

U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION

National Policy

ORDER 8120.23 CHG 1

Effective Date 7/25/14

SUBJ: Certificate Management of Production Approval Holders

1. Purpose. This change contains guidance related to specific components of the certificate management (CM) process.

2. Who This Change Affects. This change affects all Washington headquarters branch levels of the Aircraft Certification Service, Flight Standards Service, and the Regulatory Support Division; the Aviation System Standards office; the branch level in the Aircraft Certification Service directorates and regional Flight Standards Service divisions; all Aircraft Certification Offices; all Manufacturing Inspection District Offices and Manufacturing Inspection Satellite Offices; all Flight Standards District Offices; the Aircraft Certification Branch and Flight Standards Branch at the Federal Aviation Administration (FAA) Academy; all applicable representatives of the FAA; and all international field offices.

3. Explanation of Changes. This change-

a. Incorporates 21 significant and minor changes to components of the CM process. These include amendment of the definition of "inactive" with regard to production approval holders, clarification of how to prepare and document Quality System Audits to reflect current Certificate Management Information System capabilities, and several policy clarifications regarding the supplier audit process.

b. Clarifies policy and details procedures to verify accuracy and completeness of CM files and documentation. This includes updated procedures pertaining to the review and completion of schedules, reports, forms, and retention of objective evidence.

c. Incorporates several changes based on input through the directive feedback system, prior field office reviews, and corrective and preventive action reports.

4. Disposition of Transmittal Paragraph. Retain this transmittal sheet until the directive is cancelled by a new directive.

8120.23 CHG 1

Remove Pages Dated **Insert Pages** Dated i thru v 02/25/2013 i thru v 07/25/2014 viii thru ix 02/25/2013 viii thru ix 07/25/2014 2-2 thru 2-4 2-2 thru 2-4 02/25/2013 07/25/2014 3-2 02/25/2013 3-2 07/25/2014 02/25/2013 3-3 3-3 02/25/2013 3-4 02/25/2013 3-4 07/25/2014 3-6 thru 3-8 02/25/2013 3-6 thru 3-8 07/25/2014 3-9 thru 3-10 3-9 thru 3-10 02/25/2013 02/25/2013 3-11 02/25/2013 3-11 07/25/2014 3-13 thru 3-14 3-13 thru 3-14 02/25/2013 07/25/2014 3-16 02/25/2013 3-16 07/25/2014 3-17 02/25/2013 3-17 02/25/2013 3-18 thru 3-19 02/25/2013 3-18 thru 3-19 07/25/2014 3-20 thru 3-21 3-20 thru 3-21 02/25/2013 02/25/2013 3-22 02/25/2013 3-22 07/25/2014 3-25 thru 3-26 3-25 thru 3-26 02/25/2013 02/25/2013 3-27 thru 3-30 02/25/2013 3-27 thru 3-30 07/25/2014 3-31 thru 3-33 02/25/2013 3-31 thru 3-33 02/25/2013 3-37 thru 3-39 3-37 thru 3-39 02/25/2013 07/25/2014 3-41 02/25/2013 3-41 07/25/2014 3-42 thru 3-43 02/25/2013 3-42 thru 3-43 02/25/2013 3-44 thru 3-46 02/25/2013 3-44 thru 3-46 07/25/2014 4-2 02/25/2013 4-2 07/25/2014 4-6 02/25/2013 4-6 07/25/2014 4-10 02/25/2013 4-10 07/25/2014 5-1 5-1 02/25/2013 07/25/2014 B-3 02/25/2013 B-3 07/25/2014 B-5 02/25/2013 B-5 07/25/2014 E-1 02/25/2013 E-1 07/25/2014 I-1 02/25/2013 I-1 07/25/2014

PAGE CHANGE CONTROL CHART

8120.23 CHG 1

Remove Pages	Dated	Insert Pages	Dated
M-1	02/25/2013	M-1	07/25/2014
N-1	02/25/2013	N-1	07/25/2014
O-1	02/25/2013	O-1	07/25/2014
P-1	02/25/2013	P-1	07/25/2014
R-1	02/25/2013	R-1	07/25/2014

Tana 20 -

James D. Seipel Acting Manager, Design, Manufacturing, & Airworthiness Division Aircraft Certification Service

U.S. DEPARTMENT OF TRANSPORTATION FEDERAL AVIATION ADMINISTRATION



Effective Date: 02/25/2013

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.

Fund 9.

Frank P. Paskiewicz Deputy Director, Aircraft Certification Service

Page

Table of Contents

Paragraph

I

Chapter 1. General

1-1.	Purpose of This Order1-1
1-2.	Audience
1-3.	Where Can I Find This Order
1-4.	Cancellation1-1

Chapter 2. Certificate Management Procedures

Section 1. General Information

2-1.	Chapter Information and Format	.2-1
2-2.	Overview	.2-1
2-3.	Assignment of CM Coordinator	.2-2
2-4.	Status of a PAH	.2-2
	Figure 2-1. CM Life Cycle Process	.2-4

Chapter 3. Ongoing CM Responsibilities

Section 1. Introduction

3-1.	CM Tasks	3-1
	Figure 3-1. CM Responsibilities (Ongoing) Minimum Requirements	3-1
3-2.	CM Plan	3-2
3-3.	Coordination of Requests for Supplier Surveillance Assistance with Other CAAs	3-2
3-4.	Recording Noncompliances	3-3
3-53-6.	Reserved	3-3

Section 2. Risk-Based Resource Targeting

3-7. RBRT Assessment Tool	-4
3-8. Scope	-4
3-9. RBRT Risk Levels	
3-10. RBRT Assessment of Facilities	-4
3-11. Modification of RBRT Assessment	-5
3-12. Modification of RBRT Assessment Tool	
3-133-14. Reserved	-6

Table of Contents (Continued)

Paragraph	
-----------	--

Page

8120.23 CHG 1

Section 3. Quality System Audit

Part 1. QSA Introduction

3-15. General	
163-17. Reserved	3-6

Part 2. QSA Auditor Appointment and Training

3-18. General	
3-19. Appointing Officials	.3-7
3-20. Criteria for Candidate Selection	
Figure 3-2. Criteria for Candidate Selection and Team Member Appointment	.3-8
3-21. Criteria for Appointment	.3-8
Figure 3-3. Criteria for Team Leader Appointment	
3-22. Review of Appointment	
3-23. Reinstatement of Auditors Failing to Meet Appointment Review Criteria	
3-243-25. Reserved	

Part 3. Selection and Scheduling of QSAs

3-26. QSA Intervals	
3-27. Selection of Facilities To Be Audited	
3-28. Scheduling of QSAs	
3-29. Selection of QSA Auditors	
Table 3-1. Selecting a PI or AE as an Auditor	
3-30. Notification of Facilities To Be Audited	
3-31. Modifications to Scheduled Audits	
3-323-33. Reserved	
3-31. Modifications to Scheduled Audits	

Part 4. QSA Procedures

Subpart A. QSA Preparation

Page

Table of Contents (Continued)

Paragraph	
-----------	--

Subpart B. Conduct of the Audit

3-40. Team Leader or Principal Auditor Coordination with Facility Representative	3-22
3-41. Pre-Audit Team Meeting	3-23
3-42. Pre-Audit Conference	3-23
3-43. Audit of System Elements	3-24
3-44. Recording Noncompliances	3-26
3-45. Audit Meetings	3-26
3-46. Post-Audit Conference	3-28
3-473-48. Reserved	3-29

Subpart C. Post-Audit Activities

3-49. Preparing the QSA Report	
3-50. Quality Review of the QSA Report	
3-51. Sending the QSA Report	
3-52. Requesting Corrective Action	
3-533-54. Reserved	

Section 4. Supplier Control

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

3-55. General PAH Supplier Control Responsibilities	3-31
3-56. CM Activity	
3-57. Determination of Supplier Control	
3-583-59. Reserved	3-33

Part 2. Supplier Control Audits

3-60. Scheduling	
3-61. Supplier Selection	
3-62. Directorate Supplier Control Audit	
3-63. Coordination of Supplier Control Audits Between Directorates	
3-64. Handoff Procedures	
3-65. Notifying a PAH or Associate Facility	
Figure 3-4. Sample Supplier Control Audit Notification Letter	
3-66. Conducting and Recording a Supplier Control Audit	
3-673-68. Reserved	

Paragraph	Page
-----------	------

Section 5. Principal Inspector Audit

3-69. Scheduling	
· •	

Section 6. Product Audit

3-73. Scheduling	
3-74. Selection of Product Audit Characteristics	
3-75. Product Audit Areas	
3-76. Product Audit Criteria	
Figure 3-5. Applicability of Product Audit Criteria to Product Audit	
Areas (Minimum)	
3-77. Recording Product Audit Results	
3-78. Recording Completion of a Product Audit	
3-793-80. Reserved	

Section 7. Special Audit Items

Reserved	3-4	4	(5
----------	-----	---	---	---

Chapter 4. Special CM Responsibilities

Section 1. Introduction

I

4-1.	Section Information	.4-	1
4-24-3.	Reserved	.4-	1

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

4-4.	General MIDO/CMO Responsibilities	4-1
	Prioritization of Review.	
4-6.	Review of Changes	4-1
	Post-Review Actions	
4-84-9.	Reserved	4-2
	Figure 4-1. Sample Letter of Approval for Quality System Changes	4-3

Paragraph		Page

Section 3. Investigation of Service Difficulties

4-10. General Service Difficulties Information	4-4
4-11. Investigation	4-4
4-12. Corrective Action	
4-13. Reporting a Service Difficulty Investigation	
4-14. Foreign Manufacturers	
4-154-16. Reserved	

Section 4. PAH Noncompliances and Corrective Action

4-17. PAH Noncompliances	4-6
4-18. Types of Noncompliances	
4-19. Documenting Noncompliances	
4-20. Processing Noncompliances	
4-21. Obtaining Corrective Action.	
-4-23. Reserved	

Section 5. Unscheduled Audits or Investigations

4-24. General Unscheduled Audit Information	4-9
4-25. Non-Scheduled CM Audits	4-9
4-26. Special Audit Item	4-10
4-274-29. Reserved	

Section 6. Providing Guidance to a PAH or Associate Facility

). Guidance

Chapter 5. QSA and CMIS

5-1.	Purpose	5-1
5-2.	Files	5-1
5-3.	Database Management	5-1
5-4.	Use of the Database	5-1

Paragraph			Page		

Appendix A. RBRT Organizational and Technical Indicators

1.	Purpose	A-1
	Specific Guidance	
	Figure A-1. RBRT Indicators	A-2

Appendix B. Category Parts List

1.	Purpose	B-1
2.	Category Parts List	B-1
3.	Review of the CPL	B-1
4.	Structure of the CPL	B-1
5.	CPL Revision Process	B-1
	Figure B-1. Sample Category Parts List	B-4
	Figure B-2. CPL Revision Process Flowchart	B-5
	Figure B-3. Sample Part Categorization Memo for Requesting an Addition	
	to the CPL	B-6
	Figure B-4. Sample Part Categorization Memo for Requesting a Change	
	to the CPL	B-7
	Figure B-5. Sample Part Categorization Memo for Requesting Removal of an	
	Assembly/Part from the CPL	B-8

Appendix C. RBRT Assessment Validation Plan

1.	Purpose	.C-1
2.	Validation of Ratings for the RBRT Indicators	.C-1

Appendix D. Preparation of Clauses for Contracts for Support Services

1.	Purpose	.D-1
2.	Sample Clauses and Attachment	.D-1
	Figure D-1. Sample Certificate of Nondisclosure	

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

1.	Purpose	E-1
	Information to Include in the Notification Letter	
	Figure E-1. Sample Paragraphs for the Notification Letter	Е-2
	Figure E-2. Sample FAA Form 8100-7, QSA Customer Feedback Report	

Table of Contents (Continued)

Paragraph Pa	ige
Appendix F. Notification Letter Requirements	
 PurposeF DescriptionF Figure F-1. Notification Letter Requirements SummaryF 	7-1
Appendix G.	
ReservedC	3-1
Appendix H. Standardized Audit Criteria for PAHs and Associate Facilities	
1. Purpose	H-1 H-2 H-11 H-15 H-23 H-23 H-44
 Purpose	-1 -4
 PurposeJ. Specific GuidanceJ. Figure J-1. Sample Executive Summary for PAHs and Associate FacilitiesJ. Figure J-2. Sample Executive Summary for Facilities with No NoncompliancesJ. 	-1 -2

Paragraph	Page
Appendix K.	. Preparation Instructions for Quality System Audit Special Emphasis Items
1. Purp	poseK-1

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

1.	Purpose	L-1
	Preparing the Front of the Form	
	Figure L-1. Sample FAA Form 8100-3 (Front)	
3.	Preparing the Back of the Form	L-3
	Figure L-2. Sample FAA Form 8100-3 (Back)	

Appendix M. Process for Sending Quality System Audit Reports

1.	Purpose	M-1
	Description	
	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	.N-1
2.	Specific Guidance	.N-1
	Figure N-1. Sample FAA Form 8120-14	N-3

Appendix O. Forms Listing

1.	Purpose)-1
	Cable O-1. Forms Available From FAA Logistics Center)-1
	Cable O-2. Forms Available Within CMIS)-1

Appendix P. Acronyms

Appendix Q. Definitions

(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. A PAH may remain in an inactive status for three RBRT cycles (3 years).

(1) If the determination is to keep the PAH inactive in the third year, it must be approved by the office manager and noted in the PAH's CMIS file.

(2) If the determination is to keep the PAH inactive in the fourth year, it must be approved by the MIO and noted in CMIS.

(3) An inactive PAH will be cancelled in the fifth year unless approved by a deviation to the order signed by the Aircraft Certification Service Operational Oversight Policy Branch (AIR-140).

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

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

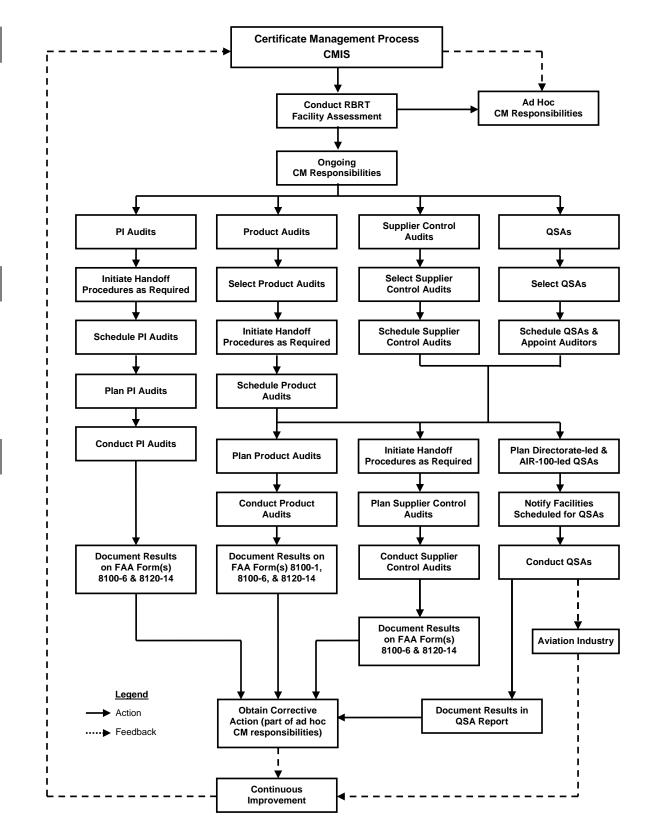


Figure 2-1. CM Life Cycle Process

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 activity, documentation expectations, etc.

a. The Aircraft Certification Service Design, Manufacturing, and Airworthiness Division (AIR-100) 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.

I

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: Having a facility with the greatest potential to produce nonconforming products, articles, or parts.

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

c. Low: Having a facility 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.

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. The AIR System Performance and Development Branch (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.

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.

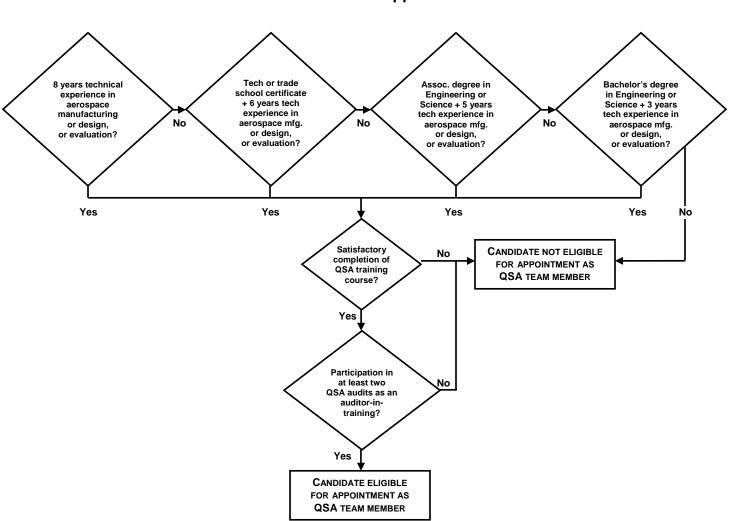


Figure 3-2. Criteria for Candidate Selection and Team Member Appointment

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 QSA training course and associated written examination. The course will provide training in the policy established in this order, including the techniques for applying the standardized 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.

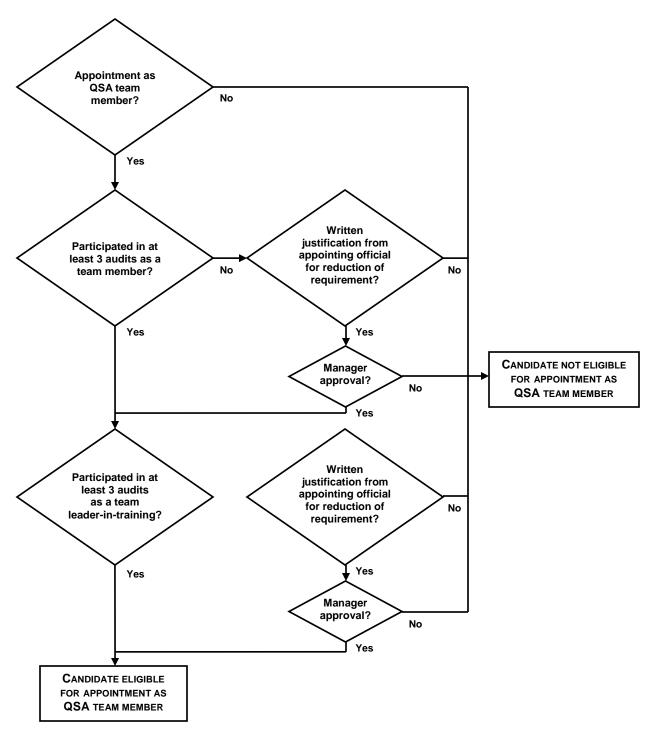


Figure 3-3. Criteria for Team Leader Appointment

(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 through issuance of a formal CMIS-generated acknowledgement letter. The letter will include the individual's discipline and office identification.

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, section 1 of this order.

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.

- (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.

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

Note 2: When necessary, the appropriate ACO and MIO managers will assign additional auditors as needed.

(3) If it is determined that one auditor is required, select an appointed team leader to perform the audit; this auditor is referred to as the principal auditor. If two or more auditors are selected for an audit, they will constitute a QSA team. Select an appointed team leader and the required number of appointed team members.

b. Types of Auditors Required. Use the criteria identified in 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:

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.

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

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

(1) Determine the number of appointed auditors required for the QSA before assigning auditors-in-training. Assign auditors-in-training only to audits for which a team is required. Do not assign auditors-in-training to a principal auditor. Auditors-in-training will supplement appointed auditors. Do not substitute auditors-in-training for appointed QSA auditors, or audit team leaders-in-training for appointed QSA team leaders.

(2) Do not assign more than two auditors-in-training or more than one team leader-in-training to any one audit. Try to assign each auditor-in-training or team leader-in-training to different team leaders during the participation phase of the training. (3) In cases where auditors-in-training or team leaders-in-training from other directorates or AIR-100 are proposed to be used in an audit, coordinate with the appointing managers to establish their eligibility.

e. Additional Resource Requirements. Additional auditors beyond the 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, 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-100, 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. At least 60 calendar days before each audit, notify through CMIS all auditors within the directorate selected for AIR-100-led QSAs and QSAs in support of other directorates. 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. The audit plan may be amended as necessary. Notify team members immediately of changes in schedule, assignments, requirements, and arrangements. Provide copies of all relevant facility documents to team members, when feasible.

d. 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) 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.

I

(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 included to support the appropriate FAA Form(s) 8100-6, or electronic equivalent, appropriately referenced, and clearly identified in accordance with FAA Order 2150.3.

(2) Team Leader or Principal Auditor.

(a) Resolve team disagreements on specific noncompliances.

(b) Discuss all noncompliances with the certificate management PI or AE, delegated facility AE, and geographic PI, as applicable.

(c) Prepare the QSA Executive Summary (refer to appendix J to this order). Prepare original forms within CMIS 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 or electronic equivalents as follows:

1 PAH or Associate Facility. Prepare one original or electronic document.

2 Facility with Multiple Production Approvals. Prepare only one original or electronic document. For example, if a facility has a PMA and a TSO authorization, prepare one original document

(e) Verify that signed original FAA Form(s) 8100-6 or electronic equivalents have been prepared for inclusion, as applicable, in each QSA report to be sent to the responsible 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 completed and signed QSA Executive Summary to the audited facility's designated representative.

(2) Summarize all noncompliances. Mention only noncompliances previously discussed with the certificate management PI and AE, the geographic PI, as applicable, and facility personnel.

c. Explain the purpose and use of 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 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 completed electronic form or printed copy must be electronically or physically signed. Prepare an original electronic form or printed copy for each PAH affected.

b. QSA Executive Summary or printed copy of electronic equivalent (appendix J to this order). Each electronic copy of the summary must be electronically signed. The printed copy presented to the PAH representative must be physically signed. All other information on electronic copies must be identical to the signed copy as presented to the PAH. Prepare an original summary or printed copy for each PAH affected.

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

d. FAA Form 8100-6 or printed copy of electronic equivalent (appendix 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-100. 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-100.

(4) Make the audit report available to the immediate supervisor of any auditors-intraining 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.

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. 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:

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) Using CMIS, acknowledge the receipt of the request.

(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 PAH or associate facility will be advised accordingly, and the requesting office will be provided a copy of the notification through CMIS. Figure 3-4 contains a sample notification letter.

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.

d. If an applicable product, article, or part is available at the supplier, a product audit will be conducted in accordance with section 6 of this chapter and recorded on FAA Form 8100-1.

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:

- a. Final product,
- b. Article,
- c. Subassembly,
- **d.** Detail parts, or
- e. 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.

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

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

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 to support unsatisfactory conditions until corrective action is deemed acceptable and any related noncompliances are closed.

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 to support any noncompliances until closure. 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.

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 will update the CMIS project folder to reflect the current quality system and include a copy of the FAA letter that acknowledges the approval of the applicable PAH quality system.

4-8. through 4-9. Reserved.

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) Immediate-Safety Impact Noncompliance. A noncompliance is deemed to have immediate safety impact when the managing office of 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.

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-100, or senior management has authority to declare an SAI based on a perceived need. The scope of the SAI, such as what is to be audited, when it is to be audited, and how results are documented, will be included in the SAI instructions that are sent to the ASI.

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

4-27. through 4-29. Reserved.

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-100 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.

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-100.

h. AIR-100 will post the updated CPL on the FAA Employees' website.

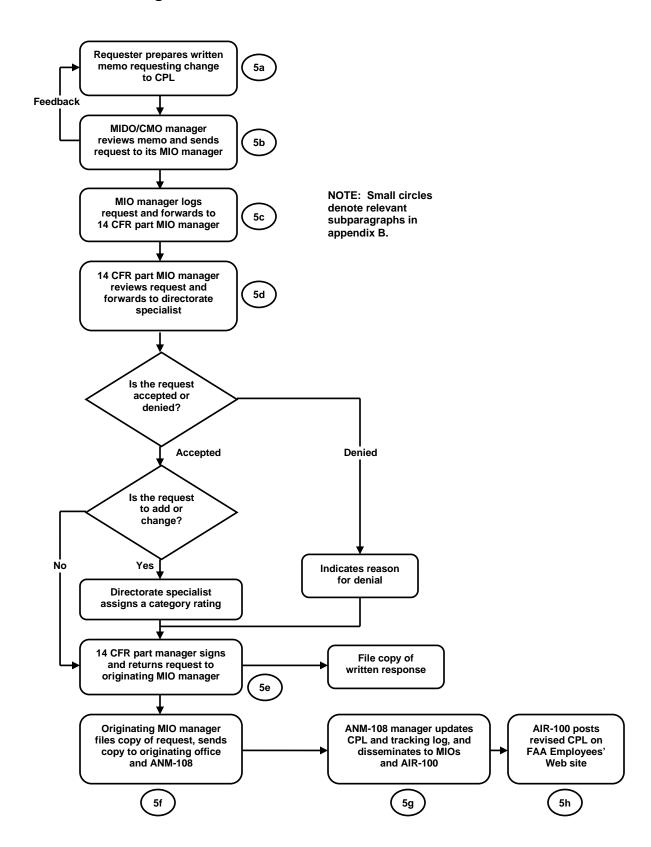


Figure B-2. CPL Revision Process Flowchart

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. <u>Write the noncompliance against the responsible</u> <u>PAH or associate facility</u>. 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 an appropriate Audit/Report Number or "N/A" as applicable.

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.

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 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.

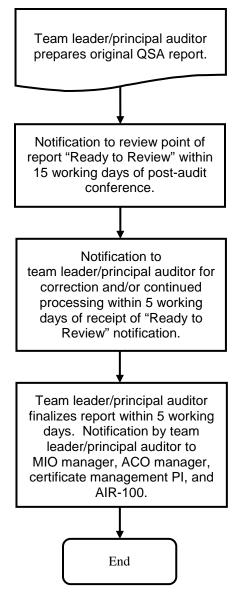
(4) Block 4. The address of the cognizant ACO or MIO manager. Enclose a prepaid self-addressed envelope in which the facility may return the form.

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 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.

Appendix O. Forms Listing

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

Table O-1. Forms Available From FAA Logistics Center

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

Table O-2. Forms Available Within CMIS

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

Appendix P. Acronyms

1.1.055	
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-40	International Policy Office
AIR-100	Design, Manufacturing, and Airworthiness Division
AIR-140	Operational Oversight Policy Branch
AIR-150	System Performance and Development Branch
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

I

I

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-100 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-100 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-100. If a deviation becomes necessary, the FAA employee involved should ensure the deviations are substantiated, documented, and concurred with by the appropriate supervisor. The deviation must be submitted to AIR-100 for review and approval. The limits of federal protection for FAA employees are defined by 28 U.S.C. § 2679.

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-100 at (202) 385-6346; however, you should also complete FAA Form 1320-19 as a followup to the conversation.