO.:** PT9999SW

(3)

NOTE TO MIO MANAGER AND COGNIZANT PRINCIPAL INSPECTOR

At the request of the principal inspector, the team put special emphasis on the supplier control system element. Although only two noncompliances were recorded, a large number of isolated incidents were recorded among the other system element criteria. See the attached FAA Forms 8100-6, isolated noncompliances Nos. 6 to 19. The team cannot say with confidence that a systemic problem exists with supplier control; however, when all of the discrepancies are taken as a whole, we believe there is a strong probability that a systemic problem may exist. We recommend that a special audit be conducted on the supplier control system element to fully determine whether a systemic problem exists.

NOTE TO ASSIGNED ENGINEERING OFFICE MANAGER AND AE

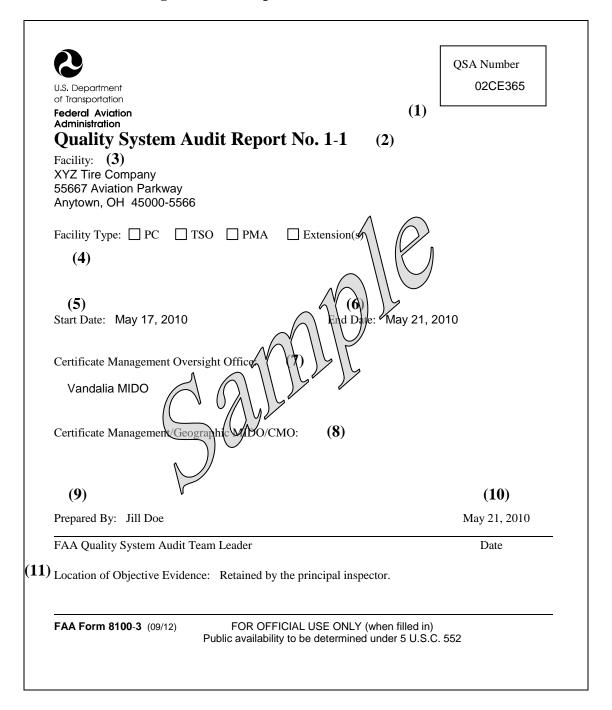
A noncompliance was recorded in the design data control system element for a suspected problem with the FAA-approved data. See the attached FAA Form 8100-6, noncompliance with FAA-approved drawings that call out incorrect or nonexistent process specifications. We recommend that this problem be investigated further.

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Appendix G. Preparation Instructions for FAA Form 8100-3, Quality System Audit Report, Cover Pages

- **1. Purpose.** This appendix provides instructions for preparing FAA Form 8100-3.
- **2. Preparing the Front of the Form.** Figure G-1 shows the front of FAA Form 8100-3 with numbered blocks. Prepare the form by inserting the following:
 - **a.** Block 1. The QSA number.
- **b. Block 2.** The report number. This number will consist of the report order sequence and the total number of separate original reports issued under the QSA number in block 1. For example, QSA Report No. 1-2 would indicate that this is the first report in a series of two separate original reports issued for a specific audit. This example could indicate in one instance that an audit was conducted at a PAH that has multiple quality systems being audited at the same time, thereby requiring issuance of two separate original reports. When only one report is required, identify it as No. 1-1.
- **c. Block 3.** The name, address, city, state (or country), and ZIP/postal code of the facility audited.
- **d.** Block 4. A checkmark in the applicable box(es) to indicate the type(s) of design or production approval the facility has; ensure the box labeled (Extension(s)) is also checked if applicable.
 - **e. Block 5.** The date of the pre-audit conference.
 - **f. Block 6.** The date of the post-audit conference.
 - **g. Block 7.** The name of the office responsible for CM oversight of the audited facility.
- **h. Block 8.** The name of the manufacturing managing office responsible for surveillance of the audited facility. No entry is required if the manufacturing managing office performs the surveillance.
- **i. Block 9.** The team leader's or principal auditor's signature. This block may be signed by a team leader-in-training but also must be countersigned by the team leader. When an electronic version of the form is used, ensure all required names are typed in.
 - **j.** Block 10. The date of signature.
- **k. Block 11.** The location of the objective evidence. Indicate if the objective evidence is attached to the report or if the objective evidence has been retained by the PI or AE.

Figure G-1. Sample FAA Form 8100-3 (Front)



3. Preparing the Back of the Form. Figure G-2 shows the back of FAA Form 8100-3 with numbered blocks. Prepare the form by inserting the following:

- **a. Block 12.** The name of each team member, including any national resource specialist, manager used, and any auditors/team leaders-in-training who participated. List the team members first. Do not enter the team leader's name.
 - **b. Block 13.** The office to which each individual listed in block 12 is officially assigned.
- **c. Block 14.** The discipline of each individual listed in block 12. Identify whether the individual is an ASI, engineer, or flight test pilot.
- **d. Block 15.** The specialty of each individual listed in block 12, as applicable. Identify engineers by systems and equipment, propulsion, airframe, or flight test specialty.
- **e. Block 16.** An "A" to identify auditors-in-training or a "T" to identify team leaders-in-training. Leave this block blank for team members.

Figure G-2. Sample FAA Form 8100-3 (Back)

Name	Office	Discipline	Specialty	Training Status (A or T)*
(12)	(13)	(14)	(15)	(16)
John Smith	Atlanta MIDO	ASI		
Fred Exe	ACE-118W	Eng	Airtraine	
Mary Lamb	ACE-117A	Eng	Airframe	A
		4/		
		<u></u>		
	1///			
				*A = Auditor-in-training T = Team
	Leader-ii	n-training		r = ream

Appendix H. Preparation Instructions for FAA Form 8120-14, Production Approval/Certificate Management Activity Report

- **1. Purpose.** This appendix provides instructions for completing FAA Form 8120-14. This form is used to document all activity, except QSAs, at PAHs and their suppliers. When combined with the respective FAA Form(s) 8100-6 and, if applicable, FAA Form 8100-1, a complete report of the activity conducted is available for subsequent planning.
- **2. Specific Guidance.** Figures H-1 and H-2 show FAA Form 8120-14 with numbered blocks. Prepare the form by inserting in:
 - **a. Block 1.** The PAH name as recorded on the production approval.
 - **b.** Block 2. The project number(s) applicable to the production approval.
 - **c. Block 3.** The name and address of the point of manufacturing facility as recorded on the production approval, or for a supplier, as listed in the FAA's facility database.
- **d. Block 4.** A check mark in the appropriate box(es) to indicate the type of production approval.
 - **e. Block 5.** The starting date and the ending date of the activity that was conducted.
 - **f. Block 6.** A check mark in the appropriate box(es) to indicate the type of activity that was conducted.
 - **g. Block 7.** The title, revision number, and date of the current quality manual that the PAH has submitted to the FAA and that the FAA has approved.
- **h. Block 8.** The date that the applicable quality manual submitted by a PAH was approved by the FAA.
- **i. Block 9.** An "X" in the column next to the system element audited when the result of the activity is satisfactory.
- **j. Block 10.** The respective FAA Form 8100-6 noncompliance numbers for the system element audited, when the result of the activity is unsatisfactory.
 - **k.** Block 11. The nomenclature and part number(s) of the product, article, or part(s) audited.
- **l. Block 12.** An "X" in the column next to the product, article, or part(s) audited when the result of the activity is satisfactory.
- **m. Block 13.** The respective FAA Form 8100-6 noncompliance numbers for the product, article, or part(s) audited, when the result of the activity is unsatisfactory.
- **n. Block 14.** The specific purchase order or quality flow down requirement audited, such as, but not limited to, the following: purchase order number, quality management system

purchase number, quality assurance procedure, engineering drawing number, general notes, or work instruction number.

- **o. Block 15.** An "X" in the column next to the specific purchase order or quality flow down requirement audited when the result of the activity is satisfactory.
- **p. Block 16.** The respective FAA Form 8100-6 noncompliance numbers for the specific purchase order or quality requirements audited, when the result of the activity is unsatisfactory.
- **q. Block 17.** Enter the names, titles, and office symbols of all FAA personnel who participated in the activity.
- **r. Block 18.** The typed or printed name and signature of the person conducting the audit. In most cases, this will be the PI responsible for the PAH.
 - **Note 1:** ACAIS does not allow the user to provide a traditional signature to FAA Form 8120-14. However, when the user is logged in using a specific login and password, the user can populate block 18 with their name to demonstrate completion of FAA Form 8120-14.
 - **Note 2:** When FAA Form 8120-14 is used to document a PI audit or manufacturing managing office audit with multiple team members, the signature in block 18 must be that of the team leader. This form, with the above signature, can then be used to support the continued appointment as a QSA team leader in accordance with paragraph 3-22 of this order.
 - **s.** Block 19. The office symbol of the person completing this form.
 - **t.** Block 20. The date this form is completed.

Figure H-1. Sample FAA Form 8120-14 (Front)

Production Approval /Certificate Management

U.S. Department of Transportation Federal Aviation Administration	Activity Report				
Applicant/PAH:	Project No.(s):				
Name:	(1)			(2	2)
Point of Manufacture:					
	(3)				
Facility:	1.7		City:		
DBA:	State/Province:				
Address 1:	Country:				
Address 2:	Postal Code:				
Address 3:			gion:		
Production Basis: □PC	□PMA □TSOA(4) Activity	Dates:	From: mm/do	1/yyyy	To: mm/dd/yyyy(5)
Activity: □MIDO Audit	☐PI Audit ☐Supplier Contr	rol Audit	Other	(6)	
Quality Manual:	(7)				
Title:	(7)				
Revision:					
Date:					
Date of FAA Approval of Quality Manual: mm/dd/yyyy (8)					
	TEM ELEMENT		FACTORY	UNS	ATISFACTORY
Ī		"🖍" į	fapplicable	List	FAA Form 8100-6
				Non	compliance No.(s)
(a) Design data control		(9)		(10)	
(b) Document control					
(c) Supplier control					
(d) Manufacturing proces	s control				
(e) Inspecting and testing					
(f) Inspection, measuring	, and test equipment control				
(g) Inspection and test sta	tus				
(h) Nonconforming produ	ct and article control				
(i) Corrective and preven	tive actions				
(j) Handling and storage					
(k) Control of quality reco	ords				
(1) Internal audits					
(m) In-service feedback					
(n) Quality escapes					
(a) I aming anthonicad val	1		–		

FAA Form 8120-14 (10/16) SUPERSEDES PREVIOUS EDITION FOR OFFICIAL USE ONLY (when filled in)

(p) Other

Figure H-2. Sample FAA Form 8120-14 (Back)

	AUDIT RESULTS					
PRODUCT AUDITED	SATISFACTORY	JNSATISFACTORY				
(Nomenclature/Part Number)	"√" if applicable	List FAA Form 8100-6				
, , , , , , , , , , , , , , , , , , ,		Noncompliance No.(s)				
(11)	(12)	(13)				
(11)		(10)				
SUPPLIER CONTROL AUDIT RESULTS						
PURCHASE ORDER/QUALITY		UNSATISFACTORY				
FLOWDOWN DECUMENTS		List FAA Form 8100-6				
FLOWDOWN REQUIREMENTS	5 11					
		Noncompliance No.(s)				
(14)	(15)	(16)				
	i i					
DADTICIDA	TING AUDITORS					
NAME PARTICIPA	TITLE	OFFICE				
	IIILE	OFFICE				
1 (17)						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
Typed/Printed Name and Signature of PI:	18)	Office Date (20)				
17	0/					

FAA Form 8120-14 (10/16) SUPERSEDES PREVIOUS EDITION

Appendix I. Forms Listing

This appendix lists the forms referenced in this order and their sources. The forms listed in table I-1 are available from the FAA Logistics Center, AML-1000, through normal supply channels. The forms listed in table I-2 are available in an electronic format within ACAIS.

Table I-1. Forms Available From FAA Logistics Center

Form Number	<u>Title</u>	<u>NSN</u>	Unit of Issue
FAA Form 8100-1	Conformity Inspection Record	0052-00-039-3001	Package
FAA Form 8130-3	Airworthiness Approval Tag	0052-00-012-9005	Pad

Table I-2. Forms Available Within ACAIS

Form Number	<u>Title</u>
FAA Form 8100-1	Conformity Inspection Record
FAA Form 8100-3	Quality System Audit Report
FAA Form 8100-6	Noncompliance Record
FAA Form 8100-7	Quality System Audit Feedback Report
FAA Form 8120-14	Production Approval/Certificate Management Activity Report

Appendix J. Acronyms

14 CFR Title 14 of the Code of Federal Regulations

AC Advisory Circular

ACAIS Aircraft Certification Audit Information System

AD Airworthiness Directive AE Assigned Engineer

AIR Aircraft Certification Service

AIR-100 Design, Manufacturing, and Airworthiness Division

AIR-400 International Policy Office

AIR-500 Planning and Program Management Division

ASI Aviation Safety Inspector
CAA Civil Aviation Authority
CM Certificate Management

CMO Certificate Management Office

CPL Category Parts List

DAR Designated Airworthiness Representative
DER Designated Engineering Representative

DMIR Designated Manufacturing Inspection Representative

FAA Federal Aviation Administration

FAI First Article Inspection

FSDO Flight Standards District Office

MIDO Manufacturing Inspection District Office

MIO Manufacturing Inspection Office MOU Memorandum of Understanding

MRB Material Review Board

MSAD Monitor Safety Analyze Data NAS National Airspace System NDI Nondestructive Inspection

NTE Not to Exceed

ODA Organization Designation Authorization

PAH Production Approval Holder

PC Production Certificate
PI Principal Inspector

PLR Production Limitation Record PMA Parts Manufacturer Approval

QSA Quality System Audit

RBRT Risk-Based Resource Targeting

SAI Special Audit Item

SAIB Special Airworthiness Information Bulletin

SDR Service Difficulty Report SPC Statistical Process Control SQC Statistical Quality Control

Supplemental Type Certificate Suspected Unapproved Part Type Certificate Technical Standard Order STC SUP

TC

TSO

Appendix K. Definitions

- **1. Additional CM Responsibilities.** The performance of special CM tasks that may be accomplished on an as-required basis.
- 2. Aircraft Certification Audit Information System (ACAIS). Electronic data system that incorporates several aspects of CM functions. Functions available within ACAIS are certification management tasks along with the planning, scheduling, and conducting of audits.
- **3. Approved.** Unless used with reference to another person, means approved by the FAA or any person to whom the FAA has delegated its authority in the matter concerned, or approved under the provisions of a bilateral agreement between the United States and a foreign country or jurisdiction.
- **4. Article.** A material, part, component, process, or appliance.
- **5. Assigned Engineer (AE).** An FAA engineer to whom the assigned engineering office manager has assigned responsibility for a QSA at a particular design approval facility.
- **6. Associate Facility.** A facility that has been approved as an extension to an original PAH. The facility is owned and operated by the same corporate management as the original PAH that controls the design and quality of the product, article, or part(s), except for companies participating in joint production and/or coproduction business agreements. The associate facility must be listed as a manufacturing facility on the PC or the letter of authorization for other production approvals, for example, a PMA or TSO authorization.
- 7. **Audit.** A systematic and objective verification of compliance to a regulation, quality procedure, or approved design; also includes a subjective assessment of a procedure, process, system, or design to determine if it will produce the required results.
- **8. Auditor.** An individual the FAA appoints to perform audits.
- **9. Certificate.** A document (that is, a certificate or approval) issued by the FAA that recognizes an applicant's or PAH's established quality system and allows for the production of products, articles, or parts in accordance with an FAA-approved design.
- **10.** Certificate Management (CM). The methods by which the FAA ensures a PAH remains in compliance with those pertinent regulations that govern the manufacturing of its particular products, articles, or parts.
- 11. Commercial Part. An article that is listed on an FAA-approved Commercial Parts List included in a design approval holder's Instructions for Continued Airworthiness required by CFR 21.50. In accordance with CFR 21.50(c), a design approval holder may designate an article as a commercial part if the FAA finds the part:
 - a. Is not specifically designed or produced for applications on aircraft; and

b. Is produced only under the commercial part manufacturer's specification and marked only with the commercial part manufacturer's markings.

- **12. Corrective Action.** The measures taken to resolve unsatisfactory conditions and to prevent reoccurrence.
- 13. Days. A reference to calendar days, unless otherwise specified.
- **14. Distributor.** Any person engaged in the sale or transfer of products, articles, and parts for installation in type-certificated aircraft, aircraft engines, or propellers, and that conducts no manufacturing activities.
- **15. Effectiveness.** Process where the organization's corrective action produces the desired result.
- **16. FAA-Approved Data.** Data specifically approved by the FAA or FAA-delegated representatives, including any document referenced therein. These data may include design drawings, manuals, procedures, and specifications.
- **17. Facility.** A physical location where a PAH or its associate facility performs all or part of the quality system element functions relevant to the approval authority granted by the FAA.
- **18. Foreign Manufacturer.** A person other than an FAA PAH who causes a product, article, or part(s) to be produced outside the United States.
- **19. Internal Procedure.** A PAH's procedures that are not included as part of the FAA-approved data.
- 20. Lead Audit Office. A division/directorate office or branch assigned to coordinate a QSA.
- **21. Licensing Agreement.** A commercial agreement between a TC or an STC holder and a PAH (or applicant) formalizing the rights and duties of both partners to use the design data for the purpose of manufacturing the product, article, or part.
- **22. Major Inspection.** Inspections/tests identified by the design and production approval holder that are required to determine whether critical/key characteristics conform to the design and quality requirements and are in a condition for safe operation.
- **23. Manufacturing Managing Office.** The FAA office having responsibility for conducting CM activities of a PAH and its manufacturing facilities.
- **24. Manufacturer.** A person as defined by 14 CFR part 1, Definitions and Abbreviations, who causes a product, article, or part(s) to be produced. A manufacturer may be a PAH or a supplier to a PAH.
- **25. Noncompliance.** A PAH's operating practice that is found to be inconsistent with 14 CFR, FAA-approved data, or internal procedures. A supplier's operating practice found to be

inconsistent with a PAH's purchase order requirements is considered to be a noncompliance by the PAH.

- **26. Objective Evidence.** All the means by which any alleged fact tends to be established or disproved. These means must be factual, convincing, relevant, valid, reliable, and complete. Examples of objective evidence include interview statements, photographs, charts, maps, diagrams, documents, and records. Documents and records include items such as work travelers, inspection documents, FAA-approved drawings, PMA and TSO approval letters, airworthiness approval tags (FAA Form 8130-3, Airworthiness Approval Tag), and calibration logs.
- **27. Ongoing CM Responsibilities.** The performance of CM requirements, based on a risk assessment, that may be accomplished on a continuing basis.
- **28. Oversight.** A function performed by the FAA (or other regulator i.e., in an international country) that ensures that an aviation organization or designee complies with and uses safety-related standards, requirements, regulations, and associated procedures.
- **29. Point of Manufacturing Methodology.** The concept of conducting a focused, product-based, data-driven audit of a critical article or process at any location where manufacturing is being performed (e.g., PAH, associate facility, supplier, subtier supplier).
- **30. Principal Auditor.** An FAA-appointed team leader who acts as the sole auditor for the performance of a QSA at a specific facility.
- **31. Principal Inspector (PI).** A manufacturing inspector who has been assigned CM responsibility of a particular PAH.
- **32. Procedure.** A specific way to perform an activity or function that is documented and usually contains the purposes and scope of the activity or function: what is to be done and by whom; when, where, and how the activity or function is to be done; the materials, equipment, and documents to be used; and how the activity or function is to be controlled and recorded.
- **33. Produce.** To manufacture, or cause to be manufactured, a product, article, or part(s).
- **34. Product.** An aircraft, aircraft engine, or propeller.
- **35. Product Based System Audit.** An audit of a PAH's quality systems by examining compliance to regulations and approved procedures using particular products when practical. It is a planned and recorded activity that relies on using selected products and articles, (to the maximum extent practical), for determining whether the product or article conforms to approved data, as well as whether the PAH complies with the quality system requirements, including procedures and special processes established to meet those requirements.
- **36. Production Approval.** A document issued by the FAA to a person that allows the production of a product, article, or part in accordance with its approved design and approved quality system, and can take the form of a PC, a PMA, or a TSO authorization.

37. Production Approval Holder (PAH). The holder of a PC, PMA, or TSO authorization, who controls the design and quality of a product, article, or part(s). A person who has been issued a production approval by the FAA.

- **38. Quality Escape.** A product or article that has been released from a quality system and does not conform to the applicable design data and/or quality system requirements.
- **39. Quality System.** A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles.
- **40. Quality System Data.** Data that provide a description of the quality system required by 14 CFR part 21 for a PAH. These data would encompass the methods, procedures, processes, inspections, tests, specifications, charts, lists, forms, etc., which the PAH employs to produce products, articles, or parts.
- **41. Quality System Element.** A specific activity or function that may affect the maintenance of FAA-approved design or quality data, such as design data control, manufacturing controls, and supplier control. Such activities are subject to audit of the adequacy and implementation of approved procedures.
- **42. Requesting Manufacturing Managing Office.** An office that requests associate facility CM from another office having geographic responsibility of the area in which the facility is located.
- **43. Risk-Based Resource Targeting (RBRT).** A structured process designed to support AIR management in determining risk, assigning resources based on that risk, and prioritizing multiple projects.
- **44. Root Cause.** The underlying cause of a systemic or recurring noncompliance, usually identified through structured analysis.
- **45. Special Audit Item (SAI).** An item, process, or area that senior management has determined requires specific focus during audits.
- **46. Standard Part.** A part manufactured in complete compliance with an established government or industry-accepted specification that contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

Note: Examples of specifications include, but are not limited to, National Aerospace Standards (NAS), Air Force-Navy Aeronautical Standard (AN), Society of Automotive Engineers (SAE), SAE Aerospace Standard (AS), and Military Standard (MS).

47. Supplier. Any person, as defined by 14 CFR 1.1, at any tier in the supply chain, who provides a product, article, or service that is used or consumed in the design or manufacture of, or installed on, a product or article.

- **48. System.** An activity or function that may affect the maintenance of an FAA-approved design, quality data, or the design approval system.
- **49. Warranty Return.** When a customer returns or notifies the PAH that they received a product or article that does not meet its intended function.

Appendix L. Administrative Information

- **1. Delegation of Authority.** AIR-100 is responsible for issuing, revising, or canceling the material in this order.
- **2. Deviations.** Adherence to the procedures in this order is necessary for uniform administration of this directive material. Any deviations from this guidance material must be coordinated and approved by AIR-100. If a deviation becomes necessary, the FAA employee involved should ensure the deviations are substantiated, documented, and concurred with by the appropriate supervisor. The deviation must be submitted to AIR-100 for review and approval. The limits of federal protection for FAA employees are defined by 28 U.S.C. § 2679.
- 3. **Distribution.** This order is distributed to Washington Headquarters division levels of the Flight Standards Service, to the branch levels of AIR, to the branch levels in the regional Flight Standards divisions and Aircraft Certification divisions/directorates, to all FSDOs, to all assigned engineering offices, to all AIR field offices, to all manufacturing managing offices, to the Aircraft Certification and Airworthiness Branches at the Federal Aviation Administration Academy, and to the Flight Standards Service Regulatory Support Division.
- **4. Electronic Signature.** The use of an electronic signature for the issuance of a PC and a PLR, or a production approval letter (that is, PMA, or TSO authorization) is not permitted.
- **5. Forms.** This order identifies several forms used for the audit, approval, and CM of production activities. Some of the forms are provided by AIR-100 in electronic format. Appendix I, Forms Listing, to this order provides a listing of the forms and their sources.
- **6. Records Management.** Refer to FAA Order 0000.1, *FAA Standard Subject Classification System*; FAA Order 1350.14, *Records Management*; or your office Records Management Officer (RMO)/Directives Management Officer (DMO) for guidance regarding retention or disposition of records.
- 7. **Related Publications.** Orders referenced in this directive list only the basic order number. It is the responsibility of the user to establish that the latest revision/amendments are being used.
- **8. Requests for Information.** All public requests for information regarding production approval or CM activities will be processed in accordance with the Freedom of Information Act (refer to FAA Order 1270.1).
- **9. Suggestions for Improvement.** Please forward all comments on deficiencies, clarifications, or improvements regarding the contents of this order to:
 - a. 9-AWA-AVS-AIR-DMO@faa.gov, or
 - b. Complete the form online at https://ksn2.faa.gov/avs/dfs/Pages/Home.aspx.

FAA Form 1320-19, Directive Feedback Information, is located as appendix M to this order for your convenience. If you require an immediate interpretation, please contact AIR-100 at (202) 267-1575; however, you should also complete FAA Form 1320-19 as a follow up to the conversation.

Appendix M. FAA Form 1320-19, Directive Feedback Information



FAA Form 1320-19 (10-98)

Directive Feedback Information

Please submit any written comments or recommendations for improving this directive, or suggest new items or subjects to be added to it. Also, if you find an error, please tell us about it.

Subject: FAA Order 8120.23A To: 9-AWA-AVS-AIR-DMO@faa.gov or complete the form online at https://ksn2.faa.gov/avs/dfs/Pages/Home.aspx (Please check all appropriate line items) ☐ An error (procedural or typographical) has been noted in paragraph _____ on ☐ Recommend paragraph ______ on page ______ be changed as (attach separate sheet if necessary) ☐ In a future change to this directive, please include coverage on the following subject (briefly describe what you want added): ☐ Other comments: ☐ I would like to discuss the above. Please contact me. Submitted by: ______ Date: _____ FTS Telephone Number: ______ Routing Symbol: _____