U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

National Policy

ORDER 8120.21

Effective Date:
09/14/2012

SUBJ: Certificate Management of Production Approval Holders

This order provides guidance and assigns responsibility for the implementation of the Aircraft Certification Service certificate management (CM) of production activities of manufacturers and their suppliers producing products, articles, or parts 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 special CM activities, continuous improvement, and the Certificate Management Information System's role in QSAs.

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Chapter 1. General

1-1. Purpose of This Order.

a. This order defines the components of the Federal Aviation Administration's (FAA) certificate management (CM) program for production approval holders (PAH). Section 44713 of Title 49 of the United States Code (49 U.S.C.) requires the FAA to inspect aircraft during manufacture. CM is the FAA's method for meeting this requirement, and auditing is the key component of CM. The purpose of an audit is to verify that a PAH has established and continues to follow approved procedures in the production of products, articles, and parts that conform to their approved type design and are in an airworthy condition for safe operation.

b. Title 14 of the Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products, Articles, and Parts, includes requirements for PAHs and FAA production approval applicants. Specifically, part 21 requires a PAH to obtain FAA approval of a written description of its quality system that ensures each product, article, and part conforms to its approved design and is in a condition for safe operation. This written description must include procedures for each of 14 quality system elements in 14 CFR § 21.137. Sections 21.146, 21.316, and 21.616 also require a PAH to maintain this quality system in compliance with these approved procedures and ensure each completed product, article, or part conforms to its approved design and is in a condition for safe operation.

c. As some audit processes in the Certificate Management Information System (CMIS) are automated, there may be differences in CMIS processes and the stated manual processes defined in this order. Where this is the case, the automated process in CMIS takes precedence over the manual process stated in this order.

> **Note:** The use of the word "should" throughout this order refers to a recommended practice. The associated activity is not a requirement; therefore, a record of completion is not required.

1-2. Audience. All FAA employees who participate in CM activities conducted at a PAH and its associate facilities and suppliers.

1-3. Where Can I Find This Order. You can find this order at on the Directives Management System website at http://www.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 8100.7E, Aircraft Certification Systems Evaluation Program, dated April 16, 2010, and all associated changes are canceled.

1-5. Effective Date. This order is effective September 14, 2012.

Chapter 2. Certificate Management Procedures

2-1. Chapter Information and Format. Chapter 3 of this order describes ongoing CM responsibilities and chapter 4 describes special CM responsibilities. Chapter 5 defines the role of CMIS regarding Quality System Audit (QSA) data. Appendixes A through S provide specific CM-related references and other administrative and feedback guidance.

2-2. Overview. CM responsibilities for a PAH or an associate facility will be accomplished by the Manufacturing Inspection District Office (MIDO)/Certificate Management Office (CMO) having responsibility of the geographical area in which the PAH or associate facility is located. The FAA remains responsible for CM when a product, article, or its supplied parts are produced in a location other than the United States. CM includes the following two functional responsibilities, each of which is further detailed in chapters 3 and 4 of this order. Figure 2-1 of this chapter depicts the CM life cycle process.

a. Ongoing CM Responsibilities. The MIDO/CMO responsible for a specific PAH or associate facility within its geographical boundaries accomplishes the following tasks on a continuing basis. Any tasks required to be scheduled and conducted at a supplier facility located in another U.S. geographical area should be handled in accordance with paragraph 3-64 of this order. For tasks required to be scheduled and conducted outside the United States, refer also to paragraph 3-3 of this order.

(1) Schedule and conduct Risk-Based Resource Targeting (RBRT) assessments of PAHs and associate facilities to identify any increased potential for producing nonconforming products, articles, or parts.

(2) Schedule and conduct principal inspector (PI) audits and QSAs at PAHs and associate facilities based on RBRT assessments.

(3) Schedule and conduct supplier control audits to determine that PAHs and associate facilities are satisfactorily controlling their suppliers.

(4) Schedule and conduct a product audit for QSA, PI, and supplier control audits in accordance with figure 3-1 of this order.

b. Special CM Responsibilities. The following tasks are accomplished on an as-required basis by the MIDO/CMO responsible for a specific PAH or associate facility 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 3-64 of this order.

(1) Audit changes to a PAH's or associate facility's quality system that may affect the inspection, conformity, or airworthiness of the product, article, or part(s).

(2) Investigate service difficulties that involve quality system problems.

(3) Investigate regulatory violations.

(4) Ensure appropriate corrective actions have been proposed and taken for all noncompliances identified at a PAH or associate facility.

(5) Determine the need for unscheduled PI audits, QSAs, supplier control audits, product audits, and other investigation activity (for example, suspected unapproved part (SUP) investigation) necessary to ensure continued compliance with applicable regulations.

(6) Provide guidance and assistance to the PAH and associate facility as necessary.

2-3. Assignment of CM Coordinator. Many of the tasks identified in this chapter for Manufacturing Inspection Office (MIO), MIDO, or CMO managers are primarily administrative. A high degree of operational efficiency may be achieved by assigning many of these tasks to a designated CM coordinator. Directorate 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 (refer to chapter 3 of this order).

c. Maintain supplier control audit list (refer to chapter 3 of this order).

d. Dissemination of general CM-related information.

2-4. Status of a PAH. For purposes of CM, the status of a PAH and its applicable project(s) can be identified as one of the following:

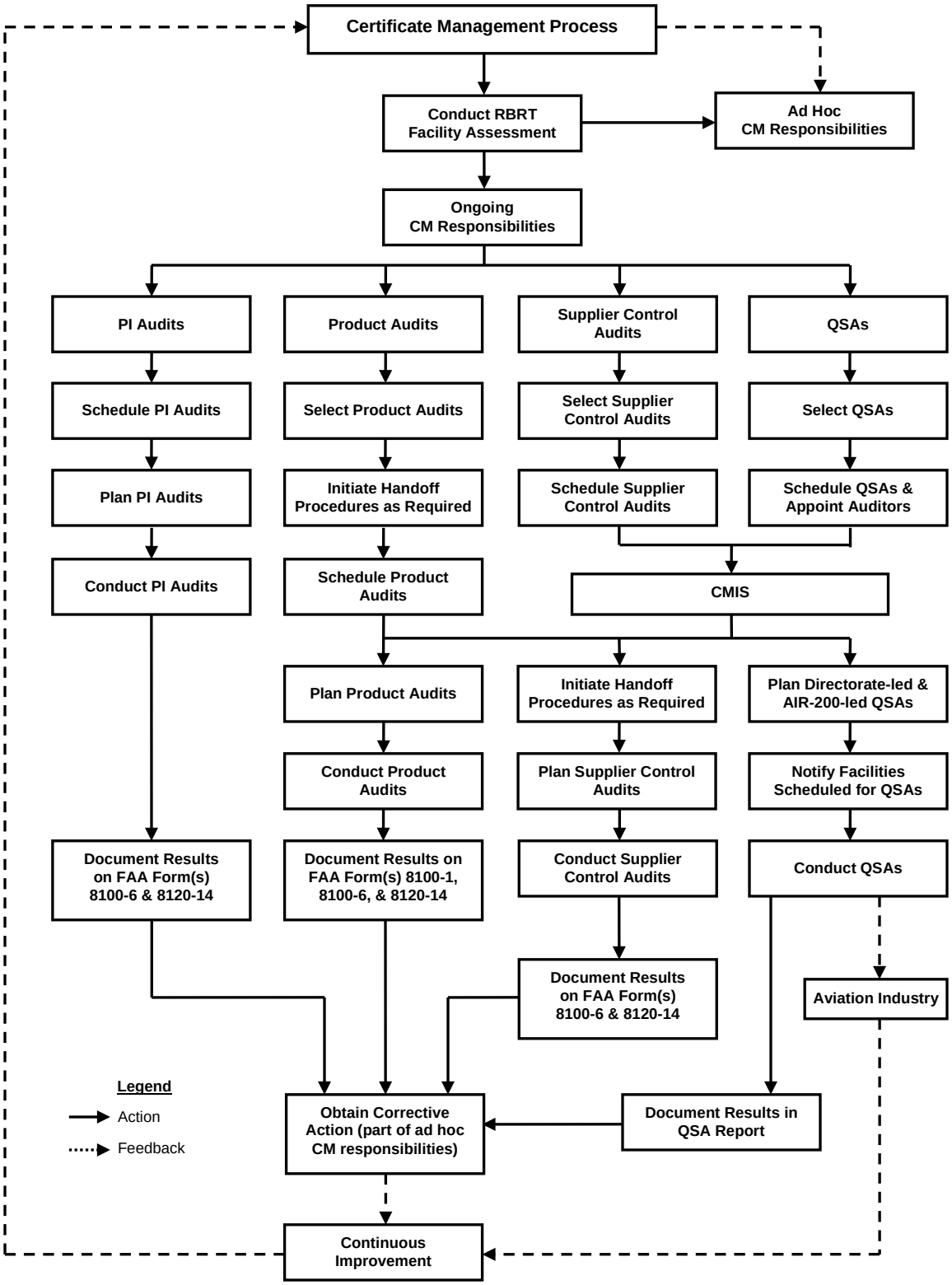
a. Pending. The FAA has received the production approval application and is in the process of auditing it, but has not yet issued the production approval.

b. Active. The FAA has issued the production approval and the PAH has produced and/or shipped products, articles, or parts within the past 12 months.

c. Inactive. The FAA has determined that the PAH has not produced or shipped products, articles, or parts within the past 12 months.

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

Figure 2-1. CM Life Cycle Process



Chapter 3. Ongoing CM Responsibilities

Section 1. Introduction

3-1. CM Tasks. Sections 2 through 6 of this chapter provide detailed guidance for accomplishing ongoing CM responsibilities. Figure 3-1 of this order provides a summary of the tasks associated with ongoing CM. These tasks are accomplished on a continuing basis, and are minimum requirements only. Additional CM tasks may be performed at the discretion of the managing office.

Figure 3-1. CM Responsibilities (Ongoing) Minimum Requirements

Risk Level / CM Activity	LOW	MEDIUM LOW	MEDIUM HIGH	HIGH
Collection of Facility Information	During PI audits; by telephone in out years	During PI audits	During PI audits	During PI audits
PI Audits	1 every 24-36 months; audit of top two noncompliant system elements/ subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data	1 not to exceed (NTE) every 18 months; audit of all system elements/ subelements applicable at the specific facility will be completed in the interval between QSAs (Refer to Note 1)	1 NTE every 18 months; audit of all system elements/ subelements applicable at the specific facility will be completed in the interval between QSAs (Refer to Note 1)	1 every quarter; audit of all system elements/ subelements applicable at the specific facility will be completed in the interval between QSAs
Supplier Control Audits			1 supplier NTE every 18 months (Refer to Note 1)	3 suppliers annually (Refer to Note 2)
Product Audits	1 during every PI audit	1 during every QSA and PI audit	1 during every QSA, PI audit, and supplier control audit	1 during every QSA and supplier control audit; 2 every 12 months in conjunction with PI audits
QSAs		32-48 months	32-48 months	1 NTE every 24 months (Refer to Note 1)

General Note: Functions associated with shaded blocks are optional based on justified need (for example, audit results, history, investigation, or service difficulties).
Note 1: NTE frequency is determined from the ending date of the last audit or, in the case of a new PAH, from its production approval date.
Note 2: For PAHs having a screened supplier listing > 50 ≤ 100, conduct 6 supplier control audits annually. For PAHs having a screened supplier listing > 100, conduct 9 supplier control audits annually.

3-2. CM Plan. A CM plan assists the PI in planning and tracking the performance of ongoing CM responsibilities. Within a timeframe established by the MIO, each MIDO/CMO may prepare a CM plan annually for each PAH and associate facility after RBRT assessments have been completed. The MIDO/CMO may subsequently amend the CM plan as necessary to include additional or reduced requirements and schedule changes. As a minimum, the CM plan should include the following:

a. Name of PAH or associate facility.

b. Current RBRT risk level.

c. Schedules for PI audits, QSAs, product audits, and supplier control audits to be conducted within the geographical boundaries of the MIDO/CMO. For supplier control audits, and product audits at suppliers, include the names of the suppliers.

d. List of handoffs or Civil Aviation Authority (CAA) requests sent, including, as a minimum, the name of the geographic MIDO/CMO that has accepted the handoff or the CAA that has accepted the request, the type of audit requested, the name of the facility receiving the audit, and the name of the responsible PAH or associate facility.

e. List of handoffs or CAA requests received, including, as a minimum, the name of the geographic MIDO/CMO or CAA that has requested the handoff, the type of audit or surveillance requested, and the name of the applicable facility.

> **Note:** The scheduling function in CMIS is intended to provide a starting point in the development of the CM plan. Should an inconsistency develop between the CMIS-generated number, frequencies, or scheduled dates of CM activities and the requirements in figure 3-1 of this order, figure 3-1 will take precedence.

3-3. Coordination of Requests for Supplier Surveillance 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 surveillance assistance from the bilateral CAA. Such assistance requests may take various forms at the PAH's supplier (for example, ongoing surveillance, supplier control audits, or product audits), and may or may not be agreed to by the CAA, depending upon its availability of resources, common production approval facilities, etc. Requests for supplier surveillance assistance should be transmitted from the MIO manager of the 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 the details of the type of support requested, the methodology by which it will be performed (this is usually the normal surveillance system, procedures, and documentation of the local CAA), the frequency of the surveillance activity, documentation expectations, etc.

a. AIR-200 has established management plans with certain European CAAs that permit those CAAs to conduct supplier surveillance activity on the FAA's behalf, in accordance with FAA Order 8120.13, International Cooperative Supplier Surveillance Program (ICSSP) Procedures. The management plans with the current ICSSP participants may be found at the

Aircraft Certification Service (AIR) Work Tools page on the FAA Employees' website. Supplier surveillance 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 surveillance activity itself in another country or jurisdiction, for whatever reason(s), 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 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 Policy Office, AIR-40. Send an electronic facsimile (fax), scanned copy, or e-mail of the letter 45 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, at a minimum, include the following information:

(a) Identity of the facility to be audited.

(b) Type of supplier surveillance activity to be conducted (supplier control audit, product audit, ongoing surveillance, etc.). Provide a general outline of what will be included in the scheduled activity.

(c) Date(s) of the scheduled activity.

(d) Number of FAA auditors participating in the scheduled activity.

(e) Name, address, telephone number, and e-mail address of responsible PI.

(2) Provide the PAH's certificate managing office with details of any noncompliance encountered during the surveillance 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 certificate 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.

3-4. Recording Noncompliances. The PI will record all noncompliances, including those reported by a CAA while performing CM activities for the FAA, on FAA Form 8100-6, Noncompliance Record, in accordance with the guidelines listed in appendix I 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.

3-5. through 3-6. Reserved.

Section 2. Risk-Based Resource Targeting

3-7. RBRT Assessment Tool. The RBRT assessment tool is used to assign risk to a PAH according to the likelihood that it will produce nonconforming products, articles, or parts, and consequential results associated with introducing those products, articles, or parts into the system. RBRT assessments and associated procedures provide a consistent and justifiable basis for effective deployment of FAA resources when performing CM. Each directorate must annually assess PAHs using RBRT assessments.

3-8. Scope. Holders of a production certificate (PC), parts manufacturer approval (PMA), and/or technical standard order (TSO) authorization and their associate facilities are subject to an RBRT assessment. Suppliers, delegated facilities, holders of a letter of TSO design approval, and PAHs in an inactive status are not subject to an RBRT assessment.

3-9. RBRT Risk Levels. The RBRT assessment of each applicable facility is based on organizational and technical indicators that demonstrate a facility's potential for producing nonconforming products, articles, or parts. Refer to appendix A to this order. The RBRT assessment results in assigning a facility one of the following risk levels:

a. High: Facilities with the greatest potential to produce nonconforming products, articles, or parts.

b. Medium (Medium Low and Medium High): Facilities with moderate potential to produce nonconforming products, articles, or parts.

c. Low: Facilities with low potential to produce nonconforming products, articles, or parts.

3-10. RBRT Assessment of Facilities. The FAA will assess facilities annually using the RBRT assessment tool.

a. The assessment of facilities will be completed annually, and not later than April 30.

b. The accuracy of the information entered into the RBRT assessment tool depends upon the PI's knowledge, with assistance from others, of the status of each facility being assessed. To this end, the PI should collect the information required to answer the indicator questions when the PI is in the facility, or by telephone for facilities in those years when PI audits are not scheduled. For a new facility, information obtained during the MIDO audit should be used.

c. The PI *may* use the Category Parts List (CPL) described in appendix B to this order to answer the criticality indicator question.

d. When appropriate, the PI should contact each facility to obtain current or clarifying information relevant to the RBRT indicators being assessed. The PI should contact each facility previously designated as inactive to determine whether the facility's status has changed.

e. The PI will conduct the RBRT assessment in accordance with the instructions provided in CMIS.

f. The RBRT assessment tool requires an approving official, usually the MIDO/CMO manager or their delegate, to review the calculated risk level and the recommended CM requirements. To the greatest extent possible, the PI and MIDO/CMO manager or their delegate should agree on the final risk level. The MIDO/CMO manager or their delegate will indicate approval in accordance with the instructions provided in CMIS.

3-11. Modification of RBRT Assessment. Circumstances may arise following the annual identification of RBRT risk levels that may challenge the assigned risk level for a specific facility. When any of the following conditions occur at a facility after a risk level has been assigned, the PI should complete a new RBRT assessment in accordance with the instructions provided in CMIS. Refer to appendix A to this order to determine the significance of the following conditions:

a. Changes in unit criticality.

b. Significant quality system changes.

c. Significant change in key management.

d. Significant turnover of critical staff.

e. Significant increase or reduction 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 change in the use of suppliers/outsourcing.

k. Significant increase in the use of foreign suppliers.

l. Movement or shift of production location or volume.

m. Expiration of a labor contract; potential labor unrest.

Note: When the schedules, as established in the CM plan, for PI audits, QSAs, product audits, and supplier control audits are impacted by a change in the assigned risk level, the PI should adjust the CM plan accordingly. Auditing activity should increase where critical manufacture or processing is occurring (including suppliers of any tier). Auditing activity should decrease for facilities or suppliers engaged in non-critical manufacture or processing.

3-12. Modification of RBRT Assessment Tool. The RBRT assessment tool includes several quasi-quantitative factors that result in the identification of quality systems according to their potential to produce nonconforming products, articles, or parts. AIR-150 will periodically audit the RBRT assessment tool. Any proposed modifications to the RBRT assessment tool require formal Aircraft Certification Management Team approval. AIR-150 will coordinate the implementation of any changes to the RBRT assessment tool, including development and dissemination of revised program guidance, updated CMIS programming, and revised RBRT assessment training materials.

3-13. through 3-14. Reserved.

Section 3. Quality System Audit

Part 1. QSA Introduction

3-15. General. The QSA is a component of CM and is a comprehensive audit program. It is a vital element within the FAA's mission of continued operational safety and is excluded from the U.S. Department of Transportation's plan to reduce internal regulations by 50 percent. The QSA—

a. Ascertains whether PAHs and associate facilities meet the applicable requirements of 14 CFR and comply with procedures established to meet those requirements.

b. Applies standardized audit criteria.

c. Populates a database for analyzing audit results and reporting trends.

d. Provides continuous improvement for the FAA by continually auditing customer feedback reports and considering proposed improvements by FAA internal and external customers.

e. Evaluates the continued integrity of the design data at PAHs and associate facilities after initial approval by the FAA. However, the QSA does not reevaluate the approval of previously approved data such as quality manuals or design data.

Note: The term "ACSEP" will continue to be used in CMIS until the release of the next major revision to CMIS. The term "ACSEP" will be synonymous with "QSA" for use within CMIS.

3-16. through 3-17. Reserved.

Part 2. QSA Auditor Appointment and Training

3-18. General. The appointing officials designated in paragraph 3-19 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.

3-19. Appointing Officials. The following 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. Aircraft Certification Office (ACO) managers and ACO branch managers.

b. MIO, MIDO, and CMO managers.

c. Directorate Standards Staff managers.

d. AIR-100 branch managers.

e. AIR-200 branch managers.

3-20. 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 3-2):

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) Technical or trade school certificate with 6 years of technical experience in aerospace manufacturing or design, or in the audit thereof.

(3) Associate's degree in engineering or science disciplines, with 5 years of technical experience in aerospace manufacturing or design, or in the audit thereof.

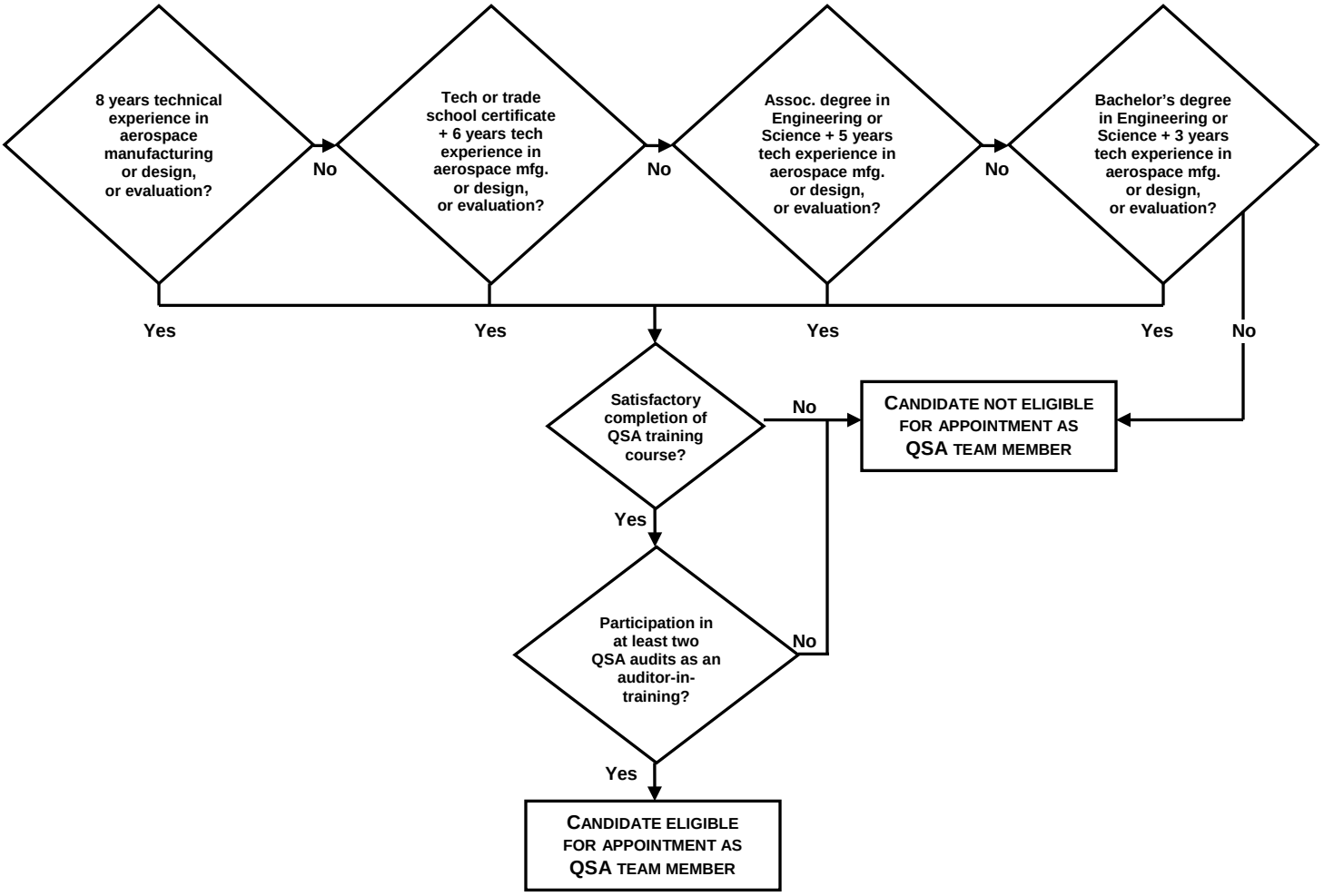
(4) Bachelor's degree or higher in engineering or science disciplines, with 3 years of technical experience in aerospace manufacturing or design, or in the audit thereof.

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 3-2. Criteria for Candidate Selection and Team Member Appointment



3-21. 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 3-2 and 3-3).

a. Team Member. Candidates must meet the following minimum requirements before appointment as a team member (refer to figure 3-2):

(1) Satisfactory completion of the (ACSEP) 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 audit criteria contained in appendix H to this order, and in coordinating team member involvement.

Note: The 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 candidate's appointing official is responsible for performing the following activities in auditing the team member candidate:

(a) Consider the candidate's previous experience and education.

(b) Consider the product complexity, facility size, and complexity of system elements audited in QSAs in which the candidate participated.

(c) Discuss with team leader(s) 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 3-21a(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 CMIS program.

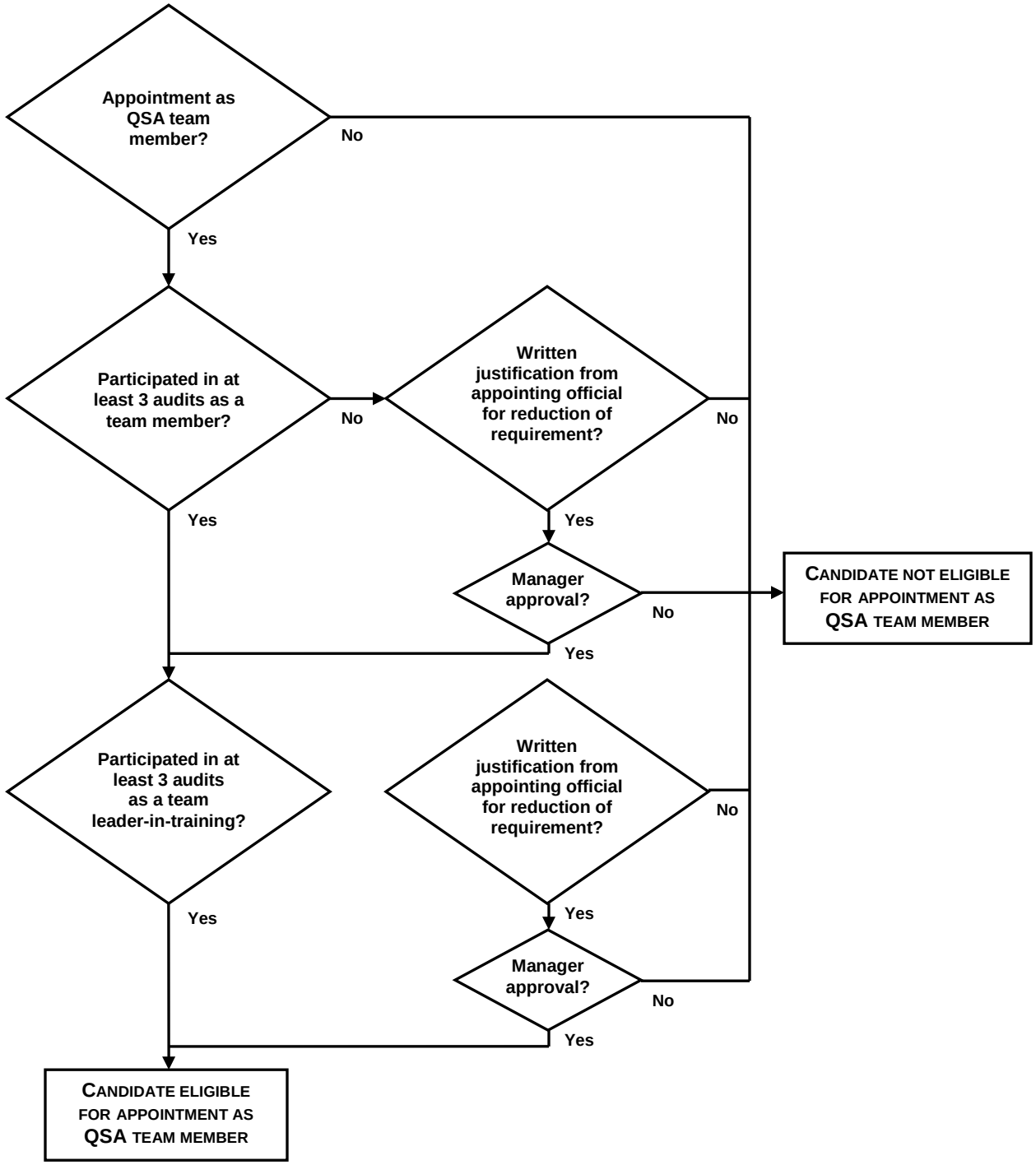
b. Team Leader. Candidates must meet the following minimum requirements before appointment as a team leader (refer to figure 3-3):

(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.

Figure 3-3. Criteria for Team Leader Appointment



(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 auditing the team leader candidate:

(a) Consider the candidate's previous experience and education.

(b) Consider the product complexity, facility size, and complexity of system elements audited in QSAs in which the candidate participated.

(c) Discuss with team leader(s), 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.

(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 3-21b(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 CMIS program.

c. The candidate's appointing official will document and track the completion of the requirements in paragraphs 3-21a and b 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 his or her appointment in writing. Ensure the appointment document includes 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.

3-22. 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 PI audits or MIDO audits in accordance with chapter 3, section 5 of this order.

Note: A supplier control audit does not count toward the continued appointment of a QSA team member.

(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, at a minimum the following requirements:

(1) Participated at an interval of once or more every 2 fiscal years as a QSA team leader or as a team leader for a PI audit or MIDO audit with multiple team members in accordance with chapter 3, section 5 of this order.

Note: A supplier control audit does not count toward the continued appointment of a QSA team leader.

(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.

3-23. Reinstatement of Auditors Failing to Meet Appointment Review Criteria. Appointing officials may reinstate auditors under their appointment authority 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 3-21a 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 3-21b of this order.

3-24. through 3-25. Reserved.

Part 3. Selection and Scheduling of QSAs

3-26. QSA Intervals. Audit intervals for PAHs and associate facilities are identified in figure 3-1 of this order.

3-27. Selection of Facilities To Be Audited. Procedures for selecting PAHs and associate facilities to be audited are identified in chapter 3.

3-28. Scheduling of QSAs. After all facilities have been selected for audit in accordance with paragraph 3-27 of this order, each 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 system elements, when known (refer to appendix H 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 that 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, 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. This office is usually the one that performs CM responsibility at the facility to be audited. For an associate facility subject to CM under the handoff procedure, the lead audit office is the geographic office receiving the handoff. The lead audit office is responsible for—

(1) Coordinating the notification letter (refer to paragraph 3-30 of this order), and

(2) Notifying the selected team leader and team members (refer to paragraph 3-34 of this order).

d. Prepare an audit schedule for the current fiscal year based on the facility selection criteria in paragraph 3-27 of this order and the duration of each audit. Annually prepare the schedule no later than July 31.

(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) RBRT 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 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 number(s).

(2) All directorate schedules will be entered into the schedule module of the CMIS program.

(3) The ACO, MIO, MIDO, and CMO managers 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 ACO, MIO, MIDO, and CMO managers should consider scheduling the facilities individually.

e. Designate an assigned engineer (AE). On the basis of the data collected for paragraphs 3-26 through 3-28d of this order, the ACO manager determines 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.

3-29. Selection of QSA Auditors. The ACO, MIO, MIDO, and CMO managers 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 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 that compliance to the applicable 14 CFR and FAA-approved data would be fully verified.

(1) Estimate the number of auditors required according to the following minimum criteria:

(a) RBRT assigned risk level.

(b) Number and complexity of applicable quality, engineering, flight test, and facility procedures and processes in place.

(c) Number of applicable system elements, when known (refer to appendix H 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).

(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 3-29a(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: When estimating the number of auditors required, include only those full-time persons who are used to support the PAH facility activity.

(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 paragraphs 3-29a(1)(a) through (f) of this order and the following criteria to determine the types of auditors required. Select appointed QSA auditors who have appropriate knowledge of the audit criteria identified in appendix H to this order applicable to the facility to be audited and, as appropriate, to the product(s) 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 3-22 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 surveillance responsibilities. Use the guidelines in table 3-1 to select the PI and/or AE as auditors:

Table 3-1. Selecting a PI or AE as an Auditor

Number of Persons Performing the Audit	PAH Facility Procedure
One- or two-person	Do not select the responsible certificate management PI. Do not select the AE if the AE is the engineer assigned design responsibility for the facility to be audited. **Note:** For audits with at least three team members, the ACO, MIO, MIDO, and CMO managers, to the greatest extent practicable, will select as auditors the PI, or assistant PI as appropriate, and/or the AE. The ACO, MIO, MIDO, and CMO managers should assess the logistical and personal burden of selecting the PI and/or AE for all applicable audits, and should assign the PI and/or AE to audits through which the greatest benefit may be obtained.
Three- or four-person	Select as a team member either the responsible certificate management PI or the AE, if the AE is the engineer assigned design responsibility for the facility to be audited. If the AE is not assigned design responsibility, both the AE and the responsible certificate management PI may be selected as team members.
Five-person or greater	Select as a team member either the responsible certificate management PI or AE, or both.

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 directorates or AIR-100/200 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 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 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 participation of the auditors with the appropriate directorate office and CMIS coordinators. Additional support may also be available from AIR-100 or AIR-200, if requested. If these sources of support are not available, the directorate may obtain outside support services to augment directorate resources. Support service personnel will be qualified and credible quality assurance experts and technology specialists and will meet the criteria for candidate selection specified in paragraph 3-20 of this order. Directorates will obtain any required support service personnel in accordance with budgetary directives. Appendix D to this order contains sample contract clauses relating to obtaining support services.

> **Note:** The cognizant directorate will complete all necessary administrative measures required for facility access by support service personnel before the scheduled QSA. The measures may include obtaining any security clearances from the prospective facility, ensuring that personnel have signed a certificate of nondisclosure for confidentiality of information (refer to appendix D to this order), and ensuring that personnel are aware of their limitations (as agreed to between the directorate and the facility to be audited) of access and entry to the facility's proprietary or sensitive processes or systems.

f. Scheduled Changes. Each directorate must update schedule changes electronically in the CMIS program at least quarterly. Audits added to the master schedule will be assigned a new QSA number in accordance with paragraph 3-28b of this order.

3-30. Notification of Facilities To Be Audited. The lead audit office identified in accordance with paragraph 3-28c of this order will notify facilities using the sample formats in appendixes E and F to this order. Coordinate with the responsible PI to ensure that 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. Appendix F to this order provides a summary of notification letter requirements. Notify facilities as follows:

a. PAH/Associate Facility. 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 or associate facility, requesting MIDO or CMO, AIR-200, and the team leader or principal auditor of any changes to the audit schedule or team composition after the notification letter has been sent.

3-31. 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 ACO, MIO, MIDO, and CMO managers will jointly reschedule any affected audit in coordination with the PI, AE, and the team leader or principal auditor, and update the schedule in the CMIS 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.

3-32. through 3-33. Reserved.

Part 4. QSA Procedures

Subpart A. QSA Preparation

3-34. Lead Audit Office. Perform, at a minimum, the following QSA preparations:

a. Notify, through CMIS, the selected audit team leader and team members, or the principal auditor, at least 60 calendar days before each directorate QSA. A record of the notification does not need to be retained.

b. Ensure logistical support for an audit within the geographical area.

3-35. ACO, MIO, MIDO, and CMO Managers. Notify, through CMIS, all auditors within the directorate selected for AIR-200-led QSAs and QSAs in support of other directorates. Send notification at least 60 calendar days before each audit. Send a copy of the notification to the lead audit office and AIR-200. A record of the notification does not need to be retained.

3-36. 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 to team members, and assigns system elements to team members. These actions, as appropriate, require coordination with the PI, 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 such items 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 available only 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 CMIS.

(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 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).

(j) Relevant issues identified in the Monitor Safety Analyze Data (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, Compliance and Enforcement Program.

(5) Agreements made between the cognizant ACO, MIO, MIDO, or CMO 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 CMIS 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) Type(s) 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) 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. 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. Forward an FAA certificate of nondisclosure (refer to appendix D to this order) to any outside support service personnel assigned no later than 35 calendar days before the audit. Obtain signed statements no later than 25 calendar days before the audit and forward them to the facility via the PI.

e. Notify the lead audit office immediately of changes in team numbers or composition.

f. Coordinate with the applicable PI or AE, or geographic PI, as necessary.

3-37. Audit Team Member. Perform these tasks:

a. Upon notification by the team leader, confirm availability for the QSA, 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, the PI, or the AE appropriate to the assigned system elements. When possible, make a preliminary selection of the procedures you plan to audit.

3-38. through 3-39. Reserved.

Subpart B. Conduct of the Audit

3-40. 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 that 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 3-36a(3) with the facility representative and arrange with the representative to have applicable information available to the FAA at the pre-audit team meeting.

3-41. Pre-Audit Team Meeting. The team leader and all team members meet in advance of 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.

i. Agreements made between the cognizant ACO, MIO, MIDO, or CMO and the facility to be audited.

3-42. 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 and support service personnel.

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 standardized audit criteria 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.

3-43. Audit of System Elements. The QSA team audits up to six system elements and conducts at least one product audit at PAHs and associate facilities. Each system element addresses a specific activity or function that may affect the maintenance of FAA-approved design or quality data. Each system element is defined in appendix H 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 system elements.

d. Review PAH supplier records by selecting a random sample of PAH supplier audit reports. (Refer to appendix H, section 6, paragraph 1a to this order.)

(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, followup, 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 CMIS 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 RBRT assessment of the PAH.

(4) Any noncompliance noted during the review of PAH supplier audit reports will be recorded under supplier control system element criteria number 602. Noncompliance will also be documented in accordance with paragraph 3-38 of this order.

> **Note:** Paragraph 3-43d and appendix H, section 6, paragraph 1a 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 audit according to any special concerns raised by the PI or AE. Use the standardized audit criteria in appendix H to this order to determine the depth of the audit in the subject area. Perform, as necessary, a combination of document and product review to determine if the system element meets applicable requirements.

> **Note:** The standardized audit criteria are a list of questions and related statements of condition in appendix H to this order used primarily to plan and document the results of the audit of each system element in a standardized manner. The criteria 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 criteria applicable to the system element assigned to be audited and should strive to audit as many of the procedures, requirements, and products related to the criteria as time allows.

f. Select at least one team member to conduct at least one product audit at a PAH or associate facility 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 additional standardized audit criteria questions and statement-of-condition practices and principles not contained in appendix H 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 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 a supplier 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.

3-44. Recording Noncompliances. Auditors will record all noncompliances on FAA Form 8100-6, or electronic equivalent, according to the guidelines in appendix I to this order.

Note: Record as a certification-related noncompliance any condition that questions the certification basis. Address the noncompliance on the Executive Summary (refer to paragraphs 3-45b(2)(c) and 3-49b, and appendix J, to this order) and as a special emphasis item in the audit report (refer to paragraphs 3-45b(2)(d) and 3-49c, and appendix K to this order).

3-45. 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.

(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 that 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 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 on noncompliance(s). The lead audit office, or requesting MIDO or CMO, as applicable, must determine the level of corrective action required (refer to paragraph 3-52 of this order).

(b) Ensure that all true copies of objective evidence are attached to 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 J to this order). Prepare original forms as follows:

1 PAH or Associate Facility. 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 ACO, MIO, MIDO, or CMO managers, the geographic PI, the AE, and the Flight Standards principal maintenance inspector (as appropriate). Use the instructions in appendix K to this order to record these special emphasis items. Prepare original documents as follows:

1 PAH or Associate Facility. Prepare one original document.

2 Facility with Multiple Production Approvals. Prepare only one original 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 have been prepared for inclusion, as applicable, in each QSA report to be sent to the responsible certificate management MIDO, CMO, or ACO having delegation oversight. Refer to paragraph 3-49d 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:

1 Reproduce the signed original FAA Form(s) 8100-6 as required for inclusion in the applicable QSA report(s) to be sent to the responsible certificate management MIDO or CMO 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 have been prepared for inclusion, as applicable, in each QSA report to be sent to the responsible certificate management MIDO or CMO having oversight.

(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 3-51a 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.

3-46. 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 copy of the completed 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 the QSA database.

d. Explain corrective action and followup 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.

3-47. through 3-48. Reserved.

Subpart C. Post-Audit Activities

3-49. 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 original audit report. Format and compile each audit report in the CMIS program. The report will consist of the following:

Note: Ensure that the QSA report identifies only noncompliances presented at the post-audit conference.

a. FAA Form 8100-3, QSA Report, or printed copy of electronic equivalent (appendix L to this order). Each form or printed copy must be an original and signed. Prepare an original form or printed copy for each PAH affected.

b. QSA Executive Summary or printed copy of electronic equivalent (appendix J to this order). Each summary must be an original and signed. Prepare an original summary or printed copy for each PAH affected.

c. QSA Special Emphasis Items or printed copy of electronic equivalent (appendix K to this order). Prepare an original list of special emphasis items or printed copy for each PAH affected.

d. FAA Form 8100-6 or printed copy of electronic equivalent (appendix I 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:** 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.

3-50. Quality Review of the QSA Report. The QSA Report contains the data that forms the basis of corrective action requests (refer to paragraph 3-52 of this order) and the QSA national database described in chapter 5 of this order. To this end, the audit report must be accurate and complete. Directorate managers (or delegated individuals) must establish a review process within their directorates that ensures accuracy and completion of the QSA report before distribution.

3-51. Sending the QSA Report. Using CMIS, the team leader or principal auditor and the responsible ACO and MIO managers (or delegated individuals) will process the QSA report as follows (refer to appendix M to this order):

a. Team Leader or Principal Auditor.

(1) Make the audit report available to the responsible MIDO/CMO 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 MIDO/CMO manager or delegate 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 ACO manager and to AIR-200. The copy for the ACO manager may be tailored according to the needs of that manager. Include copies of any objective evidence that the ACO manager may require to investigate identified special emphasis items. These copies must be sent or delivered to the attention of the ACO manager. Do not send copies of objective evidence to AIR-200.

(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. Certificate Management ACO 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:** ACO investigations of special emphasis items identified during the conduct of a QSA should be coordinated with the responsible MIDO or CMO.

3-52. Requesting Corrective Action. The PI must request corrective action in accordance with paragraph 4-21 of this order.

3-53. through 3-54. Reserved.

Section 4. Supplier Control

Part 1. Determining Supplier Control by a PAH or Associate Facility

3-55. General PAH Supplier Control Responsibilities. A PAH or associate facility 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 or associate facility should:

a. Ensure that each completed product, article, or part(s) conforms to the approved design data and is in a condition for safe operation. This responsibility is applicable without regard to:

(1) Where the supplier may be located.

(2) Whether the parts received by the PAH or associate facility 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 or associate facility are commercial or standard parts.

(7) Whether the supplier has been delegated major inspection authority.

(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 or associate facility's receiving inspection facilities only if the PAH or associate facility:

(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 number(s), time periods, or particular user/operators. This authorization will be maintained by the PAH or associate facility for review by the cognizant MIDO/CMO.

(2) Includes, in its FAA-approved quality system, controls to compensate for the absence of inspection normally conducted at the PAH's or associate facility'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 associate facility, or

(b) The supplier under a delegated inspection authority from the PAH or associate facility.

(3) Ensures that 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/associate facility or by delegated inspection authority. The shipping document for subcomponents manufactured for TSO articles should contain the TSO number. When FAA Form 8130-3, Airworthiness Approval Tag, 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 MIDO/CMO 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.

3-56. CM Activity. CM activity will be focused on the PAH's or associate facility's control of its suppliers, since the PAH or associate facility is totally responsible for all of its supplier-furnished articles and services.

a. The FAA does not approve suppliers. However, the PI should review a PAH's or associate facility'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, Decision Paper Requirements for Undue Burden and No Undue Burden Determinations Under 14 CFR Part 21 for Production and Export Airworthiness Approvals.

b. The FAA will determine if a PAH or associate facility is complying with its supplier control system by performing the following activities:

(1) PI Audit. Refer to section 5 of this chapter. Specifically, the PI will use the QSA supplier control system element criteria from Appendix H to determine if a PAH or associate facility is complying with its supplier control system.

(2) Supplier Control Audit. Refer to part 2 of this section. Specifically, the PI will determine if the supplier complies with purchase order and/or quality requirements. In some instances, this activity may be handed off to another MIDO/CMO, or may require CAA assistance.

3-57. Determination of Supplier Control. The PI may determine whether a PAH or associate facility is controlling its suppliers by reviewing the results of the PI audit at the PAH or associate facility, when applicable, and the results of the supplier control audits at the selected PAH/associate facility 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 or associate facility. 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.

3-58. through 3-59. Reserved.

Part 2. Supplier Control Audit

3-60. Scheduling. A supplier control audit is conducted as part of the CM of the PAH or associate facility that evaluates the system established to control the articles, materials, supplies, and services provided by outside sources. This audit is conducted by the MIDO/CMO assigned CM responsibility for the PAH or associate facility. If specific expertise is required during this audit, the PI should advise the MIDO/CMO manager. If a supplier control audit is required in another geographic MIDO/CMO, the PI will comply with the handoff procedures in paragraph 3-64 of this order. A supplier control audit is applicable to suppliers of a PAH or associate facility as determined by the selection process identified in paragraph 3-61 of this order. The supplier control audit will determine that the supplier complies with purchase order and/or quality requirements, including any statistical sampling that may be used. 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 or associate facility. Schedule a supplier control audit in accordance with the results of the latest RBRT assessment as follows:

> **Note:** The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. Refer also to figure 3-1 of this order. A MIDO/CMO may schedule additional supplier control audits at specific facilities when required to ensure continued operational safety.

a. High Risk Facility. For PAHs having a screened supplier listing, as described in paragraphs 3-61e and f of this order, of:

(1) Less than or equal to 50, a supplier control audit will be conducted at 3 suppliers annually.

(2) Greater than 50, but less than or equal to 100, a supplier control audit will be conducted at 6 suppliers annually.

(3) Greater than 100, a supplier control audit will be conducted 9 suppliers annually.

b. Medium Risk Facility.

(1) Medium High. A supplier control audit will be conducted every 18 months.

(2) Medium Low. A supplier control audit is not required.

c. Low Risk Facility. A supplier control audit is not required.

3-61. Supplier Selection. Selection of suppliers subject to supplier control audits will be performed as follows:

> **Note:** The supplier selection process, although automated in CMIS, may be accomplished manually. Therefore, it will be optional for the PI to enter all of the PAH's suppliers into CMIS.

a. After completing the RBRT assessment, each PI will identify the number of supplier control audits to be performed by using the guidance described in paragraphs 3-60a through c of this order.

b. Next, the PI must obtain access to the PAH's supplier listing.

c. The PI will select candidates for supplier control audits using a random sampling method to minimize biasing the results. For supplier selection purposes, a random number generator method will be used. In cases in which the supplier selection process automated in CMIS is not used, each MIO will determine the method of generating random numbers, using the Internet as a possible source. The PI will use these randomly generated numbers to determine which suppliers receive an audit. Using the random number generator method, the PI will select the appropriate minimum number of supplier control audits required.

d. The PI will match the randomly generated numbers to the PAH's or associate facility's supplier control listing. For example, Company ABC was rated as a High Risk facility and has 40 suppliers on its supplier control listing. The minimum number of supplier control audits for a High Risk facility with 40 suppliers is 3. Using the random number generator method, the PI selects the first 3 numbers from the generated list of 40 random numbers, which for the purpose of this example would be 5, 8, and 24. The PI will then count down the supplier listing and choose the 5th, 8th, and 24th suppliers on the list.

e. The PI will screen each of the suppliers selected, taking into consideration the following factors: article complexity or criticality, recipient of a supplier control audit in the previous year, significant service difficulty activity at a supplier, inspectability upon receipt, delegation of major inspections, direct-ship authority, delegation of a Materials Review Board (MRB), or supplier performance. In addition, the PI must determine if the degree of manufacture that occurs at the supplier justifies expanding the audit activity to their subtier suppliers. If, based on these factors, the PI decides not to audit a selected supplier, the PI should select the next number on the generated list and screen that supplier against the listed factors. Continue this process until the required number of suppliers is selected.

> **Note:** In addition to those factors stated within paragraph 3-61e of this order, the PI is reminded to consider the degree of manufacturing and processing activity that occurs at those suppliers that are candidates for supplier control audits. The PI is also encouraged to consult the CPL in appendix B to this order in prioritizing supplier criticality as part of the screening process.

f. As an alternative to the supplier selection process described above, the PI may apply the screening criteria identified in paragraph 3-61e of this order to all suppliers on the PAH's supplier listing, thereby compiling a screened list of suppliers suitable for a supplier control audit. The PI will then randomly select the required number of suppliers from the screened list in accordance with the procedures described in paragraphs 3-61c and d of this order.

> **Note:** In cases where the PAH or associate facility supplier base is less than or equal to the minimum number of supplier control audits required, the PI will schedule and conduct a supplier control audit at each of the PAH's or associate facility's suppliers. When the results of the supplier control audits indicate a continuing trend of effective supplier control by the PAH or associate facility, the PI may elect to reduce the number of supplier control audits to be conducted.

g. There may be reasons such as article complexity or criticality, size of the PAH's or associate facility's supplier base, significant service difficulty activity at a supplier, delegation of major inspections, or supplier performance for which the PI may want to do more than the minimum number of supplier control audits. The PI should remember, however, that the purpose of the supplier control audit is to determine that a PAH or associate facility is satisfactorily controlling its suppliers, not to audit the performance of the supplier. Specific supplier issues should be audited using the product audit described in section 6 of this chapter.

3-62. Directorate Supplier Control Audit. Each MIDO/CMO will schedule supplier control audits annually as described in paragraph 3-61 of this order.

a. The supplier control audit schedule will include the name of the selected supplier, the name of the responsible PAH or associate facility, the scheduled date of supplier control audits to be conducted by the MIDO/CMO, and identification of any supplier control audits that may be handed off to other directorates or may require the assistance of a CAA in a bilateral country.

> **Note:** When feasible, the MIDO/CMO should schedule the supplier control audit for a time when the supplier has an active purchase order from the PAH or associate facility. A supplier control 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 QSA.

b. Each MIDO/CMO will maintain supplier control audit data in accordance with the instructions provided in CMIS. This data will be used to plan resource allocation in the next fiscal year. The MIO manager will ensure that the data submitted by each MIDO/CMO are reviewed for completeness and for identification of duplicate suppliers. When the same supplier is selected by different MIDOs or CMOs, the MIO manager should ensure that only one audit is scheduled at that supplier; however, compliance to the requirements of all applicable PAHs or associate facilities should be audited at that supplier. The MIO manager should also determine which MIDO/CMO will conduct the audit, and whether representation from other MIDOs or CMOs is required. When all potential discrepancies with the data are resolved, the MIO manager will ensure that the consolidated directorate supplier control audit data is prepared and made available in CMIS.

c. The completed directorate data, described in paragraph 3-62b of this order, must be available in CMIS to all other MIO managers. All MIO managers should ensure that supplier control audit data received from other directorates are reviewed to identify duplicate suppliers, potential handoffs that affect their offices, and supplier control audits to be conducted by the FAA at multiple international suppliers in the same country.

3-63. Coordination of Supplier Control Audits Between Directorates. Coordination between MIO managers should ensure only one audit is scheduled at a supplier, whether all affected PAHs will be audited as part of the audit, and to identify audit participant(s).

a. Handoffs. MIO managers should accept and support handoffs of supplier control audits that are scheduled within the minimum requirements of paragraph 3-60 of this order. MIO managers should ensure that supplier control audits that are handed off to their directorates are added to their directorate supplier control audit lists and scheduled. Updated directorate supplier control audit lists should be provided to the other MIO managers. There should be no handoffs of supplier control audits that are scheduled beyond the minimum number required, unless an agreement is made with the MIO of the directorate where the supplier is located. Contentious handoffs, such as those that have significant resource implications, should not be scheduled at this time. Participants should discuss contentious handoffs and agree on an appropriate solution.

b. Supplier Control Audits To Be Conducted by the FAA at Multiple International Suppliers in the Same Country. MIO managers should identify one FAA office as a lead office to coordinate all audit activities, which includes notifying the responsible CAA and inviting its participation. MIO managers should determine whether representation from other MIOs is required.

3-64. Domestic Handoff Procedures. After receipt of the finalized Directorate Supplier Control Audit data referenced in paragraphs 3-62 and 3-63 of this order, the following handoff procedures will be used for suppliers located in the United States:

a. The MIDO/CMO will forward a memorandum to the MIDO/CMO having geographical responsibility of the area in which the supplier is located, no later than 75 days before the scheduled audit. The memorandum will indicate the type of audit that should be conducted, that is, supplier control audit or product audit, and will include all pertinent information regarding the audit including, when appropriate:

(1) The name and address of the supplier and the responsible PAH, including the PAH's project number.

(2) The name, title, and telephone number of the person to contact at the supplier and PAH facilities who can furnish purchase order(s), quality system data, technical data, and other pertinent information.

(3) 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.

(4) Any delegation of MRB and/or technical data change control authority.

(5) Any authority permitting direct shipment.

(6) Any other information regarding specific supplier activities that should be audited, such as a new process or new technology.

(7) Information pertinent to a product, article, or part(s) to be audited, such as part number, next level of assembly, or service difficulty or warranty return history.

b. When a geographic MIDO/CMO receives a request for a supplier control audit or product audit located within its geographical boundaries, it will:

(1) Advise the requesting MIDO/CMO of receipt of the request within 30 days.

(2) Add the audit to the CM plan.

(3) Notify the responsible PAH or associate facility in accordance with paragraph 3-65 of this order.

(4) Submit a memorandum to each requesting MIDO/CMO upon completion of the supplier control audit or product audit. This memorandum should summarize the results of the audit, and include all applicable FAA Form(s) 8100-6, 8100-1, and 8120-14. The requesting MIDO/CMO will consider its handoff request complete upon receipt of this memorandum.

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 handoff to the geographic MIDO/CMO is appropriate for this purpose, the following handoff procedures will be used:

(1) The MIDO/CMO will forward a memorandum to the MIDO/CMO 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, when appropriate:

(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 PAH facilities that can furnish purchase order(s), 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.

(f) A copy of the supplier's corrective action response to the PAH.

(2) When a geographic MIDO/CMO receives a request for a corrective action validation at a facility located within its geographical boundaries, it will:

(a) Advise the requesting MIDO/CMO of receipt of the request within 30 days.

(b) Submit a memorandum to the requesting MIDO/CMO 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. The requesting MIDO/CMO will consider its handoff request complete upon receipt of this memorandum.

3-65. Notifying a PAH or Associate Facility. Before conducting a supplier control audit, the MIDO/CMO that will be conducting the audit will notify the responsible PAH or associate facility. The PI should prepare a notification letter and send it to the PAH no later than 30 days before the audit. 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 3-64b of this order, the office receiving the request will send the notification letter to the PAH or associate facility and provide a copy to the requesting office. Figure 3-4 contains a sample notification letter.

Figure 3-4. Sample Supplier Control Audit Notification Letter

U.S. Department of Transportation

Federal Aviation Administration

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

July 13, 2011

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

Dear Ms. Brown:

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 the conduct of a supplier control audit. The audit is scheduled to be conducted on November 12, 2011, 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 Seattle 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 Gotta

Julia Gotta
Seattle Manufacturing Inspection
District Office

cc: Fort Worth MIDO

Sample

3-66. Conducting and Recording a Supplier Control Audit. Every effort should be made to conduct a supplier control audit when the supplier has an active purchase order from the PAH or associate facility. The supplier control audit will be conducted using the PAH's quality flow-down requirements noted on the applicable purchase order. 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, subtier suppliers, and design data.

a. If circumstances arise and an active purchase order 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.

> **Note:** The system element standardized audit criteria listed in appendix H 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 audit criteria number when documenting noncompliances on FAA Form 8100-6.

b. A supplier control audit must be recorded on FAA Form 8120-14 by the person conducting the audit. One form will be completed for each supplier control audit conducted. Each handoff is considered a separate supplier control audit. Prepare the form in accordance with appendix N to this order. Document noncompliances on FAA Form 8100-6. Refer to appendix I to this order.

c. 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.

3-67. through 3-68. Reserved.

Section 5. Principal Inspector Audit

3-69. Scheduling. A PI audit is an audit conducted by a PI at a PAH or associate facility, normally by the PI assigned CM responsibility. If specific expertise is required during a PI audit, the PI should advise the MIDO/CMO manager. A PI audit will be scheduled in accordance with the results of the latest RBRT assessment. QSA system element criteria from this order will be used to conduct PI audits. The PI audit will be scheduled and conducted as follows:

> **Note:** The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. Refer also to figure 3-1 of this order. A MIDO/CMO may schedule additional PI audits at specific facilities when required to ensure continued operational safety.

a. High Risk Facility.

(1) A PI audit will be conducted at each High Risk facility at least once every quarter.

(2) Audit of *all* system elements/subelements *applicable* at the specific facility *will be* completed at least once in the interval between QSAs. A few of the system elements/subelements should be audited during each PI audit. Initial emphasis should be placed on audit of the top two noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.

b. Medium Risk Facility.

(1) A PI audit will be conducted at each Medium Risk facility at least once every 18 months.

(2) Audit of *all* system elements/subelements *applicable* at the specific facility *will be* completed at least once in the interval between QSAs. A few of the system elements/subelements should be audited during each PI audit. Initial emphasis should be placed on audit of the top two noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.

c. Low Risk Facility.

(1) A PI audit will be conducted at each Low Risk facility at least once every 24 to 36 months.

(2) Audit of the top two noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data, *will be* completed at least once in the 24- to 36-month period.

3-70. Recording a PI Audit. Record a PI audit on FAA Form 8120-14. Complete one form for each PI audit conducted. Prepare this form in accordance with appendix N to this order. Document noncompliances on FAA Form 8100-6. Refer to appendix I 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 3-43d(2)(a) through (c) of this order on FAA Form 8100-1.

3-71. through 3-72. Reserved.

Section 6. Product Audit

3-73. Scheduling. A product audit evaluates the effectiveness of the PAH's or associate facility's quality system and the airworthiness of products using critical and certain non-critical characteristics and/or processing attributes generated during the manufacturing process. The product audit may be initiated at any point in the manufacturing process after inspections have been completed. The product audit is conducted at a PAH or associate facility, but may also be conducted at a supplier facility where a product, article, part(s) is manufactured. If specific expertise is required during this audit, the PI should advise the MIDO/CMO manager. If a product audit is required in another geographic MIDO/CMO, the PI will comply with the handoff procedures in paragraph 3-64 of this order.

Note: Whenever an applicable product, article, or part is available, a product audit will be conducted at scheduled QSAs, PI audits, and supplier control audits as specified in figure 3-1,of this order.

3-74. 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 or associate facility's engineering drawings, process specifications, test specifications, and quality system procedures.

(4) SDRs. 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.

3-75. Product Audit Areas. The product audit may be divided into one or more of the following areas:

a. Final product,

b. Subassembly,

c. Detail parts, or

d. Raw material.

3-76. 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. Figure 3-5 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, associate facility, or applicable supplier. The PAH's, associate facility's, or applicable supplier's personnel are responsible for the handling of the article(s) 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 measurement(s) 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 article 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 software part 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, proper authorizations; proper use of statistical sampling; for example, certificate of conformance, work travelers, blueprints, specifications, and first article inspection 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.

Figure 3-5. Applicability of Product Audit Criteria to Product Audit Areas (Minimum)

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

3-77. 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. The PI will retain all applicable objective evidence in accordance with Manual FAA-IR-04-01.

3-78. 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. 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 a supplier control audit, it may be recorded on the same form prepared for those activities. When a product audit is conducted as a stand-alone activity, one form will be completed for each product audit completed. Prepare this form in accordance with appendix N to this order. The PI will retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. Any corrective action required should be accomplished in accordance with chapter 4, section 5 of this order.

3-79. through 3-80. Reserved.

Section 7. Special Audit Items

Reserved.

Chapter 4. Special CM Responsibilities

Section 1. Introduction

4-1. Section Information. Sections 2 through 6 of this chapter provide guidance for accomplishing special CM responsibilities. The tasks discussed below are accomplished on an as-required basis.

4-2. through 4-3. Reserved.

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

4-4. General MIDO/CMO Responsibilities. The cognizant MIDO/CMO 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, article, or part(s). Any inadequacies in the quality system must be identified to the PAH for corrective action.

> **Note:** The approval 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 approve the changes.

4-5. Prioritization of Review. Review of a facility's changes to its quality system should be prioritized according to its RBRT risk 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 RBRT risk level will be prioritized by date of notification or receipt of applicable data.

4-6. Review of Changes. The cognizant MIDO/CMO should review changes to the quality system to ensure that:

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 4-6a and b of this order may often be verified through data review alone. In some instances, however, onsite inspection or review may be required.

4-7. Post-Review Actions. The cognizant MIDO/CMO 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.

(2) The PI should update the CMIS project folder to reflect the current quality system.

4-8. through 4-9. Reserved.

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, 2010

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 meets [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 become necessary as a result of subsequent inspections and/or audits.

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

Document Name: Quality Management Manual.

Document Number: 101248

Revision Number: C

Date: June 30, 2010

Sincerely,

Dewey Revu

Dewey Revu
Principal Inspector

Sample

Section 3. Investigation of Service Difficulties

4-10. 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/.

b. MIDO/CMO and ACO Investigation. Upon receipt of an SDR, the MIDO/CMO 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 cognizant ACO is responsible for overseeing the certificate holder's corrective action to any design deficiencies.

c. MIDO/CMO Responsibility. The MIDO/CMO 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.

4-11. 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.

4-12. Corrective Action. The MIDO/CMO 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 ACO.

4-13. Reporting a Service Difficulty Investigation.

a. Service Difficulty Investigation Report. The MIDO/CMO 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 MIDO and/or taken by the manufacturer including a copy of the MIDO letter to the manufacturer and the manufacturer's reply.

(7) Effect on products in service.

(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 MIDO/CMO 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. Organization Designation Authorization (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 MIO and geographic ACO, which should initiate any actions deemed appropriate for the particular service difficulty involved.

4-14. Foreign Manufacturers. Foreign manufacturers are exempted from the reporting requirements of § 21.3. When foreign manufactured products, articles, or parts approved under § 21.29, § 21.500, § 21.502, or § 21.621 are involved in service difficulties, the MIO in the directorate where the service difficulty occurred will initiate an investigation. A complete report will be provided to the MIO and Standards Staff of the 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 under § 13.19 would also be necessary. Coordinate such enforcement action through the Assistant Chief Counsel, Enforcement Division, AGC-300, AIR-40, and the State Department.

4-15. through 4-16. Reserved.

Section 4. PAH Noncompliances and Corrective Action

4-17. PAH Noncompliances. FAA CM responsibilities often result in identifying PAH noncompliances, which may or may not be regulatory violations of 14 CFR or FAA-approved data. When a noncompliance is determined to be a regulatory violation, it must be processed in accordance with FAA Order 2150.3 and the AIR Enforcement Program as described in AIR Work Instructions (for example, AIR-002-035-W1). Nonregulatory violations fall outside the scope of the FAA's compliance and enforcement program.

4-18. Types of Noncompliances. The following are the types of noncompliances typically identified during oversight, investigative, and surveillance activities that require corrective action to be taken. They are divided into regulatory and nonregulatory noncompliances to meet the requirements of the FAA's compliance and enforcement program.

a. Regulatory Noncompliances.

(1) Safety-Related Noncompliance. A noncompliance is safety-related when the PI, typically in conjunction with the aviation safety engineer, determines an unsafe condition exists on a product, article, or part that requires immediate action. If the noncompliance affects delivered products, articles, or parts, obtain from the facility a list of the end users affected and immediately notify the cognizant affected FAA office.

(2) Systemic Noncompliance with 14 CFR or FAA-Approved Data. A noncompliance is a systemic noncompliance when the PI finds a systemic breakdown in the PAH's compliance with the applicable 14 CFR or FAA-approved data.

(3) Systemic Noncompliance with Purchase Order Requirements (by a supplier to a PAH or associate facility). A noncompliance is a systemic noncompliance with purchase order requirements when the PI finds a systemic breakdown in a supplier's compliance with the purchase order requirements flowdown from the PAH or associate facility to the supplier.

(4) Isolated Noncompliance with 14 CFR or FAA-Approved Data. A noncompliance is an isolated noncompliance when the PI finds an isolated occurrence of noncompliance with the applicable 14 CFR or FAA-approved data.

(5) Isolated Noncompliance with Purchase Order Requirements (by a supplier to a PAH or associate facility). A noncompliance is an isolated noncompliance with purchase order requirements when the PI finds an isolated occurrence of noncompliance with the purchase order requirements flowdown from the PAH or associate facility to the supplier.

b. Nonregulatory Noncompliances.

(1) Systemic and Isolated Noncompliance with the Facility's Internal Procedures. A systemic and isolated noncompliance to a facility's internal procedures is when a PAH fails to follow self-imposed internal procedures that do not violate 14 CFR and are not part of the FAA-approved system. Because these procedures are self-imposed, these noncompliances are considered nonregulatory noncompliances.

(2) Certification-Related Noncompliance. A certification-related noncompliance is when a condition exists where the data the FAA has approved does not meet 14 CFR. These noncompliances are considered nonregulatory noncompliances.

4-19. Documenting Noncompliances. As indicated in paragraph 3-4 of this order, noncompliances are recorded on FAA Form 8100-6. The PI will review each item on FAA Form 8100-6 to determine if the noncompliance is a regulatory or nonregulatory violation. Once the PI determines the appropriate categorization of the noncompliances, they will take the following actions:

a. Regulatory Noncompliances. Regulatory noncompliances will be processed in accordance with the guidance outlined in FAA Order 2150.3 and AIR Work Instructions (for example, AIR-002-035-W1).

b. Nonregulatory Noncompliances. Nonregulatory noncompliances are generally processed using the following steps:

(1) Issue a letter informing the PAH of the conditions found and requesting them to provide a corrective action response.

(2) Follow up with the PAH to verify actions have been taken.

4-20. 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 will retain the FAA Form 8100-6 and all applicable evidence in accordance with Manual FAA-IR-04-01, AIR Records Management Requirements Manual.

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 handoff, the FAA Form 8100-6 will be transmitted to the requesting MIDO/CMO for action.

d. If the PI determines, subsequent to finalizing an audit, that the noncompliance recorded on FAA Form 8100-6 is incorrect and should be changed, the PI will:

(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 QSA 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.

4-21. Obtaining Corrective Action. Corrective action for regulatory noncompliances will be performed in accordance with AIR Work Instructions (for example, AIR-002-035-W1). Corrective action for nonregulatory noncompliances will be processed in accordance with paragraph 4-19(b) of this order.

4-22. through 4-23. Reserved.

Section 5. Unscheduled Audits or Investigations

4-24. General Unscheduled Audit Information. Chapter 3 of this order provides for scheduled PI audits, product audits, supplier control audits, and QSAs. However, any one of these audits may be performed on a non-scheduled basis at the discretion of the managing office whenever necessary to ensure continued operational safety. Other investigations may arise for purposes such as SUP or whistleblower allegations.

4-25. Non-Scheduled CM Audits. The 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 associate facility should be provided as soon as practicable. For a PAH or associate 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 SDRs.

d. SUP investigations.

e. Excessive owner/operator complaints.

f. PAH's or associate facility's refusal/failure to take appropriate corrective action.

g. PAH's or associate facility's inability to control suppliers.

h. Renewal of a PAH's or associate facility's production activity after a prolonged period of inactivity.

i. Relocation of production facility.

j. Surveillance 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, 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 surveillance 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 surveillance to be conducted on behalf of the CAA; and documentation to be submitted to the CAA. The responsible geographic MIO will ensure that the request is complete before assigning it to a MIDO/CMO.

(2) The responsible geographic MIDO/CMO 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 geographic MIDO/CMO will prepare a cover letter to accompany the documentation and forward it to AIR-40 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 surveillance activities at a U.S. manufacturer, the FAA may be invited to observe or participate. The responsible geographic MIDO/CMO 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.

4-26. Special Audit Item. An SAI is an item, process, or area that senior management has determined requires specific focus during audits. The Manufacturing Inspection Management Team, AIR-200, 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.

4-27. through 4-29. Reserved.

Section 6. Providing Guidance to a PAH or Associate Facility

4-30. Guidance. The PI should provide guidance to a PAH or associate facility as necessary for the manufacturing of products, articles, or parts 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.

Chapter 5. QSA and CMIS

5-1. Purpose. Audit data resulting from PAH CM activities is stored in CMIS. Upon extraction from CMIS, this data can be manipulated using 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 directorate, by production approval type, or by other categories as supported by the data available within CMIS. CMIS data may also be used to study various aspects of the performance of QSAs on an as-required basis.

5-2. Files. CMIS contains all QSA-related forms, including FAA Form 8100-3, the QSA Report; FAA Form 8100-6, the Noncompliance Record; and FAA Form 8100-7, the QSA Customer Feedback Report.

5-3. Database Management. AIR-200 is responsible for monitoring CMIS and will, as appropriate, do the following:

a. Review the database as follows:

(1) Enter into CMIS any completed FAA Form 8100-7 as returned by the facility.

(2) Highlight noncompliance trends with respect to the system elements.

(3) Analyze noncompliance trends with respect to the system elements.

(4) Highlight trends emerging in the performance of QSAs.

b. Provide selected data and reports.

Note 1: All recipients of CMIS audit data will use the information internally only and will not release results outside of AIR. Refer to appendix R, paragraph 9 to this order.

Note 2: The term “ACSEP” will continue to be used in CMIS until the release of the next major revision to CMIS. The term “ACSEP” will be synonymous with “QSA” for use within CMIS.

5-4. Use of the Database. Directorates may use CMIS to obtain reports on noncompliances, frequently used 14 CFR references, and PAH compliance. They may use the database to detect shifts in performance and statistically significant trends for different segments of the industry. Directorates also may use the database to assist in scheduling.

Appendix A. RBRT Organizational and Technical Indicators

1. Purpose. This appendix provides additional guidance to assist the PI in understanding how to rate each organizational and technical indicator.

2. Specific Guidance. There are 34 organizational and technical indicators in the RBRT assessment tool. These indicators are listed in figure A-1 of this appendix. The PI, with assistance from others, must assess each of these indicators. The information following each indicator below provides guidance to assist the PI in completing this assessment. The information is intended to prompt the PI to consider a variety of elements and issues that may be applicable to the facility being assessed, and to make an informed judgment about the facility. The number assigned to each indicator corresponds directly with the indicator number on the RBRT tool's Quality System Assessment Sheet.

Figure A-1. RBRT Indicators

ORGANIZATIONAL INDICATORS

Quality System

1. ISO 9001/AS9100 Quality System

2. Supplier Control Processes/Procedures

3. Nonconforming Material Processes/Procedures

4. Corrective and Preventive Action

5. Product/Part Configuration Control

Supplier/Outsourcing

6. Manufacture/Inspection Outsourcing

7. Design/Configuration Outsourcing

8. Testing/Validation Outsourcing

9. Stability of Suppliers

10. Suppliers of Flight Critical Parts

11. Supplier Audit History

Organizational Stability

12. Workforce Reduction/Growth/Turnover

13. Turnover of Critical Staff

14. Change in Key Management

15. Company Merger or Takeover

Relationship with FAA

16. Documented Agreement with FAA

17. Constructive Relationship with FAA

Compliance History

18. Applicant/PAH-Identified Noncompliances

19. FAA-Identified Noncompliances

20. Enforcement Action History

21. Demonstrated Independent Show Compliance

Safety Culture

22. SMS in Place

23. Employee Safety Training

24. Accident/Incident Investigation Program

25. Continued Operational Safety

26. Continuous Improvement

TECHNICAL INDICATORS

Complexity

27. Complex Part/Product/Assembly

28. Complex Manufacturing Process

29. Complex Testing Program

Service Experience

30. Injury/Fatal Accident Design Factor

31. AD/SAIB Design Factor

32. SUP/SDR History

Applicant/PAH Experience

33. Level of Experience

New/Emerging Technology

34. New/Emerging Technology

No. 1	**AS9100 Quality System**				
	Does the applicant have an AS9100 quality system?				
Possible Ratings	Yes, have an AS9100 quality system in place	Have some elements of an AS9100 quality system in place, and ISO 9001 certified	Have an AS9100 quality system in place but not ISO 9001 certified	Have some elements of an AS9100 quality system in place but not ISO 9001 certified	No AS9100 quality system elements in place and not ISO 9001 certified
Score	**1**	**2**	**3**	**4**	**5**

This indicator is meant to be a quantitative versus qualitative assessment. The assessor is not auditing the health or adequacy of the applicant/PAH's implementation of its AS9100 system elements or whether they are ISO 9001 certified. Rather, the assessor is only identifying the status of the applicant/PAH with regard to AS9100 quality system implementation, and /or ISO 9001 certification.

Currently neither AS9100 nor ISO 9001 is an FAA requirement, but we recognize the benefits of these systems. The implementation of AS9100 quality system elements and/or ISO 9001 certification are indicators of the applicant/PAH's commitment to quality management/assurance principles.

Organizations implement AS9100 and obtain registration because it assures customers the company has a good Quality Management System (QMS) in place. An organization with an effective QMS will typically meet customer expectations better than an organization that does not have an effective QMS. Many aerospace organizations implement AS9100 for improvement of internal effectiveness and productivity. To enhance supplier control some organizations require their suppliers to also implement AS9100. Other organizations implement a QMS because it has proven over the years that it leads companies to better operations, improved performance, and improved profitability.

Generally speaking, companies that embrace these quality management systems understand and have committed necessary resources to establishing mature effective quality systems. There is a high level of confidence in their ability to establish and maintain the processes and controls required to ensure that their product conforms to its type design and is in a condition for safe operation.

No. 2	**Supplier Control Processes/Procedures**				
	Does the applicant/PAH have processes/procedures in place to control suppliers used in design, manufacture, inspect and/or test product/parts that conform to type design data?				
Possible Ratings	Process in place/uses only certified or accredited suppliers *or* supplier control is not applicable	Process in place/uses some certified or accredited suppliers	Process in place/ applicant/PAH has no requirement for certification or accreditation of suppliers	Process/ procedure documented, but inadequate or not implemented	No documented supplier control system
Score	**1**	**2**	**3**	**4**	**5**

This indicator focuses on the applicant/PAH's supplier control processes/procedures. In assessing this indicator, the strength and adequacy of the supplier control system is critical. The supplier control system should address all suppliers, including those providing manufacturing, engineering, or testing services. The applicant/PAH must control its suppliers to ensure that the products, parts, and/or services provided conform to applicant/PAH requirements/approved design data and are in a condition for safe operation. To accomplish this, the applicant/PAH is responsible for establishing, documenting, implementing, and maintaining a supplier control system that provides the following:

- Method to document organizational and technical requirements, processes, and procedures imposed on the supplier. This is normally documented in purchase orders, invoices, and/or other documents.
- Method to identify how the applicant/PAH audits, selects, approves, controls, and maintains its suppliers and supplier control system.
- Method to communicate with FAA representatives any applicable reporting requirements, delegation of major inspection, direct-ship authority, use of foreign suppliers, and any changes to its quality or supplier control system.
- The supplier control system should be well documented and stable, and not subject to constant changes.

Applicant/PAHs may implement supplier control systems that require or limit the selection of suppliers based on third-party certification or accreditation. Examples may include ISO 9001 certification or accredited in accordance with AC No. 00-56. While these applicant/PAH's requirements do not replace the applicant/PAH's responsibilities, they are generally considered as indicators of a robust supplier control system and a commitment to ensuring each supplier furnishes products, parts, and/or services that conform to its approved design data and are in a condition for safe operation.

Where the supplier control system's processes/procedures are inadequate and undefined (that is, not documented) the risks are greater.

No. 3	**Nonconforming Material Processes/Procedures**				
	Does the applicant/PAH have processes/procedures in place to control, review, and properly disposition nonconforming material (i.e., Material Review Board)?				
Possible Ratings	Process in place/fully implemented		Process documented, but not implemented		Process inadequate or not documented
Score	**1**	**2**	**3**	**4**	**5**

This indicator focuses on the applicant/PAH's ability to ensure that only products, articles, and parts that conform to their design data are produced and accepted by the applicant/PAH. The applicant/PAH should document and implement an adequate nonconforming material control system that includes the following:

- Methods to document, identify, segregate, audit, and disposition all nonconforming products, articles, and parts.
- Methods to identify and communicate to the FAA when correction and/or acceptance of a nonconformity constitutes a major change to approved design data.
- Process to notify the FAA when changes to the nonconforming material control system are necessary.

The documentation for these processes should be considered in the context of the need. A small company may only require an elementary informal process. On the other hand, a large company may require formal and detailed documentation that is readily available to all employees.

Signs of implementation of the process should be self-evident in the form of the paperwork that is generally required to support the process, such as inspection records, nonconforming material routing documents, and MRB documents. However, the level of implementation may be more difficult to assess.

Where the nonconforming material control system's processes/procedures are inadequate and undefined (that is, not documented) the risks are greater.

No. 4	**Corrective and Preventive Action**				
	Does the applicant/PAH have processes/procedures in place to identify root cause, implement corrective action, and prevent recurrence of nonconforming conditions?				
Possible Ratings	Process in place/fully implemented		Process documented, but not implemented		Process inadequate or not documented
Score	**1**	**2**	**3**	**4**	**5**

The applicant/PAH should have processes/procedures to document and implement their corrective and preventive actions necessary to detect, correct, and eliminate the causes of nonconformity. Consider if the process is adequate, documented, and implemented. Examples of nonconformities could include:

- Products, parts, or services that do not conform to approved design data and/or quality system requirements.
- Products, parts, or services that do not comply with the CFR requirements.
- Engineering or testing services that do not conform to the applicant's or purchase order's requirements, etc.

The following should be considered when assessing this indicator:

- Method to identify, document, and review nonconformity or noncompliances.
- Method to identify, audit, and document root causes of nonconformity or noncompliances.
- Method for determination and implementation of appropriate corrective and preventive actions.
- Method for documenting all results of corrective and/or preventive actions.
- Method to monitor and audit the effectiveness of corrective actions.

The documentation for these processes should be considered in the context of the need. A small company may only require an elementary informal process. On the other hand, a large company may require formal and detailed documentation that is readily available to all employees.

Signs of implementation of the process should be self-evident in the form of the paperwork that is generally required to support the process, such as inspection records, routing documents, and corrective action requests. However, the level of implementation may be more difficult to assess.

Where the corrective and preventive action systems' processes/procedures are inadequate and undefined (that is, not documented) the risks are greater.

No. 5	**Product/Part Configuration Control**				
	Does the applicant/PAH have processes/procedures in place to document and control the baseline product/part configuration?				
Possible Ratings	Process in place/fully implemented		Process documented, but not implemented		Process inadequate or not documented
Score	**1**	**2**	**3**	**4**	**5**

This indicator focuses on the applicant/PAH's design control and configuration management processes/procedures. Changes are not uncommon or necessarily problematic. The applicant/PAH should have an integrated process to control the design, from drawing initiation through the manufacturing of the part. This should be true even for new applicants where changes occur often and the risk can be offset by a strong process or procedure. When assessing this indicator, discussion of specific points between the ACO and the MIDO may be beneficial.

In assessing this indicator, the strength and adequacy of this process is critical and should address all design details, including those provided by suppliers or to suppliers. To accomplish this, the applicant/PAH should establish, document, implement, and maintain an adequate design control and configuration management system that provides the following:

- A method in which changes are well described and fully documented in a timely and consistent manner. If they're not, the process may be inadequate. Also look for positive characteristics, such as simplicity and ease of administration. Keep in mind that automated systems (for example, CAD) often require qualified staff to manage them.
- A method to address changes made to correct airworthiness problems should be well controlled by the process. Changes that result from or influence a mandatory action, such as an AD, should be segregated from other design changes.

- A method to categorize and implement changes, such as major or minor, as well as applicable methods to submit design changes to the FAA.

The documentation for these processes should be considered in the context of the need. A simple part at a small company may only require an informal and simple process. On the other hand, complex products at a large company may require formal and detailed documentation that is readily available to all employees. Signs of implementation of the process should be self-evident in the form of the various paperwork that is generally required to support the process, such as engineering change notices, routing documents, and inspection records. However, the level of implementation may be more difficult to assess.

While new companies may have a thoroughly defined process, they may not have had an opportunity to demonstrate it and should be rated appropriately.

No. 6	**Manufacture/Inspection Outsourcing**				
	Does the applicant/PAH outsource the manufacture and/or inspection of products, parts, and/or assemblies? (Select the one furthest to the right that applies)				
Possible Ratings	No outsourcing	Yes, to domestic certified or accredited suppliers (e.g., ISO 9001)	Yes, to domestic suppliers only (not certified or accredited)	Yes, to domestic suppliers and/or foreign suppliers in bilateral countries	Yes, to foreign suppliers in non-bilateral countries
Score	**1**	**2**	**3**	**4**	**5**

Increased use of suppliers in manufacturing and delegation of inspection authority can raise potentially serious quality concerns. This indicator assesses the level or extent that the applicant/PAH relies on outsourcing and the type of suppliers they choose. Identification of the level and type of outsourcing will also enable the FAA to audit resources necessary to provide regulatory oversight. This assessment is meant to be data driven and is not an assessment of the applicant/PAH's supplier control system.

The term "outsourcing" when used in this assessment is meant to include the manufacture or inspection of any product, part, material, or related manufacturing process that is provided from a source other than the applicant/PAH. Outsourcing does *not* include activities performed by FAA resources (that is, FAA employees and designees) while performing their certification/surveillance functions.

The proximity of the supplier to the applicant/PAH has an impact on the complexity of supplier control and the risks associated with outsourcing. Generally, the applicant/PAH's control of local certificated or accredited suppliers is less complex than that of a foreign supplier.

The applicant/PAH may use a combination of the types of suppliers identified, so the assessor should select the type of supplier furthest to the right that is applicable.

No. 7	**Design/Configuration Outsourcing**				
	Does the applicant/PAH outsource the engineering design, configuration control, and/or design change control of parts and/or assemblies?				
Possible Ratings	No outsourcing	Yes, to domestic certified or accredited suppliers (e.g., ISO 9001)	Yes, to domestic suppliers only (not certified or accredited)	Yes, to domestic suppliers and/or foreign suppliers in bilateral countries	Yes, to foreign suppliers in non-bilateral countries
Score	**1**	**2**	**3**	**4**	**5**

Increased use of suppliers in engineering and design can raise potentially serious concerns. This indicator assesses the level or extent that the applicant/PAH relies on outsourcing and the type of suppliers they choose. Identification of the level and type of outsourcing will also enable the FAA to audit resources necessary to provide regulatory oversight. This assessment is meant to be data driven and is not an assessment of the applicant/PAH's supplier control system.

The term "outsourcing" when used in this assessment is meant to include the engineering or design of any product, part, material, or related service that is provided from a source other than the applicant/PAH. In some cases, an independent designated engineering representative (DER)/designated airworthiness representative (DAR) could provide services (outsourcing) to an applicant/PAH as a private party, independent of their designation. Outsourcing does *not* include activities performed by FAA resources (that is, FAA employees and designees) while performing their FAA certification/surveillance functions.

The proximity of the supplier to the applicant/PAH has an impact on the complexity of supplier control and the risks associated with outsourcing. Generally, the applicant/PAH's control of local certificated or accredited suppliers is less complex than that of a foreign supplier.

The applicant/PAH may use a combination of the types of suppliers identified, so the assessor should select the type of supplier furthest to the right that is applicable.

No. 8	**Testing/Validation Outsourcing**				
	Does the applicant/PAH outsource the engineering testing and/or validation of materials, parts, and/or assemblies?				
Possible Ratings	No outsourcing	Yes, to domestic certified or accredited suppliers (e.g., ISO 9001)	Yes, to domestic suppliers only (not certified or accredited)	Yes, to domestic suppliers and/or foreign suppliers in bilateral countries	Yes, to foreign suppliers in non-bilateral countries
Score	**1**	**2**	**3**	**4**	**5**

Increased use of suppliers in testing and validation can raise potentially serious concerns. This indicator assesses the level or extent that the applicant/PAH relies on outsourcing and the type of suppliers they choose. Identification of the level and type of outsourcing will also enable the FAA to audit resources necessary to provide regulatory oversight. This assessment is meant to be data driven and is not an assessment of the applicant/PAH's supplier control system.

The term "outsourcing" when used in this assessment is meant to include the testing or validation of any product, part, material, or related service that is provided from a source other than the applicant/PAH. In some cases, an independent DER/DAR could provide services (outsourcing) to an applicant/PAH as a private party, independent of their designation. Outsourcing does *not* include activities performed by FAA resources (that is, FAA employees and designees) while performing their FAA certification/surveillance functions.

The proximity of the supplier to the applicant/PAH has an impact on the complexity of supplier control and the risks associated with outsourcing. Generally, the applicant/PAH's control of local certificated or accredited suppliers is less complex than that of a foreign supplier.

The applicant/PAH may use a combination of the types of suppliers identified, so the assessor should select the type of supplier furthest to the right that is applicable.

No. 9	**Stability of Suppliers**				
	To what extent does the applicant/PAH consistently use the same suppliers?				
Possible Ratings	Great extent or no outsourcing		Moderate extent		Not at all
Score	**1**	**2**	**3**	**4**	**5**

This indicator assesses the stability of the applicant/PAH's supplier resources. The adequacy of the applicant/PAH's supplier control is assessed in another indicator.

When assessing this indicator, the consistent use of suppliers should be considered in context to the amount/volume of outsourcing, the type of supplies or services used, and the reasons for choosing different or more suppliers. When auditing this indicator, consider the following:

- High volume production and/or various types of supplies and services may dictate the need for multiple sources of supplies, materials, and/or services. If the applicant/PAH consistently uses an established supplier set or has adequate supplier control, this may not be of concern. Conversely, outsourcing of a single critical component to multiple suppliers may create disastrous results. The criticality of the materials, parts, or services outsourced should be considered. If a company uses suppliers for both critical and minor activity, the stability of the critical material, part, or service supplier should have more of an impact when auditing consistency.
- Generally, once a company has established the necessary supplier base, it should remain fairly stable. If not, consideration should be given as to why. Routine replacement of suppliers due to availability, cost, or timing may not be of concern. However, a continuous need to replace suppliers may indicate poor supplier performance and/or inadequate controls by the applicant/PAH.
- When assessing this indicator, consideration should be given to where and how long the applicant/PAH has been using suppliers. When rating a new applicant or a PAH proposing the new use of suppliers (for example, the use of suppliers where previously not used), the company will not have been able to demonstrate to a "great extent" that they use the same suppliers consistently. Therefore, they should be audited accordingly, in combination with the other considerations.

No. 10	**Suppliers of Flight Critical Parts**				
	To what extent does the applicant/PAH use suppliers of flight critical parts?				
Possible Ratings	Not at all		Moderate extent		Great extent
Score	**1**	**2**	**3**	**4**	**5**

Increased use of suppliers in manufacturing flight critical parts can raise potentially serious concerns. This indicator assesses the extent that the applicant/PAH relies on suppliers to provide flight critical parts. Identification of the extent that the applicant/PAH uses flight critical parts suppliers provides the FAA with valuable information for assessing risk and determining where to apply resources. This assessment is meant to be data driven and is not an assessment of the applicant/PAH's supplier control system.

In assessing this indicator, flight critical parts are those that would be rated either a 4 or 5 (equivalent to Category 1) when answering the criticality indicator question.

No. 11	**Supplier Audit History**				
	To what extent do the results of FAA audits of the applicant/PAH's prior supplier audits indicate adequate supplier control by the applicant/PAH?				
Possible Ratings	Great extent		Moderate extent		Not at all
Score	**1**	**2**	**3**	**4**	**5**

This indicator focuses on one aspect of the applicant/PAH's supplier control system- supplier audits. The adequacy of the applicant/PAH's entire supplier control system is assessed in another indicator. The results of recent QSAs and PI audits of the applicant/PAH's prior supplier audits should be the source for assessing this indicator (for example, QSA criterion number 602).

The FAA's audit of an applicant/PAH's prior supplier audits provides valuable information for assessing risk, identifying systemic weaknesses, and determining where to apply resources. In addition, these audits help to identify those supplier control systems that are functioning as required. When rating a new applicant, the PI should consider the company's lack of significant supplier control history. Therefore, the applicant should be audited accordingly.

No. 12	**Workforce Reduction/Growth/Turnover**				
	Has the applicant/PAH's workforce changed within the last 12 months as a result of staff reductions, growth, or employee turnover?				
Possible Ratings	< 5% of workforce	5-10% of workforce	11-15% of workforce	16-20% of workforce	> 20% of workforce
Score	**1**	**2**	**3**	**4**	**5**

Workforce turnover, reductions and layoffs, growth or expansion may have an impact on organizational stability. This indicator is meant to be data driven and is not an assessment of the impact of the change in workforce. Although the indicator is meant to be data driven, the audit should be an estimate of the change in workforce of the organization.

When assessing this indicator, all positions within an organization should be considered relevant. Even turnover in insignificant positions could be a sign of organizational instability. If the change in workforce is from multiple sources, you should add the percentages for a cumulative effect.

Do not consider changes in contracted or outsourced services in this indicator. You are auditing only the workforce directly related to the applicant/PAH's organization.

No. 13	**Turnover of Critical Staff**				
	Has there been a change in critical staff in the last 12 months?				
Possible Ratings	No change		Yes, but the change does not negatively impact the applicant/PAH's ability to perform		Yes, and the change negatively impacts the applicant/PAH's ability to perform
Score	**1**	**2**	**3**	**4**	**5**

Any member of an organization can play a critical role in the company's organization and their loss can dramatically impact the products of the company. Consultation with the appropriate ACO/MIDO may be helpful in identifying these people and assessing the effect of their departure. Think about these issues if turnover of this type has occurred:

- Critical staff turnover generally has a greater impact on small companies than on large companies, all other things being equal. Critical staff may include people such as quality

inspectors, foremen, engineers, test technicians, audit staff; any one-of-a-kind specialty (for example, level III NDT) or any key FAA contact.

- If losses are replaced or backfilled, consider the background of the new staff. Internal selections may provide more familiarity with the organization than external hires, although a solid aviation or product background may compensate. Similarly, civil experience is generally better than military, due to CFR/FAA familiarity. Technical expertise, however, is paramount for individuals in these key positions.
- If losses are not replaced or backfilled, consider the context. If the company is downsizing, streamlining, or reorganizing, losses of this type will almost always impact the stability of the organization. If, on the other hand, the changes result from the end of a major project or program, there may be less of an impact to the organization.
- In any event, consider the strength of the company's organization. If it's well established, with fully documented procedures, then it may be able to absorb the loss of critical staff without significantly affecting the organization. Consider whether the organization's ability to perform remains intact, and is not being reduced as these individuals leave.

No. 14	**Change in Key Management**				
	Has there been a change in key management positions in the last 12 months?				
Possible Ratings	No change		Yes, but the change does not negatively impact the applicant/PAH's ability to perform		Yes, and the change negatively impacts the applicant/PAH's ability to perform
Score	**1**	**2**	**3**	**4**	**5**

Management changes can have a significant impact, both positive and negative, on a company. In rating this indicator, consider the following:

- Management changes generally have a greater impact on small companies than on large companies, all other things being equal. Key managers may include people such as the director of quality/quality manager, facility manager, chief engineer, section or line managers, company FAA focal points, or company president/CEO.
- The background of new management personnel is extremely important. In general, internal selections may provide more familiarity with the organization and may be less problematic than external hires, although a solid aviation or product background may

compensate. Similarly, civil experience is often preferable to a military aviation background, since knowledge of the CFR and experience with the FAA are important.

- The reason behind any change(s) is also important. If it's performance-based, then the change may be an improvement. On the other hand, downsizing, streamlining, and reorganizations can reduce the stability of an organization.
- Consider the impact of new programs or product lines that may alter existing lines of authority and supervision and lead to organizational instability without anyone leaving the company.
- Management changes can also affect overall company philosophy or operational priorities. A shift to a more aggressive sales focus may lead to reduced emphasis on compliance to the CFR and on quality. Cost-cutting and greater "bottom line" pressure can undermine or dilute a company's focus on safety.

No. 15	**Company Merger or Takeover**				
	Has there been a company merger or takeover in the last 12 months?				
Possible Ratings	No merger or takeover		Yes, between the last 6-12 months		Yes, within the last 6 months
Score	**1**	**2**	**3**	**4**	**5**

Mergers and takeovers have become increasingly common in the aviation industry. This indicator is intended to be data driven.

Generally, mergers and takeovers have an impact on the stability of the organization. You should rate the recency of the merger or takeover based on the data, even if the situation appears to have little or no effect on the organization's stability.

No. 16	**Documented Agreement with FAA**				
	To what extent does the applicant/PAH have a documented agreement in place with the FAA?				
Possible Ratings	Great extent (e.g., PSP)		Moderate extent (e.g., MOU)		Not at all
Score	**1**	**2**	**3**	**4**	**5**

A documented agreement between the FAA and the applicant/PAH is a good indicator of the level of relationship between the two parties. Several types of agreements are used. The Partnership for Safety Plan (PSP) is usually a comprehensive detailed document and would be an indication of a significant documented relationship. Memorandums of Understanding (MOU) can have many different levels. A simple agreement about data storage is better than no agreement at all. On the other hand, some MOUs are a complex agreement bordering on the level of relationship of a PSP.

Generally, even a simple agreement is some indication of a willingness to work together and resolve issues. Therefore, this indicator should be assessed on the level of the agreement, not the effectiveness of the agreement. The issues surrounding an applicant/PAH who is not following an agreement will show up in other indicators being assessed.

No. 17	**Constructive Relationship with FAA**				
	To what extent does the applicant/PAH work with the FAA in a positive, collaborative fashion?				
Possible Ratings	Great extent	Considerable extent	Moderate extent	Limited extent	Not at all
Score	**1**	**2**	**3**	**4**	**5**

A constructive relationship between the applicant/PAH and the FAA generally minimizes project risk by reducing concerns regarding latent safety issues and allows significant issues to be resolved in a more effective and timely manner.

When auditing this indicator, you may want to consider:

- **Timeliness:** Does the applicant/PAH provide information at a time that permits the FAA to properly review the information and have adequate time to develop a response? Do they provide timely notification to the FAA of key changes, such as changes in critical staff?
- **Complete packages:** Does the applicant/PAH submit complete information to the FAA to reduce the burden on FAA resources and permit an adequate assessment by the FAA?
- **Professional conduct:** Do they try to follow the principles of the FAA's Customer Service Initiative, such as resolving issues at the local level?
- **Willingness to cooperate:** Is the applicant/PAH argumentative or do they consider the FAA's position even if they don't agree with it?
- **Follow agreements:** If an agreement is in place, does the applicant/PAH consistently follow the guidelines of the agreement?

No. 18	**Applicant/PAH-Identified Noncompliances**				
	In the past 3 years, have corrective actions been required due to applicant/PAH-identified noncompliances with the airworthiness requirements and/or production/distribution of nonconforming parts?				
Possible Ratings	Never		Yes, occasionally		Yes, frequently
Score	**1**	**2**	**3**	**4**	**5**

This data driven indicator assesses the frequency of applicant/PAH-identified nonconformities and/or noncompliances, including items such as warranty returns. The adequacy of the applicant/PAH's corrective action system is assessed in another indicator. When assessing this indicator, the assessor should keep in mind the scope, production volume, and continuity of operations. Identification of 20 noncompliances over three years of continuous production may be assessed as "occasionally", whereas 20 noncompliances over a six-month period would probably be assessed as "frequently." Identification of 100 nonconforming widgets for a high volume manufacturer producing thousands of conforming parts would be less significant than identification of 100 nonconforming widgets for every 200 produced.

No. 19	**FAA-Identified Noncompliances**				
	In the past 3 years, has the FAA identified noncompliances with regulations and/or quality procedures?				
Possible Ratings	Never		Yes, occasionally or new applicant/PAH		Yes, frequently
Score	**1**	**2**	**3**	**4**	**5**

Noncompliances resulting from FAA audits (that is, QSA, MIDO audits, PI audits, supplier control audits, engineering audits) of an applicant/PAH are a key part of any company's quality track record. The impact of FAA-identified noncompliances is escalated because the applicant/PAH's system failed to detect the noncompliance. In short, the occurrence of FAA-identified nonconformities/noncompliances should be far less than company-identified corrective actions.

In auditing this indicator, keep in mind the scope and continuity of operations. The risk associated with some situations is unacceptable and even a single occurrence may need to be considered as occurring frequently. The following situations are potentially unacceptable:

- Systemic noncompliances in critical system elements which generally include, but are not limited to, supplier control, manufacturing processes, special manufacturing processes, and design data control.
- One or more safety-related noncompliances or evidence that any system element is not under control.
- Any repeat noncompliances, either in QSAs, PI audits, product audits, or supplier control audits. Companies that have been through multiple audits and are not improving or holding steady.
- Sudden and significant negative changes in a company's performance (for example, from a single, minor noncompliance to multiple noncompliances).

No. 20	**Enforcement Action History**				
	In the past 3 years, have identified noncompliances with the regulations and/or quality procedures resulted in enforcement action(s)?				
Possible Ratings	None		Enforcement action with no civil penalties		Enforcement action with civil penalties
Score	**1**	**2**	**3**	**4**	**5**

This indicator is intended to be data driven. Enforcement actions and the assessment of a civil penalty against a PAH are significant actions undertaken by the FAA and should be rated accordingly.

No. 21	**Demonstrated Independent Show Compliance**				
	To what extent has the applicant/PAH demonstrated the ability to independently show compliance?				
Possible Ratings	Great extent		Moderate extent		Little to no extent
Score	**1**	**2**	**3**	**4**	**5**

Examples of evidence of successfully showing compliance include analysis of data, testing, and production of conforming parts.

An important consideration is that the applicant/PAH needs to have demonstrated its ability to independently show compliance. Therefore, newly formed companies or new applicants to the FAA may not have a significant history and should be audited appropriately. On the other hand, a company that has not had the opportunity to demonstrate their ability may opt to provide information to the FAA that documents the ability of their personnel to independently show compliance. In such cases, it may be appropriate to consider the information and rate the organization more favorably.

No. 22	**SMS in Place**				
	Does the applicant/PAH have an SMS in place that incorporates attributes of the AIR SMS-Provider documentation?				
Possible Ratings	Comprehensive		Partial SMS		No SMS
Score	**1**	**2**	**3**	**4**	**5**

Currently, implementation of SMS attributes is not an FAA requirement, but we recognize the benefits of an applicant/PAH having a comprehensive SMS. Implementation of SMS attributes or elements is an indication of the applicant/PAH's commitment to safety. The system should provide a systematic approach to identify and achieve the acceptable level of safety risk, as well as establish the mechanisms necessary to deliver and monitor safety performance. When assessing this indicator, consider all of the attributes listed below in determining the applicant/PAH's level of SMS implementation. Keep in mind that in most cases they may already have established attributes of a SMS without identifying them as such.

Attributes of a comprehensive SMS include implementation of safety management requirements and a safety culture.

Safety management system requirements include the following:

- Organizational structure and responsibility
- Documentation, configuration, and records management
- Operational procedures and controls
- Safety risk management
- Safety assurance
- Safety promotion

Safety culture attributes include the following:

- Cooperation
- Commitment
- Shared values of the importance of safety
- Open communication
- Seek safety improvements that exceed requirements/regulations

No. 23	**Employee Safety Training**				
	Does the organization support and document an employee training program that promotes safety?				
Possible Ratings	Training required, records kept and reviewed		Training supported, but not required. Records kept, but not reviewed.		None exists
Score	**1**	**2**	**3**	**4**	**5**

The relevancy of training should be taken into account. If, as the assessor, you feel that training provided by the organization promotes safety in aviation, then you should consider it. The overall contribution of the training to aviation safety is not important. The indicator is *not* trying to assess the organization's training program. Rather, if a company has a required and documented training program of any level that promotes aviation safety, it is a good indication that they have an organization with a culture that promotes safety.

Keep in mind that training that promotes safety can take many different forms. An organization may require key personnel to attend meetings related to safety, such as "lessons learned" or awareness training that is not "academic" in nature, but may be considered relevant.

No. 24	**Accident/Incident Investigation Program**				
	Does the organization have a documented and experienced accident/incident investigation program?				
Possible Ratings	Documented team with extensive experience		Documented team with limited experience		None exists
Score	**1**	**2**	**3**	**4**	**5**

Generally, the company should have a documented program, with experienced personnel assigned to monitor and investigate what they produce. The programs that are in place, and can contribute to aviation safety, can be a good indicator that the company has a culture of safety. If no investigatory programs are in place, even for new companies, it is generally a cause for concern.

When auditing this indicator, consider the investigation program in the context of what the company produces. Companies producing TC level products may have dedicated and trained teams to investigate accidents and incidents applicable to their products. Conversely, a company producing non-critical parts may only need people who investigate defects for warranty purposes.

No. 25	**Continued Operational Safety (COS)**				
	To what extent has the applicant/PAH demonstrated a positive approach to Continued Operational Safety issues?				
Possible Ratings	Great extent; company takes initiative and implements corrective action		Moderate extent; responds only as prompted by authorities or customers		No extent; not responsive or not demonstrated
Score	**1**	**2**	**3**	**4**	**5**

This indicator assesses an applicant/PAH's approach to maintaining the safety of their product, article, or part. Are they proactive, reactive, or generally non-responsive? Key variables associated with this indicator include the following:

- Proactive responsiveness may include: demonstrated understanding of the issue(s) involved; timely, thorough, and complete action to fix problems; and taking steps to avoid repetition (for example, by making changes to their system). The absence of one or more of these attributes is generally cause for concern.
- In some cases, non-responsiveness may be unintentional or due to mitigating circumstances. Non-responsiveness from an experienced applicant/PAH should be considered an issue.
- When responding to FAA inquiries and information, fast, professional, and thorough responses should be the norm. Frequent contact and interaction with the FAA, initiated by the company, should also be viewed positively. An unwillingness to share information, on the other hand, particularly on the part of management, can impede communication and cooperation.
- Newly formed companies or new applicants to the FAA may not have a significant history and should be audited appropriately. However, a company that has not had the opportunity to demonstrate their ability may opt to provide information to the FAA that documents their process for proactively gathering data, identifying issues, and resolving COS issues. Although this may not be as significant as a demonstrated history, it is an indication of a favorable approach. In such cases, it may be appropriate to consider the information and rate the organization more favorably.

No. 26	**Continuous Improvement**				
	Does the company support a continuous improvement environment?				
Possible Ratings	Strongly supports (e.g., documented requirement, periodic review, corrective action taken)		Moderately supports (e.g., supported, but not documented)		Does not support *or* negative environment
Score	**1**	**2**	**3**	**4**	**5**

Changes are a regular, recurring, and expected part of the applicant/PAH's programs. Separating the positive changes, initiated in support of a continuous improvement environment, from the negative changes is the key.

Characteristics of a good continuous improvement environment may include the following:

- Planning- well thought-out changes, adequate resources dedicated, impact identified, and solutions analyzed before implementation.
- Do-Changes/improvements are documented, training is developed and provided, interim review/oversight is implemented.
- Check-Ongoing and ad hoc review/audit of process, documented results.
- Act- Need for new changes/improvements identified, provides a continuous "closed loop" process.

Identification of the need or motivation for change is also critical. Changes identified in support of continuous improvement may include: process improvements/enhancements, corrective action, increases to efficiency, reliability, repeatability, and workmanship. Changes primarily driven by inadequate planning or scheduling, reactive or insufficient corrective action, or personal gain, generally create negative impacts.

No. 27	**Complex Part/Product/Assembly**				
	How complex is the part, product, assembly, design change, including integration with product, or modification/alteration?				
Possible Ratings	Not complex		Moderately complex		Highly complex
Score	**1**	**2**	**3**	**4**	**5**

Auditing the complexity of a product, design change, modification/alteration, assembly, part, or appliance involves a number of variables. Consideration of the following points can assist you in auditing this indicator. Discussing specific points with the directorates, the ACO, and/or MIDO may also be beneficial.

- The degree to which the design deviates from conventional or traditional practices may be considered. If the design involves revolutionary design concepts, it may be considered more complex, even for simple components. Additionally, traditional designs used in new applications should also be considered. This may be particularly true for technology that has been used for years in one category of aircraft, but has migrated to other categories where it has not been widely used.
- The number of components, subsystems, or subassemblies in the end item often drives its complexity. Any dynamic or rotating parts or assemblies, as well as if the item or any of its elements is life-limited, are also strongly linked to complexity. Similarly, the more functions the item performs, and/or the more failure modes it has, the greater its complexity.

- For airborne software, the DO-178 “level of software” correlates to complexity. The functionality and integration of the software drives complexity. Accordingly, complexity of designing Level A through E software should be assessed as Highly complex through Not complex respectively.
- The degree of integration and/or interdependence of the end item with other parts or systems is also a complexity driver. In general, clear functional boundaries between the item and other components or systems create less complexity than overlapping or integrated relationships. If any other systems are dependent on the end item, that typically increases overall complexity.
- The materials used in the end item are also relevant to complexity. Incorporation of any nontraditional, exotic, or revolutionary materials, and/or material(s) that haven’t been used in this way before, increase complexity. Limited knowledge or expertise can make simple things complicated.

For TSO authorization applications, the incorporation of non-TSO functions should also be considered. (Refer to FAA Order 8110.4, Type Certification.)

Generally, the incorporation of non-TSO functions add to the complexity of the issuance of a TSO authorization. If the non-TSO function is complex, difficult to review and fully understand, requires a high degree of interface with the product it will be installed upon, or incorporates new or novel technology, then complexity would be greatly increased. In contrast, if the manufacturer has done early coordination with the ACO, and the non-TSO function is of a simple nature where the performance is easily understood, then the extent of the complexity may not be high.

No. 28	**Complex Manufacturing Process**				
	How complex is the manufacturing process?				
Possible Ratings	Not complex		Moderately complex		Highly complex
Score	**1**	**2**	**3**	**4**	**5**

Demonstrating compliance can be complicated by the complexity of the methods used to manufacture the product, article, or part(s). Generally, the more complex the manufacturing process, the more likely that there could be latent safety issues or difficulty in demonstrating compliance. Assess the complexity of the manufacturing process from the perspective of your area of expertise. You may want to consider the effect on assembly, installation, and validation of the design features and components.

For some areas of expertise the effects of the complexity may traditionally be insignificant. However, the effects of the complexity of manufacturing may not be obvious. New or difficult methods of manufacturing or intolerant design requirements, such as critical dimensioning or tight manufacturing tolerances, could identify a need to conduct new tests or influence "traditional" testing. This might result in a change to test techniques or new techniques altogether, to properly audit regulatory compliance.

Auditing the complexity of the manufacturing process requires consideration of a number of variables. Major criteria to apply in this regard include the following:

- The number and type of steps involved in a process often drive complexity. Generally, the more things that must be tracked, controlled, and/or sequenced, and the more special processes involved, the more complex the process. In particular, the number of process elements that must be critically controlled is a complexity driver.
- The latitude, or lack thereof, afforded to system operators is also frequently linked to complexity. Other characteristics to look for include detailed and intricate process specifications, and/or frozen or limited process changes subject to engineering source approval. Similarly, the more frequently the process is audited or validated, the greater its probable complexity.
- Multiple, in-depth, and expensive testing requirements for the end item or product can also be a reflection of manufacturing process complexity. Intricate and sophisticated test procedures are sometimes, but not always, required based on how the product was manufactured.
- Outsourcing of manufacturing processes, both production and testing, is also an element to consider. Outsourcing of these processes to highly expert firms is sometimes, but not always, necessary due to the complexity of the process.

No. 29	**Complex Testing Program**				
	How complex is the testing program for the part, product, assembly, design change, or modification/alteration?				
Possible Ratings	Not complex		Moderately complex		Highly complex
Score	**1**	**2**	**3**	**4**	**5**

Testing requirements can come from a variety of sources. Consider testing done in support of production, the flight test program, and any other testing done to validate or demonstrate compliance. Consider the following:

- Complexity of testing is many times a question of program scope. A new design would most likely require a larger scope of testing than a derivative or follow-on design. For

any certification program, the suite of tests is largely defined by the scope of the design changes, and, for a derivative, the specific changes made to the airplane. As the program scope increases, so does the array and complexity of testing that becomes necessary. On the other hand, it is important to keep in mind that small design changes can sometime result in large and complex testing programs.

- It is also important to note that when analysis techniques are used to show compliance, this is often an indication that the testing methods are not complex. Analysis is usually permitted only when the method has been shown to be reliable, usually supported by testing that has been validated. If a combination of testing and analysis is used, then this should also be considered when making the audit.
- Testing done in support of production may be an integral part of establishing the airworthiness of the product, article, or part. In some instances, this testing can be very complex, and therefore, should not be overlooked.
- Consideration should also be given to the uniqueness of the testing. Some testing programs may be complex, but are well understood over years of application.
- The number and variety of tests in a program should be considered. Some standards require many different types of tests. Others require a single type of test to be run several times.
- Consideration should be given to the ease of the test(s), as well as the general understanding of how to successfully complete the test(s). Some testing programs are relatively simple to complete, but improper selection of test articles is common. Therefore, these standards should be rated higher. Conversely, some tests are very complex, but test procedures and proper selection of test articles are well defined.
- Another consideration is whether specialized equipment and training is needed to perform the testing. If specialized equipment is needed, it generally follows that special qualifications to operate and maintain the equipment are needed. If either special equipment or training is needed to perform the testing, this should be taken into consideration.

No. 30	**Injury/Fatal Accident Design Factor**				
	Have the same or similar designs been factors in injury or fatal accidents?				
Possible Ratings	No accidents		Contributing factor		Casual factor
Score	**1**	**2**	**3**	**4**	**5**

Generally, if an incident or accident involved the same or similar design, then it is cause for concern when considering the probability of a noncompliance occurring.

It is also important to consider whether the same or similar design was a contributing or causal factor in an injury or fatal accident. Even the appearance that the design was involved could be relevant. Therefore, it is not necessary to wait until the official accident report is finalized before considering the design as a contributing factor. However, confidence of the contribution should be taken into account.

It is also important to note that it is not just the design itself that should be considered. If the project being audited is a modification or replacement part, the history of the product being modified is also relevant. If the product has had an incident/accident in a relevant area to the part/modification, consideration should be given.

Note: The PI will use databases in assessing this indicator. In the absence of such databases, the PI should assess the indicator based upon their knowledge of any issues specific to the PAH. If the PI has no knowledge of any issues, they should score the indicator as a 1.

No. 31	**AD/SAIB Design Factor**				
	Have the same or similar designs been factors in the issuance of an AD or SAIB?				
Possible Ratings	None		Contributing factor		Causal factor
Score	**1**	**2**	**3**	**4**	**5**

Generally, if an AD or special airworthiness information bulletin (SAIB) exists for the same or similar design, then it is cause for concern when considering the probability of a noncompliance occurring.

It is important to consider if the same or similar design was a contributing or causal factor in the issuance of the SAIB or AD. It is important to note that draft SAIBs or ADs are relevant. Therefore, it is not necessary for the SAIB to be released or the AD to be published in the Federal Register to be considered relevant. However, the confidence in the contribution to the development of the SAIB or AD should be taken into account.

It is also important to note that it is not just the design itself that should be considered. If the project being audited is a modification or replacement part, the SAIB and AD history of the product being modified is also relevant. If the product has had an SAIB or AD in a relevant area to the part/modification, it should be considered.

Note: The PI will use databases in assessing this indicator. In the absence of such databases, the PI should assess the indicator based upon their knowledge of any issues specific to the PAH. If the PI has no knowledge of any issues, they should score the indicator as a 1.

No. 32	**SUP/SDR History**				
	Have similar designs been the subject of SUP reports or SDRs?				
Possible Ratings	None		Some		Numerous
Score	**1**	**2**	**3**	**4**	**5**

SUPs or SDRs can be a cause for concern. Generally, the more SUPs or SDRs, the higher the level of concern. However, it is not as simple as the number of reports that should be considered. When considering the number of reports, several factors should be considered.

First, the relevancy of the report to the design or manufacturing of the part should be considered. Many SDRs are related to maintenance or operation issues. In contrast, if the maintenance or operational issues could be reduced by better design or manufacturing, then it would be considered more relevant.

Another factor that should be considered is the number of reports in context to the number of parts in service. Generally, in-service problems are more common for large companies that manufacture long-life service parts, or entire aircraft and aircraft engines. For these kinds of approval holders, the key consideration is repetitive problems, and/or if a pattern of discrepancies emerges over time.

Finally, for SDRs which are attributable to the design or manufacturing of the part, modification, or product, the overall magnitude or impact of the problem is relevant. To assess the overall magnitude/impact, consideration should be given to the effects of each failure as compared to the number of units in service. For example, if an SDR involved a particularly severe or dangerous problem, a small number of failures may be considered high magnitude/impact even if a large number of products or units in service are not affected. Conversely, numerous incidents of minor impact may not always be cause for alarm, even if the number of units in service is small.

Note: The PI will use databases in assessing this indicator. In the absence of such databases, the PI should assess the indicator based upon their knowledge of any issues specific to the PAH. If the PI has no knowledge of any issues, they should score the indicator as a 1.

No. 33	**Level of Experience**				
	How experienced is the applicant/PAH in designing, manufacturing, and testing the part, similar products, and/or similar modifications?				
Possible Ratings	Highly experienced		Moderately experienced		No experience
Score	**1**	**2**	**3**	**4**	**5**

It is important that the assessor *not* include the applicant/PAH's experience with the FAA certification process for this indicator. That will be addressed by other indicators. Therefore, some applicants may be considered as experienced with the design, manufacturing, or testing of a part, modification, or product, even though they have never gone through a certification/approval effort.

When considering this indicator, you should consider all three elements of experience (design, manufacturing, and testing) within the context of the application. For some disciplines, all three elements may not apply (that is, Flight Test may consider the applicant experience for flight testing the proposed modification only). In others, the applicant's experience in design, manufacturing, and testing may all be relevant in the context of the approval sought.

The relationship between the design, manufacturing, and testing of the part, modification, or product must not be overlooked. An applicant/PAH may not have recent design experience, but has been manufacturing previously designed parts successfully. The relevant combined experience of the applicant should be audited.

Other items to consider include:

- Generally, the more experience an applicant/PAH has using a technology, designing, manufacturing, or testing a part, similar products or similar modifications, the less need for concern. When auditing an applicant/PAH's experience, you should ask "have they done this before?" and "how recently have they done this?" Relevancy of experience should definitely be considered. New applicant/PAHs that have assembled a staff with relevant and recent experience might be considered more experienced than a well-established company.

- For established companies, evidence that skill levels are being maintained or upgraded is also important. Even a simple, well-established process can be complex to those who aren't experienced in or knowledgeable of the technology involved. If a company has experience, but it has not produced a part, modification, or product in some time, then it is important to consider if the company has retained its experience over the design or production lull.

- Experience with testing should similarly not be discounted. If an applicant/PAH is unfamiliar with test requirements or techniques, then there is more concern. Applicant/PAHs can be in the poor position of "learning as they go" or become dependent on other organizations to properly develop and conduct tests. In these cases, risk is obviously increased. On the other hand, an applicant/PAH may have a strong history in testing, but not specific experience in design or manufacturing. In some cases, the experience in testing can offset some of the concern of inexperience in other areas.
- It may be appropriate to consider the applicant/PAH's experience in managing, implementation, transition, or integration issues. This could be the case if design or production data was acquired from another entity versus in-house development, or if the organization is acting as an integrator of major components from partner organizations.

No. 34	**New/Emerging Technology**				
	To what extent does the applicant/PAH propose to use new or emerging technology/techniques in design, manufacturing, and/or testing such that the different technology may affect the airworthiness of the product (i.e., aircraft, aircraft engine, or propeller) or article?				
Possible Ratings	No extent	Small extent	Moderate extent	High extent	Great extent
Score	**1**	**2**	**3**	**4**	**5**

Introduction of a new or emerging technology into design, testing, or manufacturing, whether truly original or just new to the company, can create potential issues. Often what's considered new or emerging technology is in reality an extension or iteration of existing knowledge and methods.

The history of the technology can help determine if the new/emerging designation is really appropriate. If it has never been used at all, by anyone in civil aviation, or if it has never been used in this type of application, product, or system, then it should be considered new, and a potential issue.

The breadth of the technology's usage may also be relevant. If it's specific to this manufacturer, or perhaps to only a small number of companies, then there may be cause for concern. The absence of an established body of knowledge (for example, industry standards), is also a good indicator that heightened concern may be appropriate.

The product or item's certification basis can likewise tell you if the technology is truly new. If the end item or core technology was not covered by the CFR, or if any new or revised rules resulted from its certification, it should probably be considered new technology.

How well the new process is understood by the company, the FAA, and industry in general is an important consideration. Generally, there is a greater risk in projects that use new or emerging technology simply because there may be little service experience using it. If company personnel are trained or certified in the new process, and if industry standards exist, the potential for difficulties is generally lessened. If, on the other hand, the company is implementing a one-of-a-kind process, heightened concern is probably warranted.

The extent to which the company has demonstrated control of any new process is also key. Documented repeatability and reliability should be expected, whether in the design, testing, or production realm.

Appendix B. Category Parts List

1. Purpose. This appendix describes the CPL, which *may* be used by the PI when assessing the RBRT criticality indicator.

2. Category Parts List. The CPL contains a list of assemblies and part(s) that have been assigned a category rating of 1 or 2. To receive a category rating of 1, an 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, an 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.

3. Review of the CPL. The ANM-108 MIO manager will review the CPL every six months from the date of the last change or review. This review will be documented on a review/change tracking log that is attached to the CPL. The CPL, with the attached review/change tracking log, will be posted on the FAA Employees' website.

4. Structure of the CPL. Refer to figure B-1 of this appendix. The CPL is divided into five major areas: structural assemblies, structural elements, hydraulic pneumatic components, propulsion system components, and systems and equipment. Each of these areas is further identified by the applicable 14 CFR part. Each part listed is followed by a number, or numbers, in parentheses. This number identifies the applicable 14 CFR part and the designated category. For example, under "Structural Assemblies," "Fuselage" is followed by "23-1" and "25-1." This indicates that 14 CFR parts 23 and 25 are applicable, and that the fuselage is a Category 1 in both instances. If an assembly or part is not listed on the CPL, it will be considered as Category 3.

5. CPL Revision Process. A request to add a Category 1 or 2 assembly or part to the CPL, to change the category of an existing assembly or part on the CPL, or to remove an existing assembly or part from the CPL, may be generated from any source (for example, PI or ACO). Use the following procedure to revise the CPL (refer to figure B-2):

> **Note:** A request to change the category of an existing CPL 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 (for example, unpressurized vs. pressurized), a request to change the category for a specific part 23 aircraft may be warranted if the category rating of 1 is not appropriate.

a. Prepare a Part Categorization memo and include the following as a minimum (refer to sample memos in figures B-3, B-4, and B-5):

(1) Identify and fully describe the applicable assembly or part.

(2) Identify the applicable 14 CFR part (that is, part 23, 25, 27, 29, 31, 33, or 35).

(3) Describe the reason for adding the assembly or part, for changing the category of an existing assembly or part, or for removing an existing 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 assembly or part should be added. Omit this data for a change or removal request.

(6) When requesting a change to the category of an existing assembly or part, or requesting removal of an existing assembly or part, include its current category. Omit this data for an add request.

b. The MIDO/CMO manager reviews the memo to verify that it contains the minimum required information and coordinates with the requester, if necessary. The MIDO/CMO will then send the Part Categorization memo to its respective MIO manager.

c. The MIO manager retains a copy of the request and, if the part is assigned to another directorate, forwards the memo to that MIO manager. The 14 CFR responsibilities for MIO managers are as follows:

(1) Parts 23 and 31: ACE-180.

(2) Part 25: ANM-108.

(3) Parts 27 and 29: ASW-180.

(4) Parts 33 and 35: ANE-180.

d. The responsible MIO manager forwards the memo to a directorate specialist. The directorate specialist will investigate and coordinate the data described in the memo with the appropriate ACO. The directorate specialist will then complete the “Coordination” section of the Part Categorization memo as follows:

(1) Indicates whether the action taken is to “Accept” or “Deny” the request.

(2) If the action is to accept either a request to add an assembly or part or to change an existing category, assigns the appropriate category to the 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 directorate specialist forwards the memo to the responsible MIO manager. The MIO manager will sign the completed memo and forward it to the originating MIO manager. The responsible MIO manager will retain a copy of the memo as a reference for future request reviews.

f. The originating MIO manager will file a copy of the memo, notify the originating MIDO/CMO, and send a copy to the manager, ANM-108.

g. The ANM-108 MIO manager updates the CPL, documents the new revision date in the CPL review/change log, and disseminates the revised CPL to the other MIO managers and AIR-200.

h. AIR-200 will post the updated CPL on the FAA Employees' website.

Figure B-1. Sample Category Parts List

Revision G dated 8/18/09

AIRCRAFT CERTIFICATION SERVICE CATEGORY PARTS LIST

Note: The Production and Airworthiness Division and the Manufacturing Inspection District Offices use the Category Parts List as one consideration to determine resource allocation. The CPL is a notional tool that has no scientific basis. It was developed for internal use only leading to the frequency of FAA surveillance of new products and parts manufacturing facilities. The CPL was not coordinated with the industry. The industry may or may not agree with the CPL content. The CPL posted on the internet is for information only and if used for other purposes than what is stated above it is solely at the user's risk.

Structural Assemblies	CFR part	Structural Elements	CFR part	Hydraulic Pneumatic Components	CFR part	Propulsion System Components	CFR part	Systems and Equipment	CFR part
Fuselage (23-1), (25-1)	23, 25	**Fuselage Structural Elements** Pressure Bulkheads (23-1), (25-1) Keel Beam (25-1) Longeron/Stringer (25-2) Floor Beam (25-2) Plates/Skins (25-2) Fuselage to Wing Attach Fittings (25-1) Stabilizer to Fuselage Attach Fittings (25-1) Gear to Fuselage attach Fittings (25-1) Door Hinge (on Fuselage) (25-1) Fuselage Panels (23-1), (25-1)	23, 25	Hydraulic Main Pump (23-1), (25-2), (27-1), (29-1) Main Accumulator (25-2) Main Reservoir (25-2) Auxiliary Pump (25-2)	23, 25, 27, 29	Software Thrust (EEC) (23-1), (25-1)	23, 25	**Electrical Power System** Alternator/Generator Drive System (23-2),(25-2) AC Generator-Alternator (23-2) (25-2) AC Inverter (23-2) (25-2) Phase Adapter (25-2) AC Regulator (25-2) **Fire Protection** Smoke Detection (25-2), (27-2), (29-2) Fire Detection (25-2), (27-2), (29-2) Overheat Detection (25-2), (27-2), (29-2) Extinguishing System (25-2), (27-2), (29-2) Fire Bottle-Fixed (25-2), (27-2), (29-2)	23, 25, 27, 29
Flight Control Surfaces Ailerons (23-1), (25-1) Rudder (23-1), (25-1) TE Flaps (23-1), (25-2) LE Devices (25-2) Elevator (23-1), (25-1) Spoilers (25-2)	23, 25	**Flight Control Structural Elements** Aileron Tabs (25-2) Jackscrew (23-1), (25-1) Bellcranks (23-1), (25-1) Flight Control Cables (23-1), (25-1)	23, 25	Flight Control Servo Actuators (25-2), (27-1), (29-1) Flap Actuator (25-2) Rudder Actuator (25-2) Stabilizer Actuator (25-2)	25, 27, 29	Thrust Reversers (23-1), (25-2) Auxiliary Power Units (23-1) FADEC (23-1)	23, 25	**Fuel System** Boost Pumps (23-1), (25-2), Transfer Valves (23-1), (25-2) Fuel S.O.V. (23-1), (25-1) Digital Fuel Flow System (23-2) (25-2) Fuel Dump (25-2) Fuel Hose (Single engine applications ONLY) (23-2) (27-2), (29-2) Fuel Quantity Indicator (23-2) (25-2), (27-2), (29-2) Fuel Flow Indicating (27-2), (29-2) (23-2) Fuel Pressure Indicating (27-2), (29-2) (23-2) Fuel Pump (25-2), (27-1), (29-1) **Engine Lubrication System** Oil Cooler (Single engine applications ONLY) (23-2) (27-2), (29-2)	23, 25, 27, 29

Sample

Page 1 of 2

Figure B-2. CPL Revision Process Flowchart

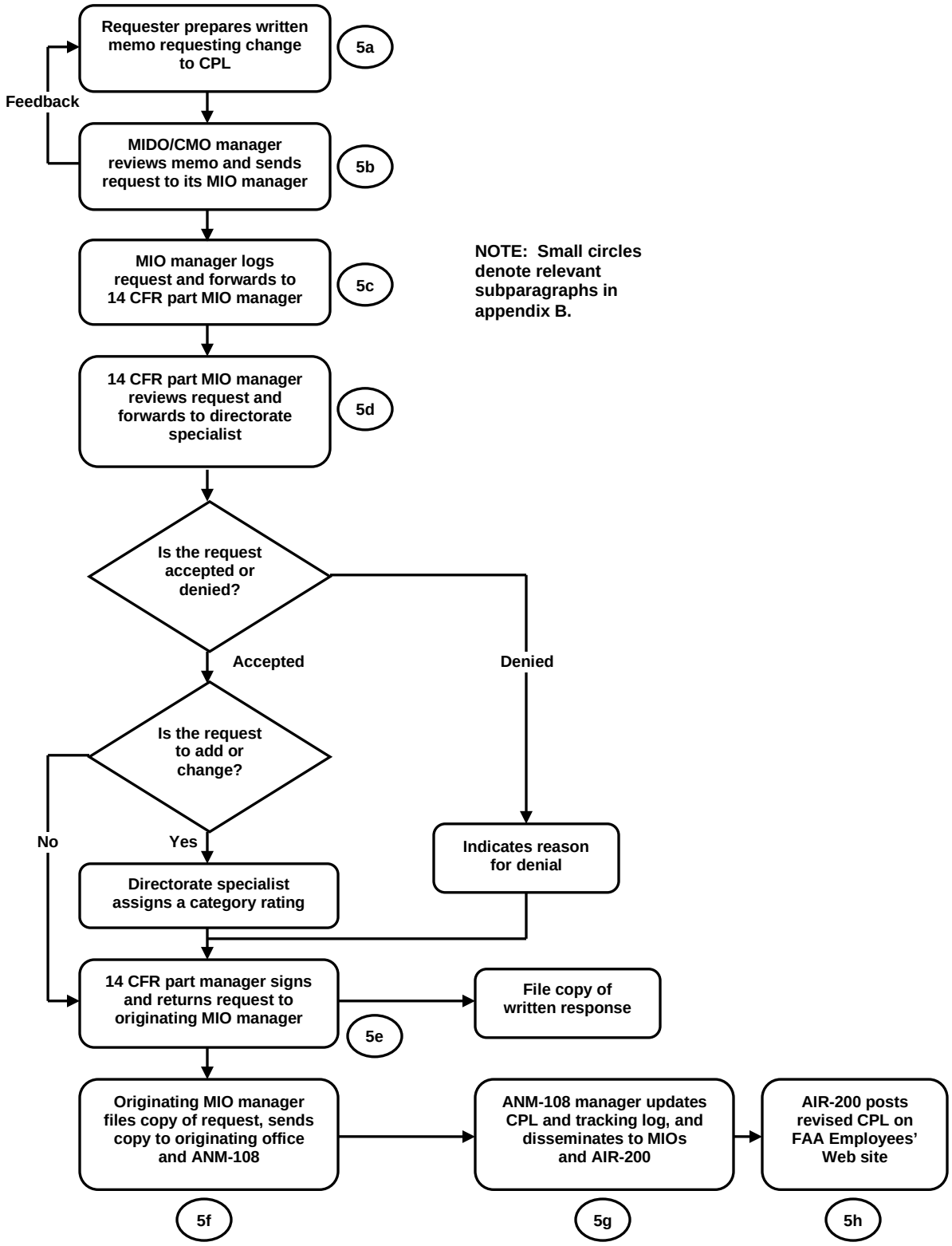


Figure B-3. Sample Part Categorization Memo for Requesting an Addition to the CPL

Federal Aviation Administration

Memorandum

Date: March 6, 2012

To: Manager, ANM-108

From: Duke E. Season, Manager, ANE MIDO-42
Donald Miller, VIA Manager, ANE-180

Prepared by: James Staney

Subject: **ACTION:** Part Categorization

Sample

We request to add the following part to the Category Parts List (CPL):

1. Part name: Fuel cell door.

2. 14 CFR part affected: 25.

3. Reason for adding part to CPL: Paint contamination on fuel cell door for Boeing 737-300 led to issuance of an Airworthiness Directive (AD).

4. The following applicable supporting data are attached: A copy of AD #2001-15-01.

5. Placement of part on CPL: Systems and Equipment, Fuel System.

Attachment
AD #2001-15-01

COORDINATION

Action on request: Accept

Category assigned: 2

C.P. Ells

C.P. Ells

Date: April 3, 2012

Figure B-4. Sample Part Categorization Memo for Requesting a Change to the CPL

Federal Aviation Administration

Memorandum

Date: March 26, 2012

To: Manager, ACE-180

From: Dewey Revu, Manager, Seattle MIDO
Kathleen Beall, VIA Manager, ANM-108

Prepared by: Ronald Reynolds

Subject: **ACTION:** Part Categorization

Sample

We request to change the existing category on the Category Parts List (CPL) for the following part.

1. Part name: Flight compartment window.
2. 14 CFR part affected: 23.
3. Reason for changing existing category: Category 1 is not appropriate for a Cessna 150 aircraft.
4. The following applicable supporting data are attached: Cessna 150 performance data.
5. Placement of part on CPL: Systems and Equipment, Window-Windshield System.
6. Current Category: 1.

Attachment
Cessna 150 performance data

COORDINATION

Action on request: Accept

Category assigned: 2

V. Small

V. Small

Date: April 23, 2012

Figure B-5. Sample Part Categorization Memo for Requesting Removal of an Assembly/Part from the CPL

Federal Aviation Administration

Memorandum

Date: April 26, 2012

To: Manager, ANM-108

From: I.C. Rotors, Manager, ASW MIDO-42
Michael Bauer, VIA Manager, ASW-180

Prepared by: Molly Gale

Subject: **ACTION:** Part Categorization

We request to remove 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 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: Systems and Equipment, Brake System and Assembly Components.

6. Current Category: 2.

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

Sample

COORDINATION

Action on request: Deny

The request to remove the part from the CPL has been denied because there are still operators of Model 707 aircraft that would need replacement deboost valves. As a result, other PAHs may apply for PMA to manufacture brake deboost valves.

C.P. Ells

C.P. Ells

Date: May 23, 2012

Appendix C. RBRT Assessment Validation Plan

1. Purpose. This appendix explains the structure and application of the RBRT assessment validation plan. The objective of the plan is to ensure that RBRT assessments rank PAHs in order of risk level associated with producing nonconforming products, articles, or parts. It also defines a basis for continually refining and modifying the RBRT assessment tool as required to achieve this objective.

2. Validation of Ratings for the RBRT Indicators. The validation is conducted as an integral part of the annual assessment of facilities described in chapter 3, section 2 of this order. It includes elements built directly into the core structure of the RBRT assessment tool and its basic application processes. As such, this validation provides a real-time validity check on the output of the RBRT assessment tool and specifically the risk levels generated by the tool.
This validation not only provides managerial oversight for the process, but may also allow for a different perspective in determining the final ratings for the RBRT organizational and technical indicators.

a. Data Source(s): The RBRT Quality System Assessment Sheet(s) located in CMIS.

b. Parties Responsible for Validation: Facility PI and MIDO/CMO manager.

c. Description: Chapter 3, section 2 of this order, as well as the RBRT assessment tool, requires the MIDO/CMO manager to review each RBRT Quality System Assessment Sheet within the RBRT assessment tool for agreement with the assigned risk level. In so doing, the MIDO/CMO manager is provided an opportunity to help ensure consistency between and among PIs in the application of the RBRT assessment tool, and to provide a second opinion for complex or ambiguous cases.

d. Expected Outcome: This validation provides a first level, normative validity check of the RBRT assessments.

Appendix D. Preparation of Clauses for Contracts for Support Services

1. Purpose. This appendix provides sample contract clauses and a sample certificate of nondisclosure for use in contracts for obtaining services to support QSAs, information systems, and system analyses.

2. Sample Clauses and Attachment. The following sample clauses provide the minimum requirements to be included in a contract for support services. Figure D-1 shows a sample attachment to the Confidentiality of Information clause requiring support service personnel to agree to its terms and conditions.

a. The following clause is applicable to all contractors:

H.1 Confidentiality of Information.

a. To the extent that the work under this contract requires that the contractor be given access to confidential or proprietary business or technical information belonging to the Government or other companies, designees, contractors, or competitors, or to the extent that in performing the work under this contract, the contractor gains access to Government data through any means, then the contractor must, after receipt thereof, treat such information as confidential and agree not to appropriate such information to its own use or to disclose such information to third parties unless specifically authorized by the contracting officer in writing; however, the foregoing obligations must not apply to the following:

(1) Information that, at the time of receipt by the contractor, is in public domain.

(2) Information that is published after receipt thereof by the contractor or otherwise becomes part of the public domain through no fault of the contractor.

(3) Information that the contractor has in its possession at the time of receipt thereof and was not acquired directly or indirectly from the Government or other companies.

(4) Information that the contractor can demonstrate was received by it from a third party who did not require the contractor to hold it in confidence.

b. The contractor must execute the certificate set forth as attachment 1 for each employee who will participate as an auditor under this contract. The certificate must be presented by the contractor’s employees or forwarded by the FAA to various companies who may be audited under the contract.

Figure D-1. Sample Certificate of Nondisclosure

Attachment 1. Certificate of Nondisclosure

The undersigned hereby agrees to the terms and conditions set forth in the clause below:

H.1 Confidentiality of Information.

a. To the extent that the work under this contract requires that the contractor be given access to confidential or proprietary business or technical information belonging to the Government or other companies, designees, contractors, or competitors, or to the extent that in performing the work under this contract, the contractor gains access to Government data through any means, then the contractor must, after receipt thereof, treat such information as confidential and agree not to appropriate such information to its own use or to disclose such information to third parties unless specifically authorized by the contracting officer in writing; however, the foregoing obligations must not apply to the following:

(1) Information that, at the time of receipt by the contractor, is in public domain.

(2) Information that is published after receipt thereof by the contractor or otherwise becomes part of the public domain through no fault of the contractor.

(3) Information that the contractor has in its possession at the time of receipt thereof and was not acquired directly or indirectly from the Government or other companies.

(4) Information that the contractor can demonstrate was received by it from a third party who did not require the contractor to hold it in confidence.

b. The contractor must execute the certificate set forth as attachment 1 for each employee who will participate as an auditor under this contract. The certificate must be presented by the contractor's employees or forwarded by the FAA to various companies who may be audited under the contract.

Sample

Authorized Contractor Agent	Date	Contractor Employee	Date

b. The following clause is applicable to support service personnel who will support QSAs and should be used in conjunction with clause H.1:

> H.2 Relationships. The contractor must provide support to the Government by completing work assigned under this contract. Support must be provided in the following areas: auditing of quality and engineering functions; collection, audit, and processing of data; and written documentation of incidents not in compliance with QSA criteria. The contractor must not provide technical direction under the contract. The contractor must abide by any limitations of access and entry to proprietary or sensitive processes or systems that the Government may stipulate. Although the effort under this contract may include the collection and processing of data, as well as the formulation of noncompliances and recommendations, the final disposition of all information must remain the sole province of the Government.

c. The following clause is applicable to support service personnel who will support database management or system analysis and should be used in conjunction with clause H.1:

> H.2 Relationships. The contractor must provide support to the Government by completing work assigned under this contract. Support must be provided in the following areas: input, analysis, and trending of data; and compilation of analytical reports. The final disposition of all information must remain the sole province of the Government.

Appendix E. Preparation of the Notification Letter to a PAH or Associate Facility

1. Purpose. This appendix provides instructions and sample paragraphs for preparing a notification letter to a PAH or associate facility for a scheduled audit.

2. Information to Include in the Notification Letter. Figure E-1 provides sample paragraphs with the minimum information to include in a notification letter to a PAH or associate facility. Additional paragraphs may be added as necessary to provide specific directorate or AIR-100/200 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. In addition, when support service personnel are used to support an audit, this paragraph must state the general purpose of the support service personnel, advise use of the FAA certificate of nondisclosure, request special requirements, and identify the support service personnel.

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 3-36a(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 ACO or MIO manager. 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 E-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 ACO or MIO manager. 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 MIDO or CMO and that questions relative to the conduct of the audit be addressed to the team leader or principal auditor.

Figure E-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/associate facility), 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 (start date) to (end date) 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.) (name) who may be reached at (telephone number). (His/Her) address is (office address). The audit team will be supported by a support service person who will be performing specific duties on behalf of the FAA. This person is identified below. This person will sign an FAA certificate of nondisclosure that will be forwarded to the facility via the FAA (principal inspector/assigned engineer) before the start of the audit. Please inform the FAA of any special requirements necessary for this person to access your facilities and restricted areas.

Support Service Person's Name	Company Affiliation
(Name)	(Company)

Attendance by a representative of senior management 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 escorts 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 pertaining to your FAA-approved quality system that was previously requested by the team leader.

One of the primary features of the QSA is continuous quality improvement. As part of this process, it is important for us to know 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 Customer Feedback Report, and return it in the enclosed prepaid self-addressed envelope 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.

Sample

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

Form Approved
OMB No. 2120-0605

U.S. Department of Transportation
Federal Aviation Administration

QUALITY SYSTEM AUDIT FEEDBACK REPORT

QSA No. **(1)** _____

Name of Audited Facility: **(2)** _____

Dates Audited: **(3)** _____

As part of the Federal Aviation Administration (FAA) and industry continuous improvement efforts for the Quality System Audit (QSA), this form is provided for your use in furnishing the FAA with comments regarding the conduct of the audit recently conducted at your facility. We sincerely encourage you to tell us how we did, and thank you for the time you will take to support our quality improvement and customer service objectives.

Please check the appropriate rating in each of the tables below, and provide any comments that you deem appropriate.

1. Pre-audit arrangements	Unsatisfactory	Poor	Satisfactory	Good	Excellent
• Timeliness	☐	☐	☐	☐	☐
• Coordination/Planning	☐	☐	☐	☐	☐

Comments/recommendations for improvement:

2. Pre-audit conference	Unsatisfactory	Poor	Satisfactory	Good	Excellent
• Communication	☐	☐	☐	☐	☐
• Presentation	☐	☐	☐	☐	☐
• Purpose of audit explained	☐	☐	☐	☐	☐

Comments/recommendations for improvement:

FAA Form 8100-7 (09/12)

Sample

Figure E-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:

4. Post-audit conference	Unsatisfactory	Poor	Satisfactory	Good	Excellent
• Communication	☐	☐	☐	☐	☐
• Explanation of executive summary	☐	☐	☐	☐	☐
• Explanation of followup actions	☐	☐	☐	☐	☐

Comments/recommendations for improvement:

5. Conduct of the audit	Unsatisfactory	Poor	Satisfactory	Good	Excellent
• Team professionalism	☐	☐	☐	☐	☐
• Overall conduct of the QSA team	☐	☐	☐	☐	☐

Comments/recommendations for improvement:

Sample

Signature (optional) Date

Please return completed form to:

(4)

FAA Form 8100-7 (09/12)

Appendix F. Notification Letter Requirements

1. Purpose. This appendix provides a tabular summary of the primary notification letter requirements identified in chapter 3, section 3, part 3 of this order.

2. Description. Figure F-1 provides a summary by facility type of notification letter requirements for which the lead audit office is responsible. It identifies the type of notification activity required and when the notification activity should be accomplished.

Figure F-1. Notification Letter Requirements Summary

FACILITY TO BE AUDITED	NOTIFICATION ACTIVITY	TIMETABLE (calendar days before audit)
♦ **PAH** ♦ **Associate Facility**	❶ Letter to facility	50
(Within area of responsibility) Ref. para. 3-30a.	❷ Copy to designated team leader or principal auditor	50
	❸ Copy to PI/AE	50

Appendix G.

Reserved.

Appendix H. Standardized Audit Criteria for PAHs and Associate Facilities

1. Purpose. This appendix provides standardized audit criteria used to document the audit of the system elements listed in figure H-1 for PAHs and associate facilities.

Figure H-1. System Elements

Section No.	System Element	Appendix H Page No.
1	Organizational Management	H-2
2	Design Control	H-11
3	Software Quality Assurance	H-15
4	Manufacturing Processes	H-23
5	Manufacturing Controls	H-44
6	Supplier Control	H-68

2. Description of System Elements Section Format. Each section of this appendix addresses one of the six system elements listed in figure H-1. Each section is formatted as follows:

a. System Element Description. This is a brief description of what the system element is intended to accomplish or control.

b. System Element Standardized Audit Criteria. The audit criteria are located in this order and can also be found as part of the order located on the FAA's website, and are formatted as follows:

(1) Standardized Audit Criteria. Each criterion is identified by a numbered question within a box. The format of each question number is based on the specific system element section number identified in figure H-1.

(2) Applicability. This identifies whether the criterion applies to a specific type of production approval (PC, PMA, and TSO authorization). A table format is used that identifies the type of facility across the top and a code for the type of applicability in the first column. The codes for the types of applicability are defined as follows:

(a) A. This row within the applicability block is used to identify the 14 CFR source requirements applicable to a specific facility. The applicability to a specific facility is indicated by the specific 14 CFR part or section reference (for example, § 21.137, Quality system).

(b) E. This row within the applicability block is used to identify the enforceable 14 CFR requirement applicable to a specific facility. The applicability to a specific facility is indicated by the enforceable 14 CFR part or section reference (for example, § 21.146, Responsibility of holder).

(c) P. This applicability code is used within the "A" row to identify criteria that reflect industry best practices and accepted total quality management principles. These practices and principles are often contained in FAA-approved data or other facility procedures. The auditor must determine the actual level of application at each facility.

(d) N. This applicability code is used within the "A" row or "E" row to indicate that the criterion is generally not applicable at a specific facility.

Note 1: Applicability indicated for a specific type of production approval includes any associate facilities established under that approval.

Note 2: When a "P" or "N" is used in the applicability table, a criterion is applicable and enforceable if it is addressed in the approval holder's FAA-approved data/quality manual. (Refer to § 21.146, § 21.316, or § 21.616)

(3) Statement of Condition. The statement of condition provides guidelines, not requirements that may assist the auditor in determining adherence to the criteria. These guidelines are not the only acceptable means of implementation. Auditors may identify additional practices in FAA-approved data or other facility procedures that indicate adherence to the requirements of the criteria.

Section 1. Organizational Management

1. System Element Description. This system element addresses the audited facility's organizational management structure and responsibilities for design control and production functions. This includes procedures and methods used to notify the FAA of specific conditions as required by the applicable CFR (such as recording, reporting, investigation, determining cause, and effecting corrective actions of significant or reported failures, malfunctions, or defects). This function also addresses internal audits whereby the facility ascertains its own abilities and procedural compliance to established policy and guidance.

2. System Element Standardized Audit Criteria. The following criteria are used to document the audit of this system element.

101. Is the production approval/authorization retained at the audited facility in which the product is manufactured and was it available to the FAA upon request?

Applicability

	PC	PMA	TSO
A	§ 21.146	§ 21.316	§ 21.616
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that the production certificate is available as required. This should include all attachments, such as the Production Limitation Record (PLR).

102. Is the audited facility operating within the production limitations of the production approval?

Applicability

	PC	PMA	TSO
A	§ 21.142	§ 21.309 § 21.316	§ 21.601
E	§ 21.146	§ 21.9 §21. 316	§ 21.9 § 21.616

Statement of Condition

a. There is objective evidence that the audited facility is manufacturing, for sale/installation, those products it is authorized to manufacture under a production approval.

103. Has the PAH provided to the FAA a document describing how its organization will ensure compliance with provisions of the regulatory subpart?

Applicability

	PC	PMA	TSO
A	§ 21.135	§ 21.305	§ 21.605
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. The policy document includes:

(1) A description of assigned responsibilities and delegated authority.

(2) A description of the functional relationship of those responsible for quality to management and other organizational components.

104. NO LONGER APPLICABLE.

105. Has the PAH provided to the FAA a quality manual describing its quality system? Are the documents prepared in the English language and retrievable in a form acceptable to the FAA?

Applicability

	PC	PMA	TSO
A	§ 21.138	§ 21.308	§ 21.608
E	§ 21.138	§ 21.308	§ 21.608

Statement of Condition

a. There is objective evidence that the quality manual, including electronically stored versions, is available in the major quality and inspection areas, and is subject to periodic review and revision.

(1) Everyone associated with the quality system is performing within their described assigned responsibilities and delegated authority.

(2) A table or organizational chart describes the functional relationship of the quality organization to management and to the other organizational components.

(3) A description of assigned responsibilities and delegated authority to make changes to the quality system is provided.

(4) The individual identified for managing the quality program has the necessary authority and organizational freedom.

106. Is quality system data, and changes thereto, submitted to the FAA?

Applicability

	PC	PMA	TSO
A	§ 21.150	§ 21.320	§ 21.620
E	§ 21.150	§ 21.320	§ 21.620

Statement of Condition

a. Each change to the quality system is subject to review by the FAA.

b. The holder of a production approval must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its product or article.

107. Are tags, forms, and other documents described and controlled?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures include, but are not limited to—

(1) A sample of each tag, form, and other document with instructions for use as applicable.

(2) A formal change control procedure.

b. There is objective evidence of observance to established procedures.

108. Has the audited facility established procedures for control of quality records?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that—

(1) Procedures are maintained for identifying, storing, protecting, retrieving, and retaining quality records.

(2) Quality records are retained for at least 5 years.

(3) Quality records having critical components are identified and retained for at least 10 years.

(4) TSO authorization technical design data necessary to determine conformity and airworthiness of each article produced, is retained by the manufacturer.

(5) Records are legible, complete, and accurate.

109. Has the PAH made appropriate notification to the FAA with regard to undue burden, relocation, or change to manufacturing facilities?

Applicability

	PC	PMA	TSO
A	§ 21.139	§ 21.309	§ 21.609
E	§ 21.146	§ 21.320	§ 21.620

Statement of Condition

a. Has “no undue burden” been determined by the FAA for PAH manufacturing facilities located outside the United States?

b. Has FAA approval been obtained before location changes to any PAH manufacturing facilities were made?

c. Has the PAH notified the FAA in writing of any change to its manufacturing facilities that may affect the inspection, conformity, or airworthiness of its product or article?

110. Are failures, malfunctions, and defects reported to the FAA?

Applicability

	PC	PMA	TSO
A	§ 21.3	§ 21.3	§ 21.3
E	§ 21.3	§ 21.3	§ 21.3

Statement of Condition

a. The organization has established procedures for reporting failures, malfunctions, and defects.

b. The organization's procedures for reporting failures, malfunctions, or defects—

(1) Establish definitions of conditions that must be reported to the FAA.

(2) Establish a method of documenting reportable conditions and a method for reporting them to the FAA.

(3) Require prompt audit of each condition to determine if it is reportable to the FAA.

(4) Require that the condition be reported to the FAA within 24 hours (with provisions for weekends and holidays) after it has determined that the failure, malfunction, or defect required to be reported has occurred.

(5) Require retention of each reported condition document, the FAA response, and the organization's disposition of the condition.

c. There is objective evidence of adherence to these procedures.

111. Are service bulletins and maintenance manuals approved by authorized personnel and coordinated with FAA engineering?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures define specific organizational and individual responsibilities for issuing service bulletins, maintenance manuals, SDRs, and other related communication.

b. Changes are approved by authorized personnel and coordinated with FAA engineering.

c. There is objective evidence of observance to established procedures.

112. Are there procedures for receiving and processing feedback on in-service failures, malfunctions, and defects?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) A requirement to include a process for assisting the design approval holder to address any in-service problem involving design changes.

(2) A requirement to include a process for assisting the design approval holder to determine if any changes to the Instructions for Continued Airworthiness are necessary.

(3) Determination of appropriate manufacturing, design, or Instructions for Continued Airworthiness responsibilities for the reported problem.

(4) A system of tracking for accountability.

(a) Records are generated and maintained.

(b) Contents of each record used include when the report was received, what was reported, and actions taken.

(c) Requirements established that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

113. Are service problems (both design and manufacturing), unairworthy conditions, unsafe features, or unsafe characteristics reported by the FAA or users investigated? Are prompt corrective actions taken by the audited facility?

Applicability

	PC	PMA	TSO
A	§ 21.3	§ 21.3	§ 21.3
E	§ 21.3	§ 21.3	§ 21.3

Statement of Condition

a. Procedures provide for—

(1) A method of investigating, identifying, locating, and reporting suspected unsafe products.

(2) Prompt corrective action, which includes, at a minimum—

(a) Root cause determination and correction of deficient design or manufacturing.

(b) A means of purging, tracking, and accountability of known unsafe products.

(3) Investigating reports of unairworthy conditions or unsafe features or characteristics reported by the FAA.

(4) Reporting investigation results and actions taken or proposed to the FAA.

b. There is objective evidence of observance to established procedures.

114. Do procedures provide a method to notify users and recall products, when necessary, when nonconformances are suspected or known to exist in products in service?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

115. Is there a means for keeping users of the product/article informed of service information, including field purges?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for informing product users of service difficulties, and of required field purges for suspected or known unsafe conditions.

b. There is objective evidence of observance to established procedures.

116. Are there procedures for planning, conducting, and documenting internal audits?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Planned and documented internal audits of personnel, procedures, operations, equipment, material, processes performed, and records in all major functional areas.

(2) Criteria for conducting compliance, systems, and product audits.

(3) A formal audit schedule that is available, approved by management, and followed.

(4) Requirements for the qualification and training of personnel who are performing the audits.

(5) Auditors who are independent of the activity being audited.

(6) Special audits when significant customer problems are detected, or when there are significant changes to processes or systems.

(7) Methods for identifying and reporting nonconformance and obtaining required corrective action.

117. Are results of internal audits reported to the appropriate facility personnel?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) A requirement to report the results of internal audits to the manager responsible for implementing corrective and preventive actions.

(2) Review of internal audit results by personnel having responsibility for the areas audited.

(3) Root cause determination and development of appropriate and prompt corrective action.

(4) Followup audits (as necessary) to ensure effective implementation of corrective action.

(5) Actions taken to determine if changes are required to the quality system or other similar processes (which may not have been audited) in addition to correcting reported noncompliance.

118. Are there procedures for implementing corrective and preventive actions to eliminate the causes of an actual or potential nonconformity to the approved design, or noncompliance with the approved quality system?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence of observance to established procedures.

119. Are there procedures for identifying, analyzing, and initiating corrective action for products or articles that have been released from the quality system, but do not conform to applicable design data or quality system requirements?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence of observance to established procedures.

Section 2. Design Control

1. System Element Description. The methods for approving, controlling, and documenting FAA-approved designs and design changes. Specific functions necessary include the planning and integration of the audited facility's procedures for continuously maintaining the integrity of design data, drawings, part lists, and specifications necessary to define the configuration and the design features of the product. This includes software used in type-certificated aircraft or related products (airborne software).

2. System Element Standardized Audit Criteria. The following criteria are used to document audit of this system element.

201. Are there procedures for the control of technical data/documents and do they include storage, maintenance, and protection?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Storing, maintaining, and protecting design data/documents to preserve their integrity, including magnetic storage media used as part of design documentation, if applicable.

(2) Identification of technical data/documents.

(3) Indication of technical data/documents approval, including FAA approval.

(4) A list of technical data/documents necessary to define configuration of the FAA-approved design.

b. There is objective evidence of observance to established procedures.

202. Are there procedures for controlling design data and subsequent changes?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence of—

(1) Use of current, correct, and approved data.

(2) Control of design and technical data document issuance, including persons authorized to obtain documents and for retrieval of obsolete documents.

(3) The method for making available to or notifying employees concerning changes in technical data.

(4) Verification that correct documents are in use for the product being produced.

(5) Current design and technical data document distribution lists.

(6) A complete and current file of technical data, including design drawings and specifications.

(7) Electronically stored and transmitted technical design and quality data are adequately controlled.

203. Do the manufacturing, quality, and service/support organizations participate in the review of design and technical data changes?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for the manufacturing organization, quality organization, and service/support organization to review design and technical data changes before release to ensure the product can be produced in conformity to an FAA-approved design.

(1) The product can be properly audited and verified to be in conformity to an FAA-approved design. Inspection equipment is available or can be procured that will adequately verify conformity to FAA-approved design, and that can be controlled for accuracy, when required.

(2) Service/product organization review design data changes before release to ensure appropriate airworthiness and service documents that are affected by the design change are revised as required.

b. There is objective evidence of observance to established procedures.

204. NO LONGER APPLICABLE.

205. Are changes to technical data referenced on FAA-approved design data (specifications, installation instructions [when applicable], and airborne software documentation) appropriately documented and approved?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide that changes to technical data referenced on FAA-approved design data are documented and approved in the same way as changes to product design.

b. There is objective evidence of observance to established procedures.

206. Are minor design changes approved under a method acceptable to the FAA?

Applicability

	PC	PMA	TSO
A	§ 21.95	§ 21.319	§ 21.619
E	§ 21.95	§ 21.319	§ 21.619

Statement of Condition

a. There is objective evidence that—

(1) Minor changes in a type design are approved by the FAA or by a method acceptable to the FAA. For example, an FAA-approved procedure whereby the PAH approves minor design changes.

(2) For TSO articles, all necessary revised data are submitted to the FAA when minor changes are made and agree with any part number plan specified in the original application.

(3) For PMA, a minor change to the design of an article has no appreciable effect on the approval basis.

b. There is objective evidence of observance to established procedures.

207. Are major design changes, including process specification changes, submitted to the FAA for approval?

Applicability

	PC	PMA	TSO
A	§ 21.97 § 21.99	§ 21.319	§ 21.619
E	§ 21.97 § 21.99	§ 21.319	§ 21.619

Statement of Condition

a. There is objective evidence that—

(1) Major design changes are submitted to the FAA for approval, including changes to manufacturing and special process specifications.

(2) Design changes resulting from applicable ADs, and design changes, which contribute to the safety of the product, are submitted to the FAA for approval.

208. Have design changes necessary to correct unsafe conditions been incorporated into the FAA-approved design, when applicable?

Applicability

	PC	PMA	TSO
A	§ 21.99	§ 21.307	§ 21.607
E	§ 21.99	§ 21.307	§ 21.607

Statement of Condition

a. There is objective evidence that design changes necessary to correct unsafe conditions have been incorporated into the FAA-approved design. This evidence may include one or more of the following:

(1) Identification of applicable ADs.

(2) Tracking the status of AD incorporation.

(3) Furnishing the customer with the AD incorporation status at the time the product is delivered.

209. Are the instructions for continued airworthiness kept current with design changes, when appropriate, and made available to appropriate persons?

Applicability

	PC	PMA	TSO
A	§ 21.50	§ 21.50	P
E	§ 21.50	§ 21.50	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

210. Is descriptive data and information on FAA-approved design changes resulting from incorporation of ADs or that contribute to the safety of the product made available to users of the product?

Applicability

	PC	PMA	TSO
A	§ 21.99	P	P
E	§ 21.99	N	N

Statement of Condition

a. There is objective evidence that all applicable descriptive data and information covering FAA-approved design changes or improvements that contribute to the safety of the product are made available to product users.

211. If commercial parts are used, has the PAH provided to the FAA a listing of parts defined as commercial, along with additional information, as required?

Applicability

	PC	PMA	TSO
A	§ 21.50	§ 21.50	N
E	§ 21.50	§ 21.50	N

Statement of Condition

a. Procedures provide for the submittal of commercial parts list and supporting data for all parts designated as commercial.

Section 3. Software Quality Assurance

1. System Element Description. This system element addresses the planning and integration of the audited facility's procedures for continuously maintaining the integrity of software used in type-certificated aircraft or related products (airborne software), and the integrity of software and related hardware used for product acceptance. Document DO-178, Software Considerations in

Airborne Systems and Equipment Certification (current edition), of the Radio Technical Commission for Aeronautics (RTCA), or comparable means, should be used as guidance for control of airborne software.

2. System Element Standardized Audit Criteria. The criteria used to document the audit of this system element are divided into two parts: Part A, Airborne Software, and Part B, Product Acceptance Software.

Part A. Airborne Software

301. Is there a Software Configuration Management Plan or procedure to control airborne software configuration?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Installation of the correct version of the software in the delivered product in accordance with the FAA-approved design.

(2) A method by which controlled software containing the FAA-approved design data is transitioned into production. The media containing the software installed in the product is directly traceable to the Software Configuration Management library.

(3) Documentation of integration of software with hardware to specify a unique version for incorporation into the product.

(4) Cross-reference of software documents to their associated software.

(5) The technical data/documents control system that includes software identification methods at the media level and at the product level. The media level identification is incorporated into the software, and the product level identifications are marked on the outside of the product indicating software configuration.

b. There is objective evidence of observance to established procedures.

302. Is there a Configuration Index Document (CID) listing all software documents under configuration control and defining the hardware and software part numbers?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for traceability of hardware and software part numbers to the drawing control system.

b. There is objective evidence of observance to established procedures.

303. Are there practices and procedures for reporting, tracking, and resolving software problems?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Corrective action procedures, for problems found subsequent to the FAA-approved design, include provisions for airborne software and hardware/software combinations. Procedures may parallel or be part of hardware corrective action procedures.

b. Problem reports addressing changes to software code are under change control.

c. The production test procedures have been modified to reflect the software change and successfully executed against the changed version.

d. There is objective evidence of observance to established procedures.

304. Is obsolete and noncurrent software media recalled and purged, when applicable?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Configuration control procedures for airborne software include methods of purging software for removal of obsolete and noncurrent media, when applicable. Procedures may parallel or be part of hardware purging procedures.

b. Procedures include methods to identify, store, or dispose of obsolete and noncurrent media, when applicable.

c. There is objective evidence of observance to established procedures.

305. Are there methods and facilities to protect computer programs from unauthorized access, inadvertent damage, or degradation?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide—

(1) Configuration control of the airborne software within the product design files.

(2) Limited access to software files and protection from unauthorized changes.

(3) Separate archives for masters and duplicates.

(4) That masters and duplicates are not revived by the same machine simultaneously.

(5) Minimized risk of deterioration and regeneration of errors on selected storage medium.

(6) Assurance that the reproduction of code occurs error free.

b. There is objective evidence of observance to established procedures.

306. Are there procedures to ensure documentation and archival for each version of the delivered airborne software version?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures (that is, version description document) provide for methods to identify, document, and archive the software environment for each version of delivered airborne software.

b. There is objective evidence of observance to established procedures.

307. Is software identified/marked externally/internally in accordance with the engineering drawing requirements?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Work instructions detail the identification/marking requirements.

b. There is objective evidence of observance to established instructions.

308. Is airborne software programmed media handled and stored properly (for example, environmental controls and magnetic interference precautions)?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for special handling of programmed media.

b. There is objective evidence of observance to established procedures.

309. Are build and load instructions established, maintained, and used?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide—

(1) Software build and load into hardware components.

(2) Successful testing of the hardware after the software load.

b. There is objective evidence of observance to established procedures.

Part B. Product Acceptance Software

310. Is there a Software Configuration Management Plan or procedure to control product acceptance software configuration?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Identification of software for an application.

(2) Control of approved versions for product acceptance.

(3) Control of obsolete and noncurrent software.

(4) Identification of software with a software configuration identification.

(5) Documentation of integration of software with hardware to specify a unique version for incorporation into the product.

(6) Cross-reference of software documents to their associated software.

(7) The technical data/documents control system that includes software identification methods at the media level and at the product level. The media level identification is incorporated into the software, and the product level identifications are marked on the outside of the product indicating software configuration.

b. There is objective evidence of observance to established procedures.

311. Are all changes to product acceptance software documented and approved?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for the method to change and approve product acceptance software. A procedure patterned after an engineering drawing change procedure is appropriate to provide a permanent record showing reason for change, revisions to the software, approvals, and effectivity.

b. There is objective evidence of observance to established procedures.

312. Are there practices and procedures for reporting, tracking, and resolving software-related product acceptance problems?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Corrective action procedures for product acceptance software may parallel or be part of manufacturing's general problem identification and corrective action procedures.

b. There is objective evidence of observance to established procedures.

313. Are there methods and facilities to protect computer programs from unauthorized access, inadvertent damage, or degradation?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Configuration control of product acceptance software to prevent unauthorized changes to the software.

(2) Limited access to software files and protection from unauthorized changes.

(3) Separate archives for masters and duplicates.

(4) Protection from corruption of masters and duplicates, ensuring they are not available in the same machine at the same time.

(5) Minimized risk of deterioration and regeneration of errors on selected storage medium.

(6) Assurance that reproduction of code occurs error free.

b. There is objective evidence of observance to established procedures.

314. Is product acceptance software verified before use?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Independent means to verify product acceptance software, and subsequent revisions, to ensure it accomplishes its intended function.

(2) Means to verify software/firmware/hardware is capable of discriminating between conforming and nonconforming parts or assemblies.

(3) Formal means of identifying approved product acceptance software.

(4) Configuration control of the product acceptance software as it relates to the product being accepted.

b. There is objective evidence of observance to established procedures.

315. Are build and load instructions established, maintained, and used?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Software build and load into hardware components.

(2) Successful testing of the hardware after the software load.

b. There is objective evidence of observance to established procedures.

Section 4. Manufacturing Processes

1. System Element Description. This system element addresses specialized actions whereby materials, parts, or assemblies are accepted, worked or fabricated, tested, inspected, stored, and prepared for shipment. For purposes of an audit these actions are broken down as follows:

a. Manufacturing and Special Manufacturing Processes. Specific functions and operations necessary for the fabrication and inspection of parts and assemblies (some examples are machining, riveting, and assembling). Also included are methods whereby materials, parts, or assemblies are worked or fabricated through a series of precisely controlled steps, and that undergo physical, chemical, or metallurgical transformation (some examples are heat-treating, brazing, welding, and processing of composite materials).

b. Material Receiving, Handling, and Storage. The methods used to accept and protect raw materials, parts, subassemblies, assemblies, and completed products during receipt, manufacture, inspection, test, storage, and preparation for shipment.

c. Airworthiness Determination. The function that provides for audit of completed products/parts thereof, and related documentation, to determine conformity to FAA-approved design data and their condition for safe operation.

2. System Element Standardized Audit Criteria. The following criteria are used to document audit of this system element. The criteria used to document the audit of this system element are divided into three parts: Part A, Manufacturing and Special Manufacturing Processes; Part B, Material Handling, Receiving, and Storage; and Part C, Airworthiness Determination.

Part A. Manufacturing and Special Manufacturing Processes

401. Are work instructions and revisions to work instructions reviewed, approved, controlled, and documented?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Preparation of work instructions and revisions to work instructions to ensure the work functions to be performed are satisfactorily accomplished. Work instructions include the following:

(a) Sequence of operations;

(b) Accept/reject criteria;

(c) Workmanship criteria;

(d) Inspection methods;

(e) Tolerance limits;

(f) Environmental conditions;

(g) Sampling plans;

(h) Special drawing notes;

(i) Skilled personnel (certified) required;

(j) Special precautions for critical product protection;

(k) Part marking and identification;

(l) Part stamp location requirements when defined by approved data;

(m) Inspection of assemblies to detect inclusion of foreign objects before closure;

(n) Reinspection of parts and assemblies that are reopened, disassembled, or tampered with; and

(o) Contamination control in hydraulic installations (for example, purging, filtration, charging, and disposal).

(2) Coordination of initial release and changes to work instructions with affected departments, such as Planning and Quality, to ensure manufacturing processes are adequately controlled.

(3) Authorized quality organization personnel review work instructions and changes before release to ensure—

(a) Inspection points are located in the manufacturing process at points that ensure conformity to FAA-approved design.

(b) Adequate inspection equipment will be available and will be controlled for accuracy, as necessary.

(c) Drawing number and revision level are referred to.

(4) Method by which temporary changes are approved by authorized personnel.

(5) Control of the number of temporary changes allowed before requiring complete incorporation of work instructions.

(6) Control and documentation of revisions to work instructions.

(7) Method by which revisions are identified on the work instructions.

(8) Record of work instruction changes.

(9) Control of obsolete work instructions.

(10) Reflection of design changes that correct unsafe conditions identified in ADs.

b. There is objective evidence of observance to established procedures.

402. Are all special processes in use identified and defined by FAA-approved design data and detailed in process specifications?

Applicability

	PC	PMA	TSO
A	§ 21.31	§ 21.303	§ 21.601
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that special processes in use are identified and documented in FAA-approved design data and/or process specifications. Process specifications address requirements, as applicable, for personnel qualifications, material, equipment, process monitoring requirements, and accept/reject criteria.

b. There is objective evidence that all requirements listed in applicable special processes in use are completed in accordance with the approved process specifications.

403. Are procedures in place for controlling manufacturing processes?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence of—

(1) Processes ensuring each product and article conforms to its approved design.

(2) New or changed processes being substantiated and approved by appropriate personnel.

(3) Verification/testing of new or changed manufacturing and special processes by responsible engineering personnel to ensure the process will produce what the design requires.

(4) Approval of process changes by appropriate personnel.

(5) Documentation of change history by responsible personnel.

404. Are special manufacturing process operators qualified and approved in accordance with the specification/manufacturer's procedures?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of periodic review of personnel certifications to ensure only qualified operators perform special processing.

405. Are records generated and maintained for all significant provisions of the quality/inspection program that have an effect on control of the conformity of the manufactured article to FAA-approved design data?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Generation and content of inspection and test records.

(a) Inspection and tests for product acceptance include, as a minimum, applicable drawing/specification number and revision levels.

(b) Results of inspection and tests for first production configuration articles.

(c) In-process inspections used to determine acceptability of an article to FAA-approved design data.

(d) Final inspection acceptability of completed end items.

(e) Periodic inspection and control of tools used as a media of inspection, including check fixtures, inspection gauges, and measurement instruments.

(f) Test data directly traceable to the material, parts, or products tested.

(g) Contents of each record should include, as a minimum, the nature and number of observations, the number and type of discrepancies found, lot identity and size, sample sizes, and resultant corrective action.

(2) Generation and content of special process records:

(a) Complete and continuous monitoring of special processes per specification requirements.

(b) Product identity and material traceability throughout the processing cycle.

(c) Special process inspection approval, such as unique special process inspection approval stamps.

(3) Record legibility, completeness, and accuracy.

(4) Requirements that storage media used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

406. Is equipment required for special processing, such as tools, gauges, instruments, timers, ammeters, or voltmeters, available and calibrated?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Equipment has evidence of current calibration and is available for controlling and monitoring special processes.

407. Is action taken to correct a manufacturing/special process that is found to be out of control?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of:

(1) Action when there is loss of control.

(2) Investigation to ensure acceptability of products produced while the process was out of control.

(3) Corrective action as a result of the analysis of trends in process to prevent nonconforming products.

408. NO LONGER APPLICABLE

409 Are procedures in place that support inspection methods that ensure all products/parts and articles will conform with the FAA-approved design?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that parts, components, and assemblies are inspected during production. The inspection system should include—

(1) Documentation and availability of criteria for determining appropriate inspection methods (attributes/characteristics).

(2) Controls of the manufacturing system when physical inspection of parts or processed material is impossible or disadvantageous.

(3) A combination of physical inspection and process control whenever either method alone is not sufficiently capable of determining the quality of parts.

(4) Inspection of assemblies to detect inclusion of foreign objects before closure.

(5) Reinspection of parts and assemblies that are reopened, disassembled, or tampered with.

(6) Contamination control in hydraulic installations (for example, purging, filtration, charging, and disposal).

(7) Procedures for the inspections and tests required to be completed for final acceptance of the completed products/parts.

410. Is the inspection status of products/parts and articles identifiable throughout the manufacturing cycle?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide methods of marking/traceability that ensure identification of inspection status throughout the manufacturing process.

b. There is objective evidence of observance to established procedures.

411. Are inspection-marking devices/stamps issued only to authorized persons and are there procedures to ensure proper control?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Responsibility for control of stamps.

(2) A listing of stamps issued to personnel.

(3) Handling of lost or returned stamps.

(4) Periodic check of all stamps to ensure legibility of stamp impressions and possession of stamps by correct personnel.

(5) The type of stamps to use for the various materials that will require stamp impressions to ensure the material/part is not damaged.

b. There is objective evidence of observance to established procedures.

412. Are special environmental controls (for example, temperature, and cleanliness) used in material storage, handling, manufacturing, and assembly areas when warranted?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Environmental controls may include—

(1) Storage of sensitive materials in the original or other appropriate container.

(2) Monitoring and recording of temperature and humidity.

(3) General housekeeping to ensure the product is not adversely affected by storage and handling (for example, dirt, dust, water damage, corrosion, compression, dropping, ultraviolet light, heat, or cold).

(4) Training of appropriate personnel in maintaining established environmental controls.

b. Corrective action procedures have been established, and corrective action is taken as required.

Part B. Material Handling, Receiving, and Storage

413. Is receiving inspection required to verify raw materials and supplier-furnished parts/service conform to the FAA-approved design data or purchase order requirements?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Conformity of supplier-furnished items, software, parts, and assemblies, including the inspection and identification of buyer-furnished material.

(2) Verification and identification of raw material, including process material (such as weld rod). Methods include—

(a) Review of certification test reports to ensure all requirements are met.

(b) Types and frequencies of analysis required to verify certifications, consisting of, at a minimum, initial and periodic verifications (dependent on supplier audits), past quality performance, and material importance.

(c) Nondestructive inspection (NDI) techniques employed to verify the quality of castings and forgings.

(d) When specified, Material Laboratory Analysis Records identifiable to batch number, serial number, or heat number for a given part number.

(e) If Material Certificate/Laboratory Analysis is for a quantity of material, serial numbers, if appropriate, identifiable to the respective Material Certificate or Laboratory Analysis.

(3) Extent of actual inspection upon receipt, depending on inspectability for conformity and quality, supplier audit results, past quality performance, inspections and reviews conducted at the supplier's facility, and relative importance of the part/material.

(4) First article inspection and test of products produced by new suppliers.

(5) Inspection and documentation requirements to meet current design data.

(6) Audit of incoming statistical data.

b. There is objective evidence of observance to established procedures.

414. Are quality system records of receiving inspection generated and maintained for products/articles/parts?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Contents of each receiving inspection record to include name, part number, sample size, type and quantity of inspections made, conformance or nonconformance, quantity and description of nonconformances found, and action taken.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that storage media used for record retention, exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

415. Are purchased shelf-life materials and products verified to ensure specification requirements are met?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Verification upon receipt of purchased material or products that have shelf-life requirements to ensure they are within specified dates.

(2) Withholding from production, purchased material or products not within the specified shelf-life requirements unless special testing is accomplished to verify conformity.

b. There is objective evidence of observance to established procedures.

416 Are age-sensitive products/parts/articles and material identified and controlled?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence that—

(1) Age-sensitive materials and materials susceptible to deterioration/corrosion are identified and controlled. This includes, as a minimum—

(a) Determination of shelf-life limits by type of material.

(b) Detailed mixing instructions if different from manufacturer's.

(c) Instructions for retest and extension of shelf life.

(d) Permissible amount of time shelf life may be extended.

(e) Identification requirements for shelf-life extension dates.

(2) Bins containing limited shelf-life items are identified.

(3) Out-of-date items in bonded areas are identified and segregated until reinspected, retested, and dispositioned.

(4) Raw materials used in composites (for example, pre-preg rolls and epoxy/adhesive materials) are in compliance with manufacturer's specifications. There is a documented trail covering receipt of material, initial testing, usage, storage, retesting, etc.

417. Are material and parts and articles awaiting acceptance segregated?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for control, identification, and segregation (where practical) of material and parts awaiting testing or inspection from those already accepted.

b. There is objective evidence of observance to established procedures.

418. Are traceable components identified in assembly records?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence that traceable components are identified in assembly records (that is, fitted parts/components/assemblies, matched sets).

419. Are completed parts and articles traceable to raw material, when applicable?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that—

(1) Completed parts can be traced to raw material through records.

(2) Traceable parts are marked and recorded.

(3) Procedures for handling rejected traceable parts are followed.

420. Is traceability for split lots maintained, including accountability for the completion of all manufacturing and inspection operations?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Control of split lots.

(2) Accountability of products through each stage of the manufacturing process.

(3) Accountability for shortages/overages as successive operations are performed.

b. There is objective evidence of observance to established procedures.

421. Are special identification and controls required if materials, parts, or articles are introduced into production before full acceptance?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Special identification and controls for material or parts introduced into production before full acceptance or release.

(2) Conditions in which the pre-release of material or parts will be allowed.

(3) Obtaining appropriate documented approvals before pre-release.

(4) Documentation of each pre-release to show approvals, reasons for pre-release, and where in the production line material or parts are allowed to progress until full release is obtained.

(5) Identification of material or parts in such a manner that they can be retrieved if full release is not obtained.

b. There is objective evidence of observance to established procedures.

422. Are appropriate methods used to prevent part damage or contamination to the part or article?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence of—

(1) Instructional guidance on the use of material handling equipment.

(2) Methods for stacking parts.

(3) Methods for tying, wrapping, or properly supporting parts to preclude shifting and falling.

(4) Methods to protect critical machined surfaces, highly polished surfaces, or plated parts. Methods include use of lift fixtures, covering on forklift contact surfaces, protective containers, wrapping, interlayering with protective material, and special racks.

(5) Methods to protect electronic parts from corrosion, pin damage, or contamination from dust or dirt. Sealed parts (for example, switches, circuit breakers, or relays) are protected from rough handling and contact damage from like parts or other products.

(6) Methods to protect product from contamination. Methods may include—

(a) Capping all openings in components (for example, tubing, valves, electrical connectors, and pumps) prone to entrapment of foreign objects.

(b) Bagging, plugging, or capping completed hose and hose assemblies.

(c) Individually packaging or properly protecting oxygen equipment, plumbing, and fittings. Methods also include cleaning instructions and subsequent protection for contaminated items.

(d) Bagging or capping of sensing devices (for example, instruments, pressure and vacuum transducers, cabin pressurization equipment, gyros, switches, or air data computers), and pressure venting when required.

(7) Special handling provisions (for example, white gloves or electrostatic discharge (ESD) control), where warranted. These provisions may include—

(a) Protective measures to prevent fingerprints (particularly the by-products of oil, moisture, and salt) from deteriorating the product or causing inadequate adhesion.

(b) Protecting grease-coated products (for example, control cables, bearings, gears, and rod ends) from dust, dirt, and corrosion.

(c) Training in special handling and storage techniques.

(d) Proper handling of ESD-sensitive supplies and parts, including the methods for clearly identifying supplies and parts that require special ESD handling.

(e) Controlled workstation conditions for removing ESD parts from special tote trays, boxes, and packaging.

(8) Methods to protect products during transit. Methods may include—

(a) Bagging, boxing, or tying parts and material to prevent intermixing.

(b) Retaining product in original containers as long as possible or practical.

(c) Foam, pads, or special packaging for delicate parts susceptible to vibration and shock damage.

(d) Covering, tying, or banding parts and material that may be blown out of carts, trucks, or dollies.

(e) Protecting parts and materials from adverse weather conditions that would affect the product.

(9) Design engineering review of recurrent product damage.

423. Are cleaners, solvents, degreasers, and other fluids adequately identified and controlled to prevent potential product damage from misapplication?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Decanting and identifying cleaners, solvents, and other fluids used in the work area, specifying types of containers to be used, requirements for re-use, and method of identification.

(2) Identifying the methods to be used when potentially damaging fluids are misapplied to a product.

b. There is objective evidence of observance to established procedures.

424. Is there proper separation and identification of products/parts and articles in storage and manufacturing areas?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence that parts and materials are identified/separated from like or similar parts and materials.

b. Contents of bins, shelves, storage areas, and manufacturing areas are identified.

Part C. Airworthiness Determination

425. Are required design changes incorporated into products/parts and articles being stored before their release for installation/shipment?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that required design changes are incorporated into a product/part in storage before installation or shipment. This evidence may include one or more of the following:

(1) Establishment of effectivity of a design change.

(2) Use of shop order or traveler.

(3) Stock purge requirements.

(4) Rework to engineering instructions, including reidentification requirements.

(5) Inspection requirements.

426. Are only conforming and properly identified products/parts/articles placed in storage and is removal/issuance of products/parts/articles controlled?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Placement in stock of products/parts/articles thereof that have met established acceptance criteria. This includes parts that have been previously installed and removed, but not nonconforming material.

(2) Control of parts that are not completed to prevent stocking under an identifying part number until complete as defined by print or specification.

(3) Authorized methods for removal or replacement of parts.

(4) Limited and controlled access to storage areas.

(5) Records to be generated and maintained for parts removed from the stock system.

(6) Issue of raw and process material accountable to a released production order.

(7) Control of parts that have been quarantined as a result of a suspected nonconformance.

b. There is objective evidence of observance to established procedures.

427. Are completed products/parts/articles properly marked?

Applicability

	PC	PMA	TSO
A	§ 45.11	§ 45.15	§ 45.15
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that—

(1) Completed products/parts/articles are properly and legibly identified.

(2) Aircraft and aircraft engines are identified by means of a fireproof plate and have the required identification data.

(3) Propellers, propeller blades, and hubs are identified by means of a plate, stamping, engraving, etching, or other approved method of fireproof identification, and have the required identification data.

(4) Manned free balloons are identified by means of a fireproof plate on the balloon envelope, basket, and heater assembly, and have the required identification data.

(5) For TSO authorizations, articles are marked with the TSO holder's name, trademark, symbol, or other FAA-approved identification and part number. In addition, each article must be marked with the applicable TSO number and letter of designation, all markings specifically required by the applicable TSO, and serial number or the date of manufacture of the article or both, unless otherwise specified in the applicable TSO.

(6) For PMA, articles are marked with the letters "FAA-PMA" and the PMA holder's name, trademark, symbol, or other FAA-approved identification, and part number. If the FAA finds the article too small or impractical (because of characteristics) to mark all (or any) of the information on the article, the information not marked on the article must be attached to the article or its container in accordance with § 45.15(d).

(7) For critical components, parts are permanently and legibly marked with a part number (or equivalent) and a serial number (or equivalent).

428. Are only conforming and properly identified products/parts/articles shipped under the production approval?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Packaging and shipping of products/parts/articles manufactured under the production approval that have met established acceptance criteria.

(2) Compliance with shipping instructions.

(3) Methods for preservation, packaging, and shipping of completed products.

(4) Subassemblies, component parts, or replacement articles that leave the manufacturer's facility as FAA-approved are identified with the manufacturer's part number, name, trademark, symbol, or other FAA-approved manufacturer's identification.

b. There is objective evidence of observance to established procedures.

429. NO LONGER APPLICABLE.

430. If an export airworthiness approval has been issued, have the necessary documents and instructions been forwarded to the aviation authority of the importing country, or to other locations as specified in the special requirements of importing countries in AC 21-2?

Applicability

	PC	PMA	TSO
A	§ 21.327	§ 21.327	§ 21.327
E	§ 21.335	§ 21.335	§ 21.335

Statement of Condition

a. There is objective evidence that—

(1) All documents and information necessary for proper operation of the products being exported have been forwarded to the cognizant aviation authority.

(2) Manufacturing assembly instructions and an FAA-approved flight test checkoff form have been forwarded to the cognizant aviation authority for unassembled aircraft being exported.

431. Have authorized personnel issued airworthiness approvals (FAA Form 8130-4 or 8130-3)?

Applicability

	PC	PMA	TSO
A	§ 21.335	§ 21.335	§ 21.335
E	§ 21.335	§ 21.335	§ 21.335

Statement of Condition

a. Procedures provide for identification of personnel authorized to issue airworthiness approvals.

b. There is objective evidence of observance to established procedures.

432. Have export airworthiness approvals been obtained for all products/parts/articles that have left the PAH's quality system?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Methods for applying for export airworthiness approvals (FAA Form 8130-4 or FAA Form 8130-3), and the responsibilities of personnel authorized to submit applications.

(2) All exported products to meet special requirements of the importing country listed in appendix 2 to AC 21-2 (current revision). Procedures provide for properly annotating any deviation on the exporting documentation and including a letter of acceptance from the importing country for such deviations.

(3) Methods for applying for domestic airworthiness approvals (FAA Form 8130-3) and the responsibilities of personnel authorized to submit applications.

(4) Retention of copies of FAA Form 8130-4 and/or FAA Form 8130-3, as applicable.

b. There is objective evidence of observance to established procedures.

For Aircraft Manufacturers ONLY

433. Are completed aircraft registered before airworthiness certification?

Applicability

	PC	PMA	TSO
A	§ 47.3 § 21.173	N	N
E	§ 21.173	N	N

Statement of Condition

a. There is objective evidence that completed aircraft are registered before issuance of airworthiness certificate.

434. Have aircraft been properly identified with nationality and registration marks before airworthiness certification?

Applicability

	PC	PMA	TSO
A	§ 45.21	N	N
E	§ 45.21	N	N

Statement of Condition

a. There is objective evidence that nationality and registration marks are displayed on aircraft, and are properly located and sized before airworthiness certification.

435. Have applicable airworthiness certificates or special flight permits been obtained for the purposes for which the aircraft is flown?

Applicability

	PC	PMA	TSO
A	Part 21 Subparts H, I	N	N
E	§ 91.203	N	N

Statement of Condition

a. There is objective evidence that proper airworthiness certificates or special flight permits have been obtained before using aircraft for their intended purposes.

436. Are flight manuals, supplements, and current weight and balance data furnished with each aircraft at the time of delivery, as applicable?

Applicability

	PC	PMA	TSO
A	§ 23.1581 § 25.1581 § 27.1581 § 29.1581 § 31.81	N	N
E	§ 21.5 § 31.81	N	N

Statement of Condition

a. There is objective evidence that aircraft flight manuals, supplements, and current weight and balance data are furnished with each aircraft, as applicable.

437. Have registration and airworthiness certificates been cancelled for aircraft whose title has passed to an importing country purchaser?

Applicability

	PC	PMA	TSO
A	§ 21.335	N	N
E	§ 21.335	N	N

Statement of Condition

a. There is objective evidence that U.S. registration and airworthiness certificates have been cancelled by the FAA (contact FAA aircraft registry office in Oklahoma City at 405-954-3116) when title passes or has passed to an importing country purchaser. This evidence includes the return of Registration and Airworthiness Certificates, Aeronautical Center Form 8050-3 and FAA Form 8100-2, to the FAA.

Section 5. Manufacturing Controls

1. System Element Description. This system element addresses specialized actions whereby a PAH ensures materials, parts, and assemblies are worked or fabricated, tested, and inspected to ensure conformity to FAA-approved design. Manufacturing controls also include methods for review and approval of materials and parts that are withheld because of departures from design data or specifications and are to be considered for installation in the finished product. For purposes of an audit, these actions are broken down as follows:

a. Statistical Quality Control (SQC). A method that may be used by the PAH to control product quality by statistical methods, and that may be used for continuous improvement and/or product acceptance. SQC includes techniques such as statistical sampling, PRE-control, and statistical process control (SPC).

b. Tool and Gauge. The function that establishes control of precision measuring devices (for example, tools, scales, gauges, fixtures, instruments, and automated measuring machines) used in fabrication, special processing, inspection, test of detail parts, assemblies, and completed products to determine conformity to FAA-approved design.

c. Testing. The function that provides for static, destructive, and functional tests of production products/parts thereof to ensure conformity to FAA-approved design.

d. Nondestructive Inspection. The application of technical methods to examine materials or components in ways that do not impair future usefulness and serviceability. These methods are used to detect, locate, measure, and audit discontinuities, defects, and other imperfections; to assess integrity, properties, and composition; and to measure geometrical characters.

e. Nonconforming Materials. A method of controlling, auditing, and dispositioning of any product/part thereof that does not conform to FAA-approved design.

2. System Element Standardized Audit Criteria. The criteria used to document the audit of this system element are divided into four parts: Part A, Statistical Quality Control (SQC), Part B, Tool and Gauge, Part C, Testing and Part D, Nondestructive Inspection.

Part A. Statistical Quality Control (SQC)

501. Has a statistical sampling inspection plan been established for acceptance of specified product characteristics at the receiving inspection and during manufacture?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence that—

(1) All characteristics essential to ensure compliance to FAA-approved design have been identified. Characteristics that, if not maintained, would or may cause an unsafe condition in the end product are identified separately.

(2) Product characteristics identified as having an impact on the safety of the end product have been 100-percent inspected.

(3) Samples have been selected that adequately represent the lot or process.

(4) Adjustments to the sampling plan are based on acceptance and quality history, and that the sampling plan is tightened to 100 percent inspection when nonconformances affecting safety are discovered.

(5) Statistical inspection conforms to sampling specifications or approved sampling plan requirements.

(6) Sampling plans do not allow the acceptance of “known defectives” in a lot, or acceptable quality levels with known defectives that would affect safety.

502. Do the engineering and manufacturing organizations participate in the review, implementation, and maintenance of SQC and SPC techniques used for product acceptance?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for the engineering organization to review SQC/SPC planning before release to ensure the maintenance of FAA-approved design.

b. Procedures provide for the manufacturing organization to review SQC/SPC planning before release to ensure the product can be produced in conformity to FAA-approved design.

c. There is objective evidence of observance to established procedures.

503. Has a satisfactory SPC method been established for acceptance of specific product characteristics?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Authority and responsibility for implementation and control of SPC.

(2) Scheduled independent audits of the SPC process to verify its continuing acceptability. This includes a conformity check of the product on a periodic basis.

(3) Identification of principal process characteristics of the product to be controlled and a determination as to the impact that a nonconformance would have on the safety of the end product.

(4) Identification of the types of control charts to be used to ensure maintenance of in-control processes. Variable control charts include charting for both range and variation around the mean.

(5) Capability studies to determine that the process can yield a product that conforms to FAA-approved design data.

(6) Test and measurement equipment study (for example, a gauge study) to identify, eliminate, or adjust for measurement errors that may contribute to process variability.

b. There is objective evidence of observance to established procedures.

504. Are appropriate SPC control limits and subgroup selections used and maintained?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Subgroups representative of the product lot.

(2) Avoidance of subgroup selection biases (for example, patterns, ease of sampling, or pre-selection).

(3) Determination and adjustment of appropriate control limits for each process.

(4) Criteria for determining when an SPC process is considered to be out of control.

(5) Rules for out-of-control conditions and are available to operators or process checkers.

(6) Regular review of the SPC charts to determine changes (for example, shifts) in the process.

(a) Review and retention of charts.

(b) Identification of personnel with the authority to stop the process when necessary.

(c) Notification of functional areas when an out-of-control condition is found, their responsibilities, and response time.

(7) Corrective action for an out-of-control condition.

(a) Additional inspection conducted to ensure product is acceptable.

(b) Audit of the need for purge action to remove suspected nonconforming products when a control chart used for acceptance shows an out-of-control condition.

b. There is objective evidence of observance to established procedures.

505. Has a satisfactory PRE-control method been established for acceptance of specific product characteristics?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Authority and responsibility for implementation and control of PRE-control.

(2) Scheduled independent audits of the PRE-control process to verify its continuing acceptability. This includes a conformity check of the product on a periodic basis.

(3) Identification of principal process characteristics, of the product to be controlled, and a determination as to the impact that a nonconformance would have on the safety of the end product.

(4) Capability studies using statistical techniques, ensuring process capability is less than the tolerance of the specific product characteristic to be measured.

(5) Test and measurement equipment study (for example, a gauge study) to identify, eliminate, or adjust for measurement errors that may contribute to process variability.

(6) Establishment of PRE-control limits based on the tolerance of the specific product characteristic to be measured to ensure maintenance of in-control processes.

(7) Qualification of the setup during production, ensuring a minimum of five consecutive parts measured fall within the target area established by the PRE-control limits.

(8) Periodic measurement during production after the setup is qualified.

(9) Corrective action to adjust the process, requalify the setup, and recall and reinspect suspected products when PRE-control limits are exceeded.

b. There is objective evidence of observance to established procedures.

506. Are pertinent personnel trained in statistical techniques?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Responsibility for training (for example, statistical sampling, PRE-control, and SPC).

(2) Training new or newly transferred employees in statistical techniques.

b. There is objective evidence of observance to established procedures.

Part B. Tool and Gauge

507. Does the specified equipment used for inspection and test have the degree of accuracy necessary to determine conformity of the characteristic being inspected?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Engineering involvement in the selection of precision measuring devices used in fabrication, inspection, and test to ensure the precision and accuracy required to determine conformity to the design feature/characteristic being inspected.

(2) Determinations and adjustments for the effects of tool wear.

(3) The degree of accuracy of all measurement devices and test equipment.

(4) Measurement devices and test equipment capable of the accuracy necessary and adequate for the intended purpose, including measurement devices and test equipment substituted for those specified.

b. There is objective evidence of observance to established procedures.

508. Are tools, gauges and equipment initially approved, periodically inspected and calibrated when applicable?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Initial inspection, calibration, and approval of all test and measurement equipment.

(a) Establishment of the accuracy of all measurement devices before initial use.

(b) Assignment of calibration methods and initial calibration interval to ensure continued accuracy.

(c) Test and measurement equipment study (for example, a gauge study) to identify, eliminate, or adjust for measurement errors that may contribute to variability.

(d) Unique identification of individual measurement devices and standards to provide traceability to the calibration records.

(e) Inclusion in the identification and calibration system of personally owned gauges used for product acceptance.

(f) Indication of the calibration status of measurement devices and standards. Typically, labels are used but other suitable controls can be provided.

(2) Periodic inspection and calibration of all measurement devices at prescribed intervals, or just before use, that will ensure their continued accuracy.

(a) Adjustment of calibration intervals based on analysis of previous calibration results, wear, stability, purpose, and degree of usage.

(b) Calibration by qualified personnel.

(c) Appropriate environmental conditions for calibration to ensure accuracy.

(d) Control of measurement devices and standards that are overdue for calibration.

(3) Tool control procedures for production tooling to ensure accuracy and repeatability for product acceptance before use.

(a) Inclusion in the calibration system.

(b) Assignment of unique identifiers.

(c) Availability of current applicable tool drawings.

(4) A documented mandatory recall system to ensure all measurement devices, calibration standards, and production tooling used for product acceptance are recalibrated at prescribed intervals.

(5) Generation and maintenance of tool and gauge records:

(a) Contain nomenclature, unique identifier, location, details of all adjustment, repair or rework accomplished, calibration history, source and date next inspection is due, and standard used.

(b) Record legibility, completeness, and accuracy.

(c) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

509. Do standards used for calibration have adequate accuracy and are they traceable to a recognized international standards organization?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Accuracy, stability, range, and resolution of the standard used for calibration appropriate for the measurement device characteristic being calibrated. The accuracy ratio of the standard is dependent on the audited facility's measurement requirements (a minimum of four times more accurate than the gauge being calibrated, if possible).

(a) Methodology to determine adequacy of the calibration standards.

(b) Certificates, reports, or data sheets attesting to the accuracy of all calibration standards.

(2) Calibrations are traceable to the National Institute of Standards and Technology or other recognized international standards organization. If no national standard exists, the basis for calibration is documented.

510. Are tools and gauges protected, maintained, and used in an acceptable environment, when specified, to ensure product conformity to FAA-approved design data?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Methods for handling, transporting, and storing measurement devices and standards to ensure required accuracy and reliability are maintained. Methods usually are in accordance with equipment manufacturer's recommendations and established industry practices.

(2) Actions taken when improper handling or storage occurs. As a minimum, an investigation is made to determine the adverse effects and action to be taken.

(3) Storage of measurement devices and standards appropriate to maintain required accuracy and fitness for use. Vibration, shock, temperature variations, humidity, and contamination are some of the detrimental factors the procedure considers.

(4) Replacement of measurement devices and standards, as required, to ensure product conformity to FAA-approved design data.

(5) Identification of environmental conditions necessary for use and calibration of measurement devices and standards.

(6) Appropriate use of measurement devices and standards in environmental conditions that might affect accuracy, stability, or calibration, such as temperature, relative humidity, vibration, electrical interference, cleanliness, or other controllable factors.

(7) Compensating corrections to calibration or measurement results obtained in an environment that departs from acceptable conditions.

(8) Preclusion from use of standards, inspection tools, gauges, instruments, and jigs that are inaccurate or beyond the scheduled calibration cycle identified. Use is precluded until rework or recalibration is accomplished.

(9) Identification and control of measurement devices and standards that require rework or recalibration.

(10) Appropriate methods for rework of measurement devices and standards, and sufficient reinspection to ensure accuracy.

b. There is objective evidence of observance to established procedures.

511. When a product has been accepted by a significantly out-of-tolerance gauge, is an audit conducted to determine the need for corrective action?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Documenting a significant out-of-tolerance condition and investigating the validity of previous measurements.

(2) Notification of the significant out-of-tolerance condition to the user of the measurement device or standard.

(3) Investigations of out-of-tolerance conditions to ensure conditions that adversely affect product quality or safety are reported to the FAA and the user, as required. This includes involvement of appropriate organizations, that is, service/product support.

b. There is objective evidence of observance to established procedures.

512. Are tool control procedures applied to NDI equipment?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Periodic calibration of NDI equipment, and generation and maintenance of records.

(2) Measurement of black light intensity on a periodic basis (preferably daily) using a calibrated black light meter.

(3) Measurement of white lights on a periodic basis using a calibrated white light meter.

b. There is objective evidence of observance to established procedure.

Part C. Testing

513. Are test procedures/applicable instructions and subsequent changes, established, maintained, and adequately controlled?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) A functional test to be conducted on every aircraft engine and every propeller.

(2) A flight test to be conducted on every aircraft (unless the aircraft will be exported unassembled).

(3) Preparation and maintenance of test procedures and instructions applicable to the products/parts produced to ensure each article conforms to FAA-approved design data. Test documents include the following, as applicable:

(a) Original and recurring correlation and calibration to an established standard or baseline, determined by the facility and approved by the FAA, of aircraft engine test cells for the verification, validation, and repeatability of acceptance testing.

(b) A specified schedule of post-test teardown inspection to verify product quality, followed by rebuild and retest. A higher frequency of post-test teardown inspection for new products until the adequacy of assembly tooling, instruction, and techniques has been demonstrated.

(4) Actions to be taken when tests fail.

(5) Approval and control of all test procedure and instruction changes by authorized personnel.

(6) Requirements for changing test procedures and instructions.

(7) Review and verification of test procedure/instruction changes to ensure product quality is not negatively impacted.

(8) Documentation of test procedure/instruction change history by responsible personnel.

b. There is objective evidence of observance to established procedures.

514. Do procedures ensure the appropriate organizations participate in the review of test instructions or procedures?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) The appropriate organization (for example, manufacturing, engineering, and/or quality) review test instructions or procedures before release to ensure the product can be tested in conformity to FAA-approved design, including that—

(a) The product can be properly audited and verified to be in conformity to the FAA-approved design. This includes the identification of inspection points that ensure conformity to FAA-approved design.

(b) Inspection equipment is available or can be procured that will adequately verify conformity to FAA-approved design and that can be controlled for accuracy, when required.

(2) The appropriate organization (for example, manufacturing, engineering, and/or quality) personnel to authorize additions, deletions, or changes to inspection points in the test instructions or procedures, based on inspection results.

b. There is objective evidence of observance to established procedures.

515. Are products/parts that have been adjusted or reworked after test acceptance retested to approved procedures?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures outline the requirements for retest of products/parts adjusted or reworked after inspection acceptance when that adjustment or rework could have an impact on the performance of those products/parts.

b. There is objective evidence of observance to established procedures.

516. Are there procedures to ensure records are generated and maintained for completed tests of aircraft, engines, propellers, or parts thereof?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Contents of each record used, including, as a minimum:

(a) Test results,

(b) Test nonconformances, and

(c) Corrective action.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that tape files, microfilm, etc., used for record retention exhibit legible data, acceptance stamps and/or signatures, as required.

b. There is objective evidence of observance to established procedures.

For Aircraft Manufacturers ONLY

517. Have flight test procedures and subsequent changes been submitted to and approved by the FAA?

Applicability

	PC	PMA	TSO
A	§ 21.137	N	N
E	§ 21.146	N	N

Statement of Condition

a. There is objective evidence that flight test procedures have been approved by the FAA before flight test.

b. There is objective evidence that changes to approved production flight test procedures and flight checkoff form(s) are submitted to and approved by the FAA.

518. In the case of aircraft, is the audited facility using flight test pilots that have been fully qualified?

Applicability

	PC	PMA	TSO
A	P	N	N
E	N	N	N

Statement of Condition

a. Procedures provide for use of flight test pilots with current FAA medical certificates who have maintained aircraft currency requirements for the model(s) being flown and who have necessary qualifications for any special procedures required.

b. There is objective evidence of observance to established procedures.

519. In the case of aircraft, is the flight checkoff form properly completed?

Applicability

	PC	PMA	TSO
A	§ 21.137	N	N
E	§ 21.146	N	N

Statement of Condition

a. There is objective evidence that—

(1) Flight checkoff form(s)have been prepared.

(2) Forms are legible, complete, and accurate.

(3) Flight test discrepancies and their correction have been documented.

(4) Satisfactory completion of all flight test requirements has been verified.

Part D. Nondestructive Inspection

520. Are NDI processes, including changes, properly documented, controlled, and reviewed for conformance with FAA-approved design data?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Engineering review of NDI processes to ensure FAA-approved design is maintained.

(2) Method of identifying and controlling revision levels of released NDI instructions.

b. There is objective evidence of observance to established procedures.

521. Are NDI operators certified, recertified, and decertified by the audited facility and performing within their limits of authorization?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Initial qualification testing of inspectors before issuance of acceptance stamps.

(2) Requalification of inspectors on a prescribed periodic basis.

(3) Vision requirements and retest on a periodic basis.

(4) Inspectors to provide identification of various levels of qualifications and various fields of expertise.

(5) Qualification of inspectors by authorized personnel.

(6) Identification and notification when requalification and vision tests are required.

(7) Documentation of employee's qualification. Qualification records for NDI operators that include—

(a) Level of certification.

(b) Educational background and experience.

(c) Statement of satisfactory completion of training.

(d) Results of most recent visual acuity examination.

(e) Actual grades obtained in each examination.

(f) Percentile weight assigned to each examination.

(g) Composite grade of all examinations.

(h) Date of certification or recertification, or both.

(i) Signature of NDI examiner.

(8) Appropriate decertification methods for operators failing to maintain qualifications.

(9) The limits of authority for conducting and interpreting test results or writing test reports.

b. There is objective evidence of observance to established procedures.

522. Are applicable NDI procedures/process specifications readily available and used by inspection personnel?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for controlled and detailed methods of inspection in each area of application.

b. There is objective evidence of observance to established procedures.

523. Are the critical NDI parameters identified and controlled?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for radiographic process.

(1) Radiographic digital, film, or other media processing per written procedures or manufacturer's instructions.

(2) If film media is used: Mixing of solutions in accordance with manufacturer's instructions and control of solution temperatures, replenishing rates, and film travel as required to produce film of the required density and free of spots, streaks, fog, or scum.

(3) Identification of digital, film, or other media so as to have sufficient information to provide traceability and date of inspection.

(4) Digital, film, or other media storage is done in accordance with recommendations from the manufacturer or other approved procedures.

b. Procedures provide for ultrasonic inspection.

(1) The use of immersion/squirter/bubbler tanks.

(2) Tanks are free of foreign materials that may inhibit adequate inspection.

(3) Wetting agent and/or corrosion inhibitor are used where needed.

(4) Couplant materials that are not detrimental to part being inspected or subsequent manufacturing operations.

c. Procedures provide for magnetic particle process.

(1) Audit of the viscosity of the system oil on a systematic and periodic basis.

(2) Audit of the suspension of magnetic particles on a systematic and periodic basis.

(3) Audit of system sensitivity using a serialized test item on a systematic and periodic basis.

d. Procedures provide for fluorescent penetrant process.

(1) Checking developers periodically in accordance with applicable specifications.

(2) Checking and recording rinse water temperature and pressure daily (where applicable).

(3) Checking emulsifiers periodically in accordance with manufacturer's recommendations or applicable specifications.

(4) Contamination testing, with results within the prescribed maximum allowable limits. This test is checked on a systematic and periodic basis.

e. Procedures provide for eddy current process.

(1) Appropriate test pieces, eddy current probes, and handling equipment.

(2) Test pieces used to adjust the sensitivity of the electronic apparatus that are free of interfering discontinuities and that contain discontinuities similar in size and composition to those expected in the products to be examined.

(3) Test pieces that provide good signal resolution and have one or more natural or artificial discontinuities, such as notches or holes.

(4) Test areas visually free of grease, oil, rust, scale, or other substances that could interfere with the inspection.

f. There is objective evidence of observance to established procedures.

524. Do procedures address NDI acceptance and rejection criteria?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Coordination of acceptance/rejection criteria with the FAA.

(2) Additional review of marginal inspection results by authorized personnel before acceptance.

(3) Use of acceptance/rejection criteria during inspection.

(4) Identification of personnel authorized to review and update acceptance/rejection criteria.

b. There is objective evidence of observance to established procedures.

525. Is corrective action taken when an NDI process is found to be out of control?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for an investigation to ensure continued acceptability of products accepted while the NDI process was out of control.

b. There is objective evidence of observance to established procedures.

526. Are adequate test pieces and NDI known-defect samples available and identified to preclude introduction into the production system?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Test pieces and samples that adequately reflect the part configuration.

(2) Test pieces and samples containing minimum size anomalies that would cause rejection of the part.

(3) Availability of American Society for Testing and Materials (ASTM) Standards or other reference material for radiographic film interpretation.

(4) Method to identify test pieces and samples with known defects used to establish NDI so as to distinguish them from production items and prevent their introduction into the production system.

b. There is objective evidence of observance to established procedures.

527. Are NDI tanks and solutions checked for compliance with specifications?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Periodic samples of tank solutions to ensure compliance with operating specifications.

(2) Processing of lab reports according to procedures to ensure that out-of-control conditions are responded to immediately.

b. There is objective evidence of observance to established procedures.

528. Are NDI inspection records generated and maintained?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Contents of each record used.

(2) Record legibility, completeness, and accuracy.

(3) Requirements that tape files, microfilm, etc. used for record retention exhibit legible data, acceptance stamps, and/or signatures, as required.

(4) Generation of inspection records that include—

(a) Acceptance of material.

(b) Inspector responsible for each area of test.

(c) Date of acceptance.

(d) Lot or serial number.

b. There is objective evidence of observance to established procedures.

Part E. Nonconforming Material

529. Is an MRB) established, documented, and operational?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that—

(1) MRB members have been identified. This includes, as a minimum—

(a) Identification of the required members of the MRB, which should include, as a minimum, representatives of both the quality and the engineering departments.

(b) Required qualifications of the quality and engineering members of the MRB and the means by which personnel are added to the MRB.

(c) A list or electronic equivalent of approved quality and engineering representative members of the MRB, the frequency MRB lists are updated, the areas where these lists are available, and a facsimile of MRB member signatures or identification stamps.

(d) Approval of MRB representatives of both the quality and the engineering departments of MRB documents that disposition nonconforming parts “accept-as-is” and “repair.”

(2) The MRB has not exceeded its scope and limits of authority. This includes, as a minimum—

(a) Disposition of minor nonconformances as “accept-as-is,” “rework,” “repair,” “scrap,” or “return-to-supplier.”

(b) Disposition of major nonconformances as “rework” (to eliminate the nonconformance), “repair” (to reduce nonconformance to minor), “scrap,” or “return-to-supplier.”

(c) The MRB has dispositioned major nonconformances as “accept-as-is” only after the major change has been approved by the FAA as a change to the FAA-approved type design.

(3) Nonconforming material is controlled from presentation to the MRB through final MRB disposition. MRB control may be accomplished through segregation (physical or electronic), marking, or tagging, etc., in a manner to preclude inadvertent release, or release by non-MRB personnel. This includes, as a minimum—

(a) Completion of all necessary MRB documents, including all required signatures of MRB personnel, before physical release of products/parts from MRB control.

(b) Identification of MRB material sent to manufacturing areas for rework or repair to preclude subsequent release without MRB approval.

(c) Identification of MRB material sent to manufacturing areas for continued processing and reinspection of the nonconformance after subsequent operations to ensure reinspection of the specified characteristic.

(4) There is objective evidence that material review records are generated and retained.

(a) Material review records include, as a minimum, part number, quantity, date, adequate description of nonconformances (including identification as major or minor change), disposition, and authorized approval.

(b) Application of "electronic" signatures are controlled, as well as authorized access to electronic data for making changes (for example, password protection).

(c) Records are legible, complete, and accurate.

(5) Nonconforming material disposition authority delegated to preliminary review personnel is limited to "scrap," "return-to-supplier," "rework," or "repair to approved standard repair procedures."

530. Are nonconforming products/parts/articles identified, controlled, and dispositioned?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. There is objective evidence that nonconforming products/parts have been identified, controlled and dispositioned. Control includes segregation of nonconforming material, usually through storage in enclosed and secure holding areas, with access limited to authorized personnel. Standard repair procedures also should be controlled.

(1) Nonconforming materials and parts/products that have been dispositioned as "scrap" are properly identified, mutilated, or disposed of to preclude inadvertent use.

(2) Parts/products dispositioned as “scrap” that are retained in lieu of mutilation and disposal are properly identified and/or physically segregated to preclude inadvertent use. For example, parts placed in a “scrap retention” crib awaiting a possible repair to be developed, or used in mock-ups or experimental testing.

(3) Parts from assemblies dispositioned as “scrap” are recovered and used only if the material review disposition shows that those parts did not contain the nonconformances that led to the “scrap” disposition.

531. Are MRB dispositions identified as major changes approved by the FAA through the design approval process?

Applicability

	PC	PMA	TSO
A	§ 21.97	§ 21.319	§ 21.619
E	§ 21.146	§ 21.319	§ 21.619

Statement of Condition

a. There is objective evidence that all nonconformance dispositions that are considered major changes to the design are submitted to the FAA for approval.

532. Does upper management review and analyze nonconforming material data to detect adverse trends and determine appropriate levels of corrective and preventive actions?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for a summary of nonconforming material data reviewed and analyzed by upper management. This includes frequency of reporting and appropriate investigations by all relevant facility organizations to reduce, prevent, and correct adverse trends.

b. There is objective evidence of observance to established procedures.

533. Do procedures provide for engineering review of nonconforming material to determine if the documented nonconformance constitutes a major or minor change to the FAA-approved type design?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

534. Is corrective action (in-plant, at suppliers, and in-service) required where processes or procedures result in a nonconforming product/article/part thereof and are the actions monitored for response, implementation, and effectiveness?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Periodic reviews of material review records to identify repetitive nonconformances. There are guidelines for initiating investigation and corrective action for repeated nonconformances that have exceeded an established limit of occurrences.

(2) Corrective action on repetitive nonconformances dispositioned “accept-as-is” to preclude de facto changes to the type design being made through MRB acceptance of those nonconformances, rather than through the FAA-approved change system.

(3) Audit of the design if a product/article/part thereof continually fails to meet the requirements of the engineering drawing.

(4) Control of any deviation system established to allow the production of products/parts thereof to increased tolerances and/or relaxed standards until the completion of corrective action. Some deviations are FAA-approved minor drawing changes to the type design.

(5) Review of material review records (including corrective action statements) for repetitive nonconformances to monitor response, implementation, and effectiveness of corrective action.

(6) Responsibilities of any Corrective Action Board (CAB) or equivalent function established, including tracking of significant corrective action.

b. There is objective evidence of observance to established procedures.

Section 6. Supplier Control

1. System Element Description. The system by which the audited facility ensures supplier materials, parts, and services conform to FAA-approved design. For the purpose of this section, the term "supplier" includes distributors.

Note: With the onset of profit- and risk-sharing ventures by many FAA approval holders, global marketing and procurement strategies, multinational and multicorporate activities, etc., there has been a significant increase in the global expansion of the world's aircraft manufacturing community. Global production includes the use of associate facilities, the issuance and acceptance of import/export airworthiness approvals, and adherence to bilateral airworthiness agreements (BAA) or bilateral aviation safety agreements (BASA).

a. Reviewing PAH supplier audit records. The auditor will review a randomly selected sample of documented audit reports from the supplier listing. Use the following guidelines when selecting the sample reports:

(1) For PAHs having a supplier listing of less than or equal to 50, the auditor will select and review at least 3 audit reports.

(2) For PAHs having a supplier listing of greater than 50, but less than or equal to 100, the auditor will review at least 6 audit reports.

(3) For PAHs having a supplier listing of greater than 100, the auditor will review at least 9 audit reports.

b. Recording reviews. The auditor will record the total number of audit reports reviewed, the identification of suppliers reviewed, and the total number of noncompliances documented. This information will be recorded on the Conformity Inspection Record (FAA Form 8100-1) and entered into CMIS as part of the QSA report.

c. Recording noncompliances. Any noncompliance noted during the review of PAH supplier audit reports will be recorded under supplier control system element criteria number 602. Any noncompliances also will be documented in accordance with paragraph 3-44 of this order.

2. System Element Standardized Audit Criteria. The following criteria are used to document audit of this system element.

601. Is the use of approved suppliers required?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Criteria for supplier acceptability based as a minimum on audit results and quality performance history for the commodities or services provided.

(2) Collection, audit, and reporting of quality performance data.

(3) A list of suppliers that have been reviewed, audited, and found to be acceptable.

(4) Removal of suppliers from the approved list that do not meet stated requirements.

(5) Notification of the FAA of new priority parts suppliers.

(6) Methods for procurement from suppliers that require special control.

(7) Furnishing a current list to suppliers containing sources audited by the PAH.

b. There is objective evidence of observance to established procedures.

602. Are initial and periodic audits of suppliers made as necessary and corrective actions taken to correct deficiencies found in the suppliers system?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Initial, and periodical as necessary, audit of suppliers, to determine their capability to meet requirements.

(2) The methods for determining the extent of the audits dependent, as a minimum, on the type, complexity, method of control, and importance of products or services procured, and the extent of the onsite audit, process reviews, document reviews, or independent product audits.

(3) Implementing and documenting effective corrective action when deficiencies are found.

b. There is objective evidence of observance to established procedures.

603. Is the supplier's quality manual (or top-level document) approved by the PAH?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide the method for reviewing and approving a supplier's quality system data.

b. There is objective evidence of observance to established procedures.

604. Are procedures for the use of other parties to perform supplier surveillance or assessments on behalf of the PAH contained in the quality manual or other documents?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for a control process that has been fully documented and includes initial and continuing approval of other parties to conduct supplier surveillance and assessments to include—

(1) Extent of authority given by the PAH.

(2) Verification that checklists used by the other party are equivalent or better than the PAH's quality procedures and surveillance criteria currently in place under the PAH's supplier control program.

(3) Verification that the other party's surveillance frequency of the supplier is commensurate with the complexity of the product and with the surveillance frequency currently established by the PAH's supplier control program.

(4) Verification that the supplier surveillance was conducted onsite by the other party.

(5) Verification that the other party has access to applicable proprietary data to the extent necessary to conduct supplier surveillance functions.

(6) Verification that the surveillance report will be made available to the FAA upon request.

b. There is objective evidence of observance to established procedures.

605. Are procedures for the use of other-party registered suppliers detailed in the quality manual or other documents?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Initial and continuing approval of other-party registered suppliers.

(2) The method used by the PAH to audit the registration process of any other-party registration body used. (Note: This applies not only to new suppliers, but to any decision by the PAH to rely on other-party registration of current suppliers.) The method should include the following items as a minimum:

(a) Verification that registration standards and checklists used by the other party are equivalent or better than the PAH's quality procedures and surveillance criteria currently in place under the PAH's supplier control program.

(b) Verification that the other party's surveillance frequency of the supplier is commensurate with the complexity of the product and with the surveillance frequency currently established by the PAH's supplier control program.

(c) Verification that the supplier surveillance was conducted onsite by the other party.

(d) Verification that the other party has access to applicable proprietary data to the extent necessary to conduct supplier surveillance functions.

(e) Verification that the surveillance report will be made available to the FAA upon request.

(f) Verification that the other party continues to be recognized or accredited.

b. There is objective evidence of observance to established procedures.

606. Do procedures require that suppliers notify the audited facility in writing when there are significant facility or organizational changes such as company name, location, or senior quality management?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

607. Does the audited facility make information available to the FAA regarding all delegation of authority to suppliers to make a major inspection/material review of any products/parts/articles?

Applicability

	PC	PMA	TSO
A	§ 21.146	§ 21.316	§ 21.616
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Delegation of authority for major inspections or material review.

(2) Material review requirements that include, as a minimum—

(a) Identification of relevant MRB procedures that define the scope and authority of the supplier MRB.

(b) Maintenance of an MRB system that meets all FAA requirements placed on the audited facility's MRB system (for example, documentation of nonconformances, maintenance of records, members of the MRB, and mutilation of "scrap" material).

(c) Process for submittal to the audited facility of supplier nonconformances considered major changes to the FAA-approved type design.

(3) All delegations of authority to suppliers for major inspection of any products/parts are available for review by the FAA.

b. There is objective evidence of observance to established procedures.

608. Does the PAH notify the FAA of suppliers authorized to direct ship?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for notification to the cognizant FAA office of each supplier authorized to direct ship.

b. There is objective evidence of observance to established procedures.

609. Are suppliers with direct ship authorization controlled to ensure only conforming parts are released?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Flow down of applicable technical and quality requirements.

(2) Authorization and requirements for direct shipment.

(3) Supplier shipping document requirements for direct shipment.

(4) Appropriate part marking/identification and packaging.

b. There is objective evidence of observance to established procedures.

610. Do procedures require that approved suppliers have a supplier control program in place for their suppliers?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence that suppliers have a supplier control program in place for their suppliers. The program should include as a minimum—

(1) Audit, approval, and surveillance of suppliers, including a method to ensure corrective action when a problem is identified.

(2) Flow down of all pertinent quality requirements.

(3) Documentation of parts/materials and special processes obtained from suppliers and submitted to the audited facility.

611. Does the audited facility flow down applicable technical and quality requirements to both U.S. and international suppliers?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for inclusion of applicable technical data and quality requirements in the purchase documents. Technical data and requirements include the following, as applicable:

(1) Special processing specifications/engineering requirements for suppliers performing special processing.

(2) Calibration traceable to a national standard and submittal of certificates for suppliers performing calibration services.

(3) Software specification requirements for suppliers providing software.

(4) Submittal of certification test reports for all shipments of raw material.

(5) Identification of raw and process material in accordance with industry and/or customer specifications.

(6) Appropriate identification and marking of products/parts thereof.

(7) Identification of the actual manufacturers of the supplies provided by warehouses and distributors.

(8) Declaration that parts were produced under the terms of the production approval.

(9) Identification of the product on which the part is eligible for installation.

(10) Special packaging and preservation requirements, when warranted for material protection.

(11) Identification of appropriate technical requirement revision levels.

(12) Notice of FAA review of supplier's facilities and products as necessary.

(13) Incorporation of design changes as specified.

(14) Notification to the audited facility of any latent defects, or defects listed in § 21.3, in products or parts previously supplied.

(15) Formalized SQC policy, when required.

(16) Requests for copies of control charts and other pertinent statistical data applicable to the time period during which the supplied products/parts thereof were produced.

(17) Submittal of supplier designs and changes to the audited facility for approval before incorporation, when required.

(18) Submittal of changes to a supplier's quality system that may affect inspection, conformity, or the airworthiness of the product.

(19) Record retention requirements.

(20) Use of the English language for quality data (for example, supplier quality procedures, certificates, reports, or other similar data required by the audited facility).

(21) A method to control the issuance and distribution of technical data and quality requirements to suppliers. Control methods include, as a minimum—

(a) Control and documentation of revisions to technical data and quality requirements (including subtier and referenced documents).

(b) Control of obsolete technical data and quality requirements.

(c) Determination of receipt status by the supplier.

b. There is objective evidence of observance to established procedures.

612. Does the audited facility control supplier design, including changes?

Applicability

	PC	PMA	TSO
A	§ 21.95 § 21.97 § 21.99 § 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for control over supplier design and changes thereto.

b. There is objective evidence of observance to established procedures.

613. Are electronically stored and transmitted technical design and quality data adequately controlled and distributed to suppliers?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for—

(1) Documentation of release status of electronic documents.

(2) Only properly released data being available online.

(3) Other documents, such as purchase orders and engineering data to reflect changes to the source document.

(4) Capability determination of in-house and supplier facility to receive and maintain electronic data.

b. There is objective evidence of observance to established procedures.

614. Does the quality organization review purchase documents before issuance?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition:

a. Procedures provide for review of purchase documents by the PAH's quality organization before issuance to ensure all pertinent requirements have been incorporated.

b. There is objective evidence of observance to established procedures.

615. Does the PAH act on supplier notifications of suspected problems with previously delivered products?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for methods used to act on notifications of nonconforming products, ensuring proper investigation and corrective action is taken.

b. There is objective evidence of observance to established procedures.

616. Do procedures require that approved suppliers have a program in place to ensure the proper operation of manufacturing software and equipment used for product/part/article inspection/test?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. There is objective evidence of observance to established procedures.

617. Does the PAH notify the FAA of all new suppliers located in other countries and of the receipt of first articles produced by those suppliers?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for notification to the FAA of all new suppliers located in other countries and of the receipt of first articles produced by those suppliers.

b. There is objective evidence of observance to established procedures.

618. Are products/articles/parts from associate facilities controlled?

Applicability

	PC	PMA	TSO
A	§ 21.137	§ 21.307	§ 21.607
E	§ 21.146	§ 21.316	§ 21.616

Statement of Condition

a. Procedures provide for—

(1) Control of products/articles/parts from associate facilities.

(2) Collection of quality performance data.

b. There is objective evidence of observance to established procedures.

619. Has an interface quality document been prepared for consortium (international/domestic) manufacturing activities?

Applicability

	PC	PMA	TSO
A	P	P	P
E	N	N	N

Statement of Condition

a. Procedures provide for a quality document that establishes an interface between the quality requirements of the international/domestic manufacturing activity and the audited facility's quality manual or procedures.

b. There is objective evidence of observance to established procedures.

Appendix I. 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 I-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 or associate facility. Prepare the form by inserting in:

a. Block 1. When the activity is a QSA, enter the QSA Number/Report Number. For all other activity, enter "N/A."

b. Block 2. The project number(s) applicable to the production approval(s) activity.

c. Block 3. A check mark in the appropriate box to indicate the type of activity that was conducted.

d. Block 4. Under "System Element Audited," enter the name of the system element in appendix H to this order to which the noncompliance is relevant. Under "Audit Criteria Number," enter the audit criteria number from appendix H to this order. For new criteria, insert the system element number assigned by appendix H to this order. 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 criteria are affected, an FAA Form 8100-6 should be completed for each condition. When noncompliances are recorded for a common condition, only one FAA Form 8100-6 should be completed.

e. Block 5. The reference controlling document. The controlling document is defined as the FAA-approved data, purchase order/quality requirements from a PAH or associate facility, 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. (Examples: 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 or associate facility 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.

f. Block 6. The applicable 14 CFR part or section that establishes the responsibility of the PAH (for example, § 21.316 or § 21.616). If the observed condition is not directly traceable to one of these requirements, 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 purposes of this order, the quality levels, from highest to lowest, are PC, TSO authorization, and PMA.

g. Block 7. A check mark in the appropriate box to indicate the type of noncompliance found. A noncompliance is indicated when it is discovered that a PAH's or associate facility's operating practices are inconsistent with 14 CFR, FAA-approved data, or internal procedures. Internal procedures refer to a PAH's or associate facility's procedures that are not included as part of the FAA-approved data. A supplier's operating practices found to be inconsistent with a PAH's or associate facility's purchase order requirements are considered to be noncompliances by the PAH or associate facility. A noncompliance is classified into one of the following four categories:

(1) Safety-Related Noncompliance: 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. This includes any noncompliance to § 21.3, including an isolated noncompliance. For a QSA, record a safety-related noncompliance only when the responsible PI determines that immediate action is required.

> **Note:** The PI should formally submit any safety-related noncompliance to the responsible PAH or associate facility in writing within 72 hours of discovery. If the noncompliance affects delivered products or services, the PI will secure from the responsible PAH or associate facility a list of the end users affected and immediately notify the cognizant ACO, MIO, MIDO, or CMO.

(2) Systemic Noncompliance: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is not safety-related and is systemic in nature, that is, is pervasive, repeatable, and represents a breakdown in the quality system.

(3) Isolated Noncompliance: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is not safety-related and is of an isolated or nonsystemic nature, that is, is not pervasive or repeatable, and does not represent a breakdown in the quality system. However, an isolated noncompliance with § 21.3 is considered a safety-related noncompliance when it meets the definition in paragraph 2g(1) of this appendix.

(4) Certification-Related Noncompliance: a noncompliance to 14 CFR that is discovered in FAA-approved data and that is not safety-related.

> **Note:** Number noncompliances sequentially beginning with the number "1."

h. Block 8. 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.

i. Block 9. 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 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 ACO, MIO, MIDO, or CMO may be required.

(7) List all objective evidence obtained that describes the encountered condition.

j. Block 10. A check in the box to indicate that the encountered condition has been discussed with the facility escort, as a minimum.

k. Block 11. The typed or printed name and signature of the person recording the noncompliance.

Note: Auditors-in-training may sign this block. However, the block must be countersigned by an appointed QSA auditor.

l. Block 12. The routing office symbol of the recorder.

m. Block 13. The date the form is completed.

Figure I-1. Sample FAA Form 8100-6

This form is a representation of the original form and not to be construed as the original form.

U.S. Department of Transportation
Federal Aviation Administration

Noncompliance Record

QSA No./Report No. *(1)*
N/A

Project No. *(2)*
PT900NE

Type of Activity: ☐ MIDO Audit ☐ PI Audit ☐ QSA ☐ Supplier Control Audit ☒ Product Audit ☐ Other *(3)*

System Element Audited: *(4)*	Controlling Document: *(5)*	Applicable CFR Section: *(6)*
Manufacturing Processes	RC Purchase Order #94 of 11/23/2007	21.607
Audit Criteria Number:		
413	FAA-approved data? ☐ Yes ☒ No	

Type Of Noncompliance: Safety-Related ☐ Systemic ☒ Isolated ☐ Certification-Related ☐ No. 1 *(7)*

Required Condition: *(8)*

RC Purchase Order (PO) #94 for rotor support couplings states: "J&J Machining Co. shall comply with RC Quality Manual, Section 4, and purchase raw materials exclusively from YOYO International Material Broker. Terms of purchase will include a request for a metallurgical lab report with each shipment. These reports will be retained by J&J Machining Co. for a minimum of 5 years."

J&J Machining Co. Quality Manual, paragraph 12.4(c), states: "All raw material purchase orders shall include a statement requiring suppliers to furnish a metallurgical lab report with each shipment. The reports will be retained by J&J Machining Co. metallurgical lab in accordance with paragraph 23.6."

Encountered Condition: *(9)* ☒ *Discussed with Facility* *(10)*

Ten J&J Machining Co. purchase orders for raw materials to be used for the manufacture of rotor support couplings under RC PO #94 were reviewed (J3-122; J3-114; J3-221; J3-98; J3-301; J3-110; J3-245; J3-15; J3-278; J3-184). All ten POs were issued to YOYO International Material Broker as required by RC PO #94, and all included the statement for furnishing a metallurgical lab report with each shipment. All raw material shipments were completed between January 2007 and March 2008. The J&J Machining Co. metallurgical lab files were reviewed to determine whether metallurgical lab reports had been furnished with each shipment required by the ten POs. Only one metallurgical lab report was found to be on file (shipment under PO #J3-122).

Attachments:

RC Purchase Order #94

RC Quality Manual, Section 4

J&J Machining Co. Quality Manual, paragraphs 12.4(c) and 23.6

J&J Machining Co. PO # J3-122; J3-114; J3-221; J3-98; J3-301; J3-110; J3-245; J3-15; J3-278; J3-184

Typed Name and Signature of Recorder: *(11)*	Office Symbol *(12)*	Date *(13)*
Julia R. Gotta *Julia Gotta*	ANE MIDO 42	5/1/11

FAA Form 8100-6 (09-12) FOR OFFICIAL USE ONLY
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Sample

Appendix J. 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 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 J-1 and J-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 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 system elements that have noncompliances recorded. Do not list 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 system element discussed.

f. Block 6. 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 J-1. Sample Executive Summary for PAHs and Associate Facilities

FEDERAL AVIATION ADMINISTRATION
QUALITY SYSTEM AUDIT (QSA)
EXECUTIVE SUMMARY

(1) **QSA NO./REPORT NO.:** 98NE278/1-1 **(2)** **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.

Design Control System Element: 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 obsolete 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 Nos. 123–666 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) J.J. Gem **(7)** August 15, 2011

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Sample

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

FEDERAL AVIATION ADMINISTRATION
QUALITY SYSTEM AUDIT (QSA)
EXECUTIVE SUMMARY

(1) **QSA NO./REPORT NO.:** 01SW334/1-1 **(2)** **PROJECT NO.:** PP0000SW

(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.

Sample

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

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Appendix K. 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 ACO and MIO managers, the PI, the AE, 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 K-1 shows a sample special emphasis items 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 system element, and referencing the relevant noncompliances. Provide a recommendation for further action required, as appropriate.

Figure K-1. Sample Quality System Audit Special Emphasis Items for PAHs and Associate Facilities

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 ACO 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 No. 20. There is a systemic problem with FAA-approved drawings that call out incorrect or nonexistent process specifications. We recommend that this problem be investigated further.

Sample

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Appendix L. 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 L-1 shows the front of FAA Form 8100-3 with numbered blocks. Prepare the form by typing in 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 MIDO or CMO responsible for surveillance of the audited facility. No entry is required if the certificate management MIDO or CMO 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 L-1. Sample FAA Form 8100-3 (Front)

U.S. Department of Transportation
Federal Aviation Administration

QSA Number
02CE365

(1)

Quality System Audit Report No. 1-1 (2)

Facility: (3)
XYZ Tire Company
55667 Aviation Parkway
Anytown, OH 45000-5566

Facility Type: ☐ PC ☐ TSO ☐ PMA ☐ Extension(s)

(4)

(5) Start Date: May 17, 2010

(6) End Date: May 21, 2010

Certificate Management Oversight Office: (7)

Vandalia MIDO

Certificate Management/Geographic MIDO/CMO: (8)

(9) Prepared By: Jill Doe

(10) May 21, 2010

FAA Quality System Audit Team Leader — Date

(11) Location of Objective Evidence: Retained by the principal inspector.

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Sample

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

a. Block 12. The name of each team member, including any national resource specialist, manager, or outside support service personnel 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 "E" to identify auditors-in-training or a "T" to identify team leaders-in-training. Leave this block blank for team members.

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

TEAM MEMBERS

Name	Office	Discipline	Specialty	Training Status (A or T)*
(12)	**(13)**	**(14)**	**(15)**	**(16)**
John Smith	Atlanta MIDO	ASI		
Fred Exe	ACE-118W	Eng	Airframe	
Mary Lamb	ACE-117A	Eng	Airframe	A

*A = Auditor-in-training
T = Team

Leader-in-training

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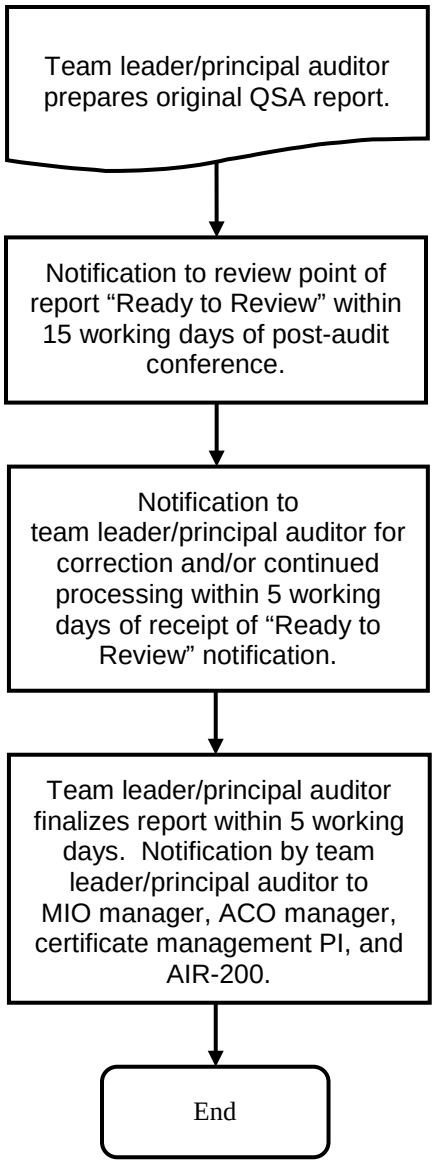
Sample

Appendix M. Process for Sending Quality System Audit Reports

1. Purpose. This appendix provides a flowchart to assist the team leader, principal auditor, MIO manager, and ACO manager in identifying where a completed QSA report, using the CMIS program, is sent and the associated action timelines. It supplements the description provided in chapter 3, section 3, part 4, subpart C of this order.

2. Description. Figure M-1 provides the flowchart to identify who is notified during the completion of a QSA report using the CMIS program.

Figure M-1. Process for PAHs and Associate Facilities



Appendix N. 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, associate facilities, 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. Figure N-1 shows FAA Form 8120-14 with numbered blocks. Prepare the form by inserting in:

a. Block 1. The name and address of the PAH or associate facility as recorded on the production approval.

b. Block 2. The project number(s) applicable to the production approval(s).

c. Block 3. The name and address of the supplier as recorded on the PAH's documentation.

d. Block 4. A check mark in the appropriate box(es) to indicate the type of production approval.

e. Block 5. A check mark in the appropriate box(es) to indicate the type of activity that was conducted.

f. Block 6. The starting date and the ending date of the activity that was conducted.

g. Block 7. The title, revision number, and date of the quality manual submitted to the FAA by the PAH or associate facility. The applicable 14 CFR part or section may also be entered. For a supplier, enter the applicable purchase order or quality system requirements from the PAH or associate facility.

h. Block 8. The date the applicable quality manual submitted by a PAH or associate facility is approved by the FAA.

i. Block 9. An "X" in the column next to the system element/subelement 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 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 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 or PI audit. In most cases, this will be the PI responsible for the PAH or associate facility.

> **Note 1:** CMIS 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 MIDO audit with multiple team members, the signature in block 18 is 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 3-21 of this order.

s. Block 19. The office symbol of the person completing this form.

t. Block 20. The date that this form is completed.

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

This form is a representation of the original form and not to be construed as the original form.

U.S. Department of Transportation
Federal Aviation Administration

Production Approval / Certificate Management Activity Report

Manufacturer/Address: RC Couplings, 10001 Admiral Square, Haverhill MA 01830 *(1)*

Project No.: PQ 1234NE *(2)*

Supplier/Address: N/A *(3)*

Production Basis: *(4)*

PC ☐ TSO authorization ☐ PMA ☒

Production Approval/Certificate Management Activity: *(5)*

MIDO Audit ☐ PI Audit ☒ Product Audit ☒ Supplier Control Audit ☐ QSA Audit ☐ Other ☐

Activity Dates: From 4/1/2010 To 4/2/2010 *(6)*

Quality Manual –Title, Revision, Date, and/or CFR Section Involved: *(7)*

RC Quality Manual, Rev. C, 12/27/2009

Date of FAA Approval of Quality Manual: 1/31/2010 *(8)*

PI AUDIT OR MIDO AUDIT RESULTS

SYSTEM ELEMENT	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No. (s)*
1. Organizational Management	*(9)*	*(10)*
2. Design Control		
3. Software Quality Assurance		
4. Manufacturing Processes		
4a. Manufacturing and Special Manufacturing Processes		#1 and #2
4b. Material Receiving, Handling & Storage		
4c. Airworthiness Determination		
5. Manufacturing Controls		
5a. Statistical Quality Control (SQC)		
5b. Tool and Gauge		#3
5c. Testing		
5d. Nondestructive Inspection		
5e. Nonconforming Material		
6. Supplier Control		

PRODUCT AUDIT RESULTS

PRODUCT AUDITED (Nomenclature/Part Number)	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No.(s)*
Rotor support coupling *(11)* P/N RC25 - 1000	*(12)*	#4 thru #6 *(13)*

FAA Form 8120-14 (09-12)

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

Sample

Figure N-1. Sample FAA Form 8120-14 (Back)

This form is a representation of the original form and not to be construed as the original form.

SUPPLIER CONTROL AUDIT RESULTS

PURCHASE ORDER/QUALITY REQUIREMENTS	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No.(s)*
(14)	*(15)*	*(16)*

Sample

PARTICIPATING AUDITORS *(17)*

NAME	TITLE	OFFICE SYMBOL

Typed/Printed Name and Signature of PI: *(18)*	Office Symbol *(19)*	Date *(20)*
Julia R. Gotta *Julia R. Gotta*	ANE MIDO 42	4/3/2010

FAA Form 8120-14 (09-12) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

Appendix O. Forms Listing

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

Figure O-1. Forms Available from FAA Logistics Center

Form Number	Title	NSN	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

Figure O-2. Forms Available Within CMIS

Form Number	Title
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 P. Acronyms

14 CFR	Title 14 of the Code of Federal Regulations
AC	Advisory Circular
ACO	Aircraft Certification Office
AD	Airworthiness Directive
AE	Assigned Engineer
AIR	Aircraft Certification Service
AIR-100	Aircraft Engineering Division
AIR-150	Safety Management Design and Analysis Branch
AIR-200	Production and Airworthiness Division
AIR-500	Planning and Program Management Division
AIR-510	Administrative Services Branch, Planning and Program Management Division
ASI	Aviation Safety Inspector
CAA	Civil Aviation Authority
CM	Certificate Management
CMIS	Certificate Management Information System
CMO	Certificate Management Office
CPL	Category Parts List
DAR	Designated Airworthiness Representative
DER	Designated Engineering Representative
FAA	Federal Aviation Administration
FSDO	Flight Standards District Office
ICSSP	International Cooperative Supplier Surveillance Program
MIDO	Manufacturing Inspection District Office
MIO	Manufacturing Inspection Office
MOU	Memorandum of Understanding
MRB	Material Review Board
MSAD	Monitor Safety Analyze Data
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

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

Appendix Q. Definitions

a. Ad Hoc CM. The performance of special CM tasks that may be accomplished on an as-needed basis.

b. 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.

c. Article. A material, part, component, process, or appliance.

d. Assigned Engineer (AE). An FAA engineer to whom the ACO manager has assigned responsibility for a QSA at a particular design approval facility.

e. 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.

f. Audit. A systematic and independent examination of an established PAH or associated facility system based on the system elements defined in appendix H to this order.

g. Auditor. An individual the FAA appoints to perform QSAs, PI audits, or supplier control audits.

h. 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.

i. Certificate Management (CM). The method by which the FAA ensures that a PAH remains in compliance with those pertinent regulations that govern the manufacturing of its particular products, articles, or parts.

j. Certificate Management Information System (CMIS). Electronic data system that incorporates several aspects of CM functions. Functions available within CMIS are certification management tasks, and the planning, scheduling and conducting of audits.

k. Commercial Part. A part not specifically designed or produced for applications on the aircraft. For the purpose of 14 CFR part 21, a design approval holder may designate an article as a "commercial part" if the FAA finds the part:

(1) Is not specifically designed or produced for applications on aircraft; and

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

l. Corrective Action. The measures taken to resolve unsatisfactory conditions and to prevent reoccurrence.

m. Days. A reference to calendar days, unless otherwise specified.

n. 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.

o. Established Industry Practice. A widely followed method of operating that achieves consistent performance of specific functions. Examples of established industry practices include a calibration recall system and an internal audit system.

p. 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.

q. Facility. A physical location where a PAH or associate facility performs all or part of the system element functions relevant to the approval authority granted by the FAA.

r. Foreign Manufacturer. A person other than an FAA PAH who causes a product, article, or part(s) to be produced outside the United States.

s. Geographic Manufacturing Inspection District Office (MIDO) or Certificate Management Office (CMO). The FAA office having responsibility for conducting CM activities of a facility located in its directorate region.

t. Internal Procedure. A PAH's or associate facility's procedures that are not included as part of the FAA-approved data.

u. Lead Audit Office. A directorate office or branch assigned to coordinate a QSA.

v. 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.

w. 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.

x. Noncompliance. A PAH's or associate facility'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 or associate facility's purchase order requirements is considered to be a noncompliance by the PAH or associate facility.

y. 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.

z. Ongoing CM. The performance of CM requirements based on an RBRT assessment that may be accomplished on a continuing basis.

aa. Principal Auditor. An FAA-appointed team leader who acts as the sole auditor for the performance of a QSA at a specific facility.

bb. Principal Inspector (PI). A manufacturing inspector who has been assigned CM responsibility of a particular PAH or associate facility.

cc. 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.

dd. Produce. To manufacture, or cause to be manufactured, a product, article, or part(s).

ee. Product. An aircraft, aircraft engine, or propeller.

ff. 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.

gg. 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.

hh. Quality System. A documented organizational structure containing responsibilities, procedures, processes, and resources that implement a management function to determine and enforce quality principles.

ii. 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.

jj. Random Sampling. A sampling procedure that ensures that each element in a population has an equal chance of being selected.

kk. Requesting MIDO or CMO. An office that requests associate facility CM from another office having geographic responsibility of the area in which the facility is located.

ll. 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.

mm. Root Cause. The underlying cause of a systemic or recurring noncompliance, usually identified through structured analysis.

nn. Special Audit Item (SAI). An item, process, or area that senior management has determined requires specific focus during audits.

oo. 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).

pp. Standardized Audit Criteria. Questions developed for each system element that the FAA QSA teams use to plan and document the audit. The applicable 14 CFR requirements, appropriate FAA ACs and directives, international standards and specifications, and established industry practices are the basis for these questions. Refer to appendix H to this order.

qq. Supplier. Any person as defined by 14 CFR part 1, Definitions and Abbreviations, that furnishes products, articles or services (at any tier in the supply-chain) that are used or consumed in the manufacture of, or installed on, aviation products, articles, or parts.

rr. Supplier Control Audit. A systematic and independent examination to determine compliance of an established supplier system, inspected product, article, or part(s), or processes with purchase order requirements, technical data, or specifications.

ss. System. An activity or function that may affect the maintenance of an FAA-approved design, quality data, or the design approval system.

tt. 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.

Appendix R. Administrative Information

1. 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 Directorates, to all FSDOs, to all ACOs, to all Aircraft Certification field offices, to all Manufacturing Inspection District and Satellite Offices, to the Aircraft Certification and Airworthiness Branches at the Federal Aviation Administration Academy, and to the Flight Standards Service Regulatory Support Division.

2. Delegation of Authority. AIR-200 is responsible for issuing, revising, or canceling the material in this order.

3. 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.

4. Forms. This order identifies several forms used for the audit, approval, and CM of production activities. Some of the forms are provided by AIR-200 in electronic format. Appendix O, Forms Listing, to this order provides a listing of the forms and their sources.

5. 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-200. 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-200 for review and approval. The limits of federal protection for FAA employees are defined by 28 U.S.C. § 2679.

6. 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, Freedom of Information Act Program.

7. 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.

8. Suggestions for Improvement. Please forward all comments on deficiencies, clarifications, or improvements regarding this order to:

Aircraft Certification Service
Administrative Services Branch, AIR-510
ATTN: Directives Management Officer
800 Independence Avenue, SW
Washington, DC 20591

FAA Form 1320-19, Directive Feedback Information, is located as appendix S to this order for your convenience. If you require an immediate interpretation, please contact AIR-200 at (202) 385-6346; however, you should also complete FAA Form 1320-19 as a followup to the conversation.

9. Records Management. Refer to FAA Orders 0000.1, FAA Standard Subject Classification System; 1350.14, Records Management; and 1350.15, Records Organization, Transfer, and Destruction Standards; Manual FAA-IR-04-01 Aircraft Certification Service Records Management Requirements Manual; or your office Records Management Officer (RMO)/Directives Management Officer (DMO) for guidance regarding retention or disposition of records.

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

U.S. Department
of Transportation
Federal Aviation Administration

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 8120.21

To: Administrative Services Branch, AIR-510

(Please check all appropriate line items)

☐ An error (procedural or typographical) has been noted in paragraph _____ on page _____.

☐ Recommend paragraph _____ on page _____ be changed as follows:
(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: _____

FAA Form 1320-19 (10-98)