CHAPTER 3. CERTIFICATE MANAGEMENT PROCEDURES

SECTION 1. INTRODUCTION

96. GENERAL. This chapter provides guidance on the method by which manufacturing inspection ensures that PAHs and associate facilities remain in compliance with those pertinent regulations that govern the manufacturing of their particular products or parts thereof, as required by 49 USC § 44713. This method is known as certificate management. Certificate management responsibilities for a PAH or an associate facility will be accomplished by the MIDO/CMO having responsibility of the geographical area in which the PAH or associate facility is located. Certificate management comprises the following two functional responsibilities, each of which is further detailed in sections 2 and 3 of this chapter. Figure 15 of this chapter depicts the CM life cycle process.

a. Ongoing CM Responsibilities. The MIDO/CMO responsible for a specific PAH or associate facility within its geographical boundaries accomplishes the following tasks on a continuing basis. Any tasks required to be scheduled and conducted at a supplier facility located in another U.S. geographical area should be handled in accordance with paragraph 133 of this order. For tasks required to be scheduled and conducted outside the United States, refer also to paragraph 105 of this chapter.

(1) Schedule and conduct risk management assessments of PAHs and associate facilities to identify any increased potential for producing nonconforming products or parts thereof.

(2) Schedule and conduct PI and ACSEP evaluations at PAHs and associate facilities based on risk management assessments.

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

(4) Schedule and conduct product audits on production products or part(s) thereof.

b. Random CM Responsibilities. The following tasks are accomplished on an as-required basis by the MIDO/CMO responsible for a specific PAH or associate facility within its geographical boundaries. Any tasks required to be scheduled and conducted at a PAH or supplier facility located in another geographical area should be handled in accordance with paragraph 133 of this order.

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

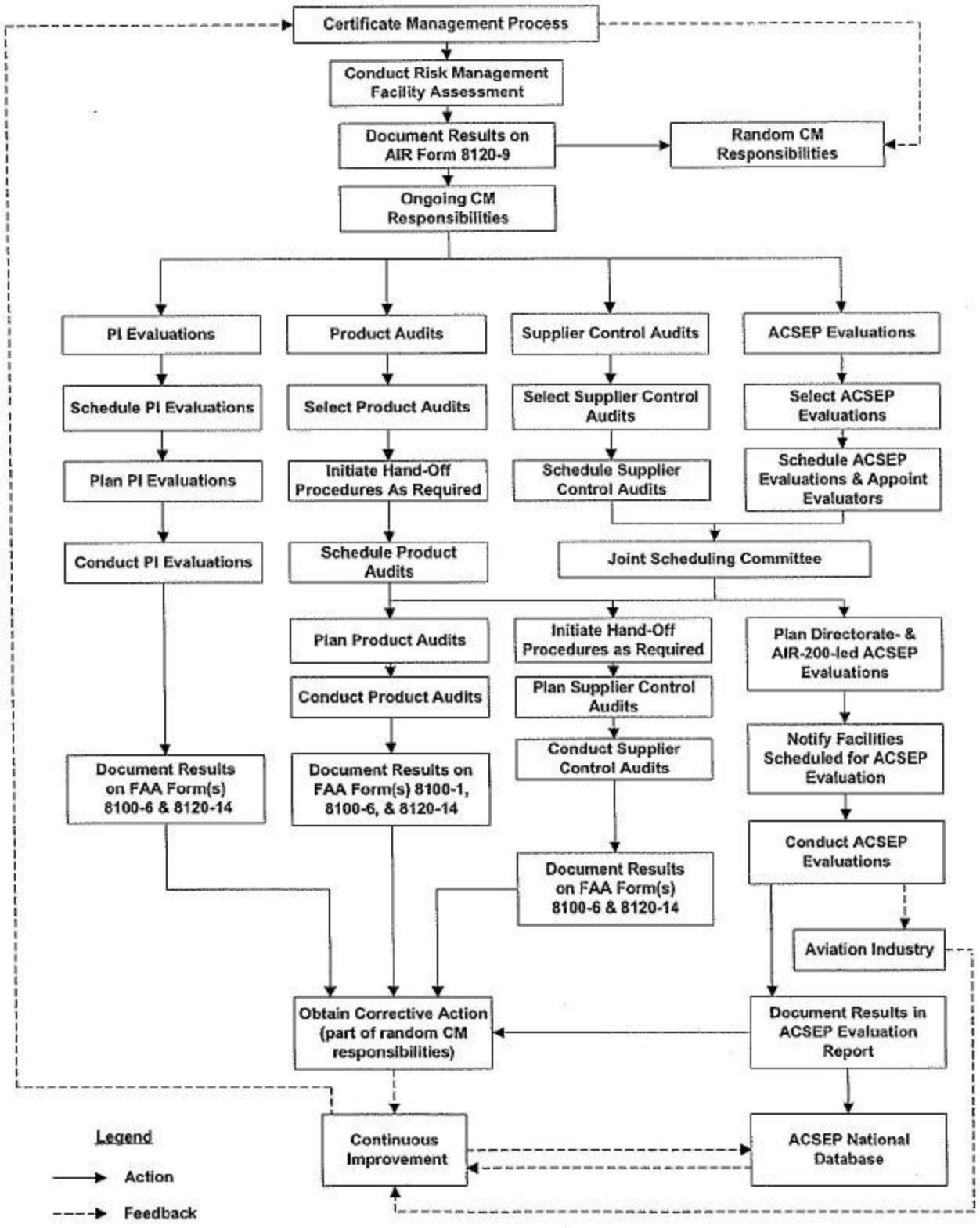
(2) Investigate service difficulties that involve quality control or inspection problems.

(3) Investigate regulatory violations.

(4) Ensure that 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 or ACSEP evaluations, supplier control audits, product audits, and other investigation activity (e.g., suspected unapproved part (SUP) investigation) necessary to ensure continued compliance with applicable regulations.

FIGURE 15. CERTIFICATE MANAGEMENT LIFE CYCLE PROCESS



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

97. ASSIGNMENT OF CM COORDINATOR. Many of the tasks identified in this chapter for 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 are as follows:

a. ACSEP candidate and evaluator appointment and training (refer to Order 8100.7).

b. Audit/evaluation scheduling and ACSEP team selection; obtaining additional resources when required (refer to Order 8100.7 and chapter 3, section 2 of this order).

c. Supplier control audit list (refer to chapter 3, section 2 of this order).

d. Dissemination of general CM-related information.

98. 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 evaluating 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 or parts within the past 12 months.

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

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

99.-102. RESERVED.

SECTION 2. ONGOING CM RESPONSIBILITIES

PART 1. INTRODUCTION

103. GENERAL. Parts 2 through 6 of this section provide detailed guidance for accomplishing ongoing CM responsibilities. Figure 16 of this order provides a graphic summary of the tasks associated with ongoing CM. These tasks are accomplished on a continuing basis, and are minimum requirements only. Tasks conducted beyond the specified frequency (e.g., not to exceed (NTE) 24 months) may be performed at the discretion of the managing office.

FIGURE 16. CERTIFICATE MANAGEMENT RESPONSIBILITIES (ONGOING)
Minimum Requirements

ONGOING CM RESPONSIBILITY	GROUP I FACILITY			GROUP II FACILITY		
	CAT 1	CAT 2	CAT 3	CAT 1	CAT 2	CAT 3
Risk Management Assessment	During PI evaluations	During PI evaluations	During PI evaluations	During PI evaluations	During PI evaluations	During PI evaluations
PI Evaluations	1 every quarter (See Note 1)	1 every quarter (See Note 1)	1 NTE every 12 months (See Notes 2 & 4)	1 every 6 months (See Note 1)	1 every 6 months (See Note 1)	1 NTE every 12 months (See Notes 2 & 4)
Supplier Control Audit	4 suppliers annually	2 suppliers annually		2 suppliers annually	2 suppliers annually	
Product Audits	2 every 12 months in conjunction w/PI evaluations; also during ACSEP evaluations	1 every 12 months in conjunction w/PI evaluations; also during ACSEP evaluations		1 every 12 months in conjunction w/PI evaluations; also during ACSEP evaluations	During ACSEP evaluations only	
ACSEP Evaluations	18-24 months	24-36 months		24-36 months	32-48 months	

ONGOING CM RESPONSIBILITY	GROUP III FACILITY			GROUP IV FACILITY
	CAT 1	CAT 2	CAT 3	CAT 3
Risk Management Assessment	During PI evaluations	During PI evaluations	During PI evaluations; by telephone in outyears	During PI evaluations; by telephone in outyears
PI Evaluations	1 NTE every 12 months (See Notes 1, 2 & 4)	1 NTE every 12 months (See Notes 1, 2 & 4)	1 NTE every 24 months (See Notes 2, 3 & 4)	1 NTE every 36 months (See Notes 2, 3 & 4)
Supplier Control Audit				
Product Audits	During ACSEP evaluations only	During ACSEP evaluations only		
ACSEP Evaluations	32-48 months	42-60 months		

GENERAL NOTE: Functions associated with shaded blocks are optional based on justified need (e.g., evaluation results, history, investigation, or service difficulties).
NOTE 1: Evaluation of ALL system elements/subelements APPLICABLE at the specific facility WILL BE completed in the interval between ACSEP evaluations.
NOTE 2: Evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.
NOTE 3: One-half of all Group III Category 3 facilities will be evaluated every fiscal year. One-third of all Group IV facilities will be evaluated every fiscal year.
NOTE 4: NTE frequency is determined from the ending date of the last evaluation or, in the case of a new PAH, from its production approval date.

104. CERTIFICATE MANAGEMENT PLAN. A CM plan assists the PI in planning and tracking the performance of ongoing CM responsibilities. Each MIDO/CMO may prepare a CM plan annually for each PAH and associate facility after risk management assessments have been completed, within a timeframe established by the MIO. 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 risk management group and category.

c. Schedules for PI evaluations, ACSEP evaluations, 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 hand-offs or CAA requests sent, including, as a minimum, the name of the geographic MIDO/CMO that has accepted the hand-off 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 hand-offs or CAA requests received, including, as a minimum, the name of the geographic MIDO/CMO or CAA that has requested the hand-off, the type of audit or surveillance requested, and the name of the applicable facility.

105. COORDINATION OF AUDIT ACTIVITIES WITH OTHER CAAs. AIR-200 has developed management plans with certain CAAs that permit those CAAs to conduct audit activity on the FAA's behalf, in accordance with FAA Order 8120.13, International Cooperative Supplier Surveillance Program Procedures. The management plans with the current International Cooperative Supplier Surveillance Program (ICSSP) participants may be found on the CM bulletin board. Audit activity conducted outside the United States will be handled in accordance with Order 8120.13 when the local authority is a program participant. However, if the FAA must conduct the supplier control audits or product audits in a country that is not an ICSSP participant or that is a participant but will not support the requested activity, the PI will perform the following activities:

a. Notify the responsible CAA and invite CAA participation as an observer. Prepare a formal letter signed by the directorate 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) of the letter 45 days prior to the audit, followed by 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 include the following information, as a minimum:

(1) Identity of the facility to be audited.

(2) Type of audit to be conducted (supplier control audit, product audit, or both). Provide a general outline of what will be included in the audit.

(3) Date(s) of the audit.

(4) Number of FAA auditors participating in the audit.

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

b. Provide the managing office with details of any finding or observation (noncompliance) encountered during the audit. 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 managing office will determine if there are any system issues or major problems that should be forwarded to the applicable CAA for its consideration.

106. RECORDING NONCOMPLIANCES. The PI will record all noncompliances, including those reported by a CAA while performing CM activities for the FAA, on Form 8100-6, in accordance with paragraph 1b and the guidelines listed in appendix 7 of 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. Reference Order 1270.1.

107. RESERVED.

PART 2. RISK MANAGEMENT

108. RISK MANAGEMENT MODEL. In the interest of safety and effective resource allocation, a risk management model has been developed to identify critical impact indicators that serve to categorize facilities according to their potential for producing nonconforming products or parts thereof. The FAA will assess annually each facility subject to a risk management assessment based on the critical impact indicators. As a result, the risk management model places each facility into one of four risk management groups according to the potential for producing nonconforming products or parts thereof. Each directorate will use the risk management model and its application procedures to provide a rational and justifiable basis for effective deployment of FAA resources for ongoing CM responsibilities.

109. SCOPE. Holders of an APIS, PC, PMA, and/or TSO authorization and their associate facilities are subject to a risk management assessment. Suppliers, delegated facilities, holders of a letter of TSO design approval, and PAHs in an inactive status are not subject to a risk management assessment.

110. RISK MANAGEMENT GROUPS. The risk management assessment of each applicable facility is based on 21 indicators that demonstrate a facility's potential for producing nonconforming products or parts thereof. See appendix 3 of this order. The assessment is also based on the category of the products or parts thereof produced. See paragraph 111 of this order. The risk management assessment results in placing a facility into one of the following risk management groups:

a. Group I: Facilities with greatest potential to produce nonconforming products or parts thereof.

b. Group II: Facilities with moderate potential to produce nonconforming products or parts thereof.

c. Group III: Facilities with low potential to produce nonconforming products or parts thereof.

d. Group IV: Facilities with little or no potential to produce nonconforming products or parts thereof.

111. RISK MANAGEMENT CATEGORIES. Risk management categories are identified as Category 1, Category 2, and Category 3, with Category 1 being the highest and Category 3 being the lowest. The overall category of a facility is based on the highest category product or part(s) thereof produced by the facility. Each of the categories is defined as follows:

a. Category 1: Failure could prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.

b. Category 2: Failure would not prevent continued safe flight and landing; resulting consequences may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.

c. Category 3: Failure would have no effect on continued safe flight and landing of the aircraft.

112. RISK MANAGEMENT ASSESSMENT OF FACILITIES. The FAA will assess facilities annually. Document facility assessment on AIR Form 8120-9, Risk Management Facility Assessment Sheet. Refer to figure 17 for a sample form.

a. Assessment of facilities and completion of AIR Form 8120-9 will be completed annually no later than April 30.

b. The validity of the information entered on AIR Form 8120-9 is dependent upon the PI's knowledge of the status of each facility being assessed. To this end, the PI should collect the information required to complete AIR Form 8120-9 anytime the PI is in the facility, or by telephone for Group III Category 3 and Group IV facilities in those years when PI evaluations are not scheduled. For a new facility, information obtained during the DO audit should be utilized.

c. The PI will use the CPL described in appendix 4 of this order to determine the category of products or parts thereof produced at each facility and to determine the overall category of each facility.

d. When appropriate, the PI should contact each facility in order to obtain current or clarifying information relevant to the risk management 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 complete AIR Form 8120-9 in accordance with the instructions provided in CMIS.

f. The MIDO/CMO manager will review each completed AIR Form 8120-9 for agreement with the PI's assessment ratings of the risk management indicators and unit criticality. To the greatest extent possible, the PI and MIDO/CMO manager should agree on the final assessment ratings for each indicator and unit criticality. The MIDO/CMO manager will indicate approval of AIR Form 8120-9 in accordance with the instructions provided in CMIS.

FIGURE 17. SAMPLE AIR FORM 8120-9

Risk Management Facility Assessment Sheet

U.S. Department of Transportation
Federal Aviation Administration

Facility Name: XYZ Aircraft Company **Response Date:** 3/11/05
Project #: PA9999CE
MIDO/CMO: Orlando **Principal Inspector:** Smith

1.	Change in Key Management	C
2.	Turnover of Critical Staff	C
3.	Reduction in Workforce/Layoffs	C
4.	Expansion or Growth	B
5.	Merger or Takeover	C
6.	ACSEP or PI/CM Noncompliances	C
7.	Civil Penalties	C
8.	Corrective Response History	C
9.	Cost of Quality	C
10.	Service Difficulties	C
11.	Complex Manufacturing Process	B
12.	Complex Product, Part, or Appliance	B
13.	New Manufacturing Process	C
14.	New/Emerging Technology	B
15.	Production Volume	B
16.	Product Continuity	B
17.	QC System Changes	C
18.	Engineering/Design Changes	B
19.	Increased Inspection Delegation to Suppliers	C
20.	Increased Use of Foreign Suppliers	A
21.	New Design in Production	B

Criticality: Category I Product, Part or Appliance

Key:
A) Applicable to company/facility for this rating period, increased potential for nonconforming products, parts, or services
B) Applicable to company/facility for this rating period, no increased potential for nonconforming products, parts, or services
C) Not applicable to company/facility for this rating period

AIR Form 8120-9 (09-06) SUPERSEDES PREVIOUS EDITION (REPRESENTATION)

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

FIGURE 17. SAMPLE AIR FORM 8120-9 (CONT'D)

Facility Name: XYZ Aircraft Company **Response Date:** 3/11/05

Project #: PA9999CE
MIDO/CMO: Orlando **Principal Inspector:** Smith

Principal Inspector: John Smith **Date:** 4/30/05

MIDO/CMO Manager: Mary Doe **Date:** 4/30/05

Assigned risk management group:	II

AIR Form 8120-9 (09-06) SUPERSEDES PREVIOUS EDITION (REPRESENTATION)

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

113. IDENTIFICATION OF RISK MANAGEMENT GROUPS. The MIO manager will score AIR Form 8120-9 in accordance with the instructions provided in CMIS. The MIO manager may delegate the scoring of AIR Form 8120-9 to the respective MIDO/CMO manager. After the scoring of AIR Form 8120-9, the PI may access CMIS to obtain the risk management group assigned by the risk management model. The PI also may use CMIS to access a Directorate Report and an Office Report. Refer to appendix 5 of this order.

114. MODIFICATION OF RISK MANAGEMENT GROUPS. Circumstances may arise following the annual identification of risk management groups that may challenge the assigned risk management group for a specific facility. When any of the following conditions occur at a facility after a risk management group has been assigned, the PI should complete a new AIR Form 8120-9 in accordance with the instructions provided in CMIS. Refer to appendix 3 for assistance in determining the significance of the following conditions:

a. Unit criticality changes from Category 1 or 2 to Category 3.

b. Unit criticality changes from Category 3 to Category 1 or 2.

c. Significant change in key management.

d. Significant turnover of critical staff.

e. Significant increase or reduction in workforce.

f. Deliberate non-responsiveness to corrective action requests.

g. Significant service difficulties attributed to manufacturing or quality problems.

h. Addition of a complex manufacturing process.

i. Addition of a complex product or part(s) thereof.

j. Significant quality or inspection system changes.

k. Significant increase in the use of foreign suppliers.

l. Movement or shift of production location or volume.

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

NOTE: When the schedules, as established in the CM plan, for PI evaluations, ACSEP evaluations, product audits, and supplier control audits are impacted by a change in the assigned risk management group or category, the PI should adjust the CM plan accordingly.

115. RISK MANAGEMENT MODEL VALIDATION PLAN. The objective of risk management is to effectively deploy FAA resources to those facilities that have the greatest potential to produce nonconforming products or parts thereof. The FAA has planned several validation tasks to ensure that this objective remains viable. Appendix 6 describes the details of the validation plan.

116. MODIFICATION OF THE RISK MANAGEMENT MODEL. The risk management model is composed of several quantitative factors that result in categorizing facilities according to their potential to produce nonconforming products or parts thereof. The risk management model validation plan periodically reviews many of these factors. Any proposed modifications to the risk management model as a result of validation, or other source, i.e., changes to indicator assessment criteria, indicator point weights, factor level rating scales, factor level combinations, and risk management group assignment decision rules, require formal Aircraft Certification Management Team approval. AIR-200 will coordinate the implementation of any changes to the model, including development and dissemination of revised program guidance, updated CMIS programming, and revised risk management program training materials.

117.-122. RESERVED.

PART 3. SUPPLIER CONTROL

SUBPART A. DETERMINING SUPPLIER CONTROL BY A PAH OR ASSOCIATE FACILITY

123. GENERAL. A PAH or associate facility may utilize suppliers when it has established an FAA-approved QC or inspection system that provides assurance that all parts 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 or part(s) thereof 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 parts received by the PAH or associate facility are standard parts.

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

(8) Whether the quality 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 parts directly to the user/operator without the parts 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 control or inspection system, controls to compensate for the absence of inspection normally conducted at the PAH's or associate facility's location, e.g., receiving inspection and test. Compensating factors should include on-site evaluations of the supplier and the inspection of the part 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 part so shipped is accompanied by a shipping ticket, invoice, or other document containing a declaration that the individual part 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 parts manufactured under PMA, PC, APIS, and TC Only also should identify the product on which the part is eligible for installation. 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 FAA Form 8130-3, Authorized Release Certificate, Airworthiness Approval Tag.

(4) Provides the appropriate part marking information to the supplier.

(5) Advises its cognizant MIDO/CMO of each direct-ship authorization.

c. Take measures to prevent suppliers from manufacturing parts without proper authority. For example, the PAH could limit projected overruns and request, in its contract with the supplier, that any unnecessary overrun parts be scrapped. The PAH may also include a clause in its contract that no parts 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.

124. CERTIFICATE MANAGEMENT ACTIVITY. The FAA does not approve suppliers. However, the PI should review a PAH's or associate facility's list of suppliers to determine if the location of a supplier outside the United States will place any undue burden on the FAA in administering part 21. A determination of undue burden is cause for rejecting the use of a supplier by the PAH or associate facility. Certificate management 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 parts and services. The FAA will determine if a PAH or associate facility is complying with its supplier control system by performing the following activities:

a. PI Evaluation. Refer to part 4 of this section. Specifically, the PI will use the ACSEP supplier control system element criteria from Order 8100.7 to determine if a PAH or associate facility is complying with its supplier control system.

b. Supplier Control Audit. Refer to part 3 of this section. Specifically, the PI will determine that 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.

125. 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 evaluation 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 evaluation, 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 should prepare Form 8100-6 and retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. The PI should request corrective action for a system breakdown in accordance with section 3, part 5, of this chapter.

126.-128. RESERVED.

SUBPART B. SUPPLIER CONTROL AUDIT

129. GENERAL. A supplier control audit is conducted as part of the CM of the PAH or associate facility, that evaluates the system established to control the parts, materials, supplies, and services provided by outside sources. This audit is conducted by the MIDO/CMO assigned CM responsibility for the PAH or associate facility. If specific expertise is required during this audit, the PI should advise the MIDO/CMO manager. If a supplier control audit is required in another geographic MIDO/CMO, the PI will comply with the hand-off procedures in paragraph 133 of this order. A supplier control audit is applicable to suppliers of a PAH or associate facility as determined by the selection process identified in paragraph 130a of this order. The supplier control audit will determine that the supplier complies with purchase order and /or quality requirements, including any statistical sampling that may be utilized. The PI should prepare an audit checklist for each supplier to be audited based on the applicable purchase order and/or quality requirements from the PAH or associate facility. Schedule a supplier control audit as follows:

NOTE: The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. Refer also to figure 16 of this order. A MIDO/CMO may schedule additional supplier control audits at specific facilities when required to ensure continued operational safety.

a. Group I Facility.

(1) Category 1 Facility. A supplier control audit will be conducted at four suppliers annually.

(2) Category 2 Facility. A supplier control audit will be conducted at two suppliers annually.

(3) Category 3 Facility. A supplier control audit is not required.

b. Group II Facility.

(1) Category 1 Facility. A supplier control audit will be conducted at two suppliers annually.

(2) Category 2 Facility. A supplier control audit will be conducted at two suppliers annually.

(3) Category 3 Facility. A supplier control audit is not required.

c. Group III or IV Facility. A supplier control audit is not required.

130. SUPPLIER SELECTION. Selection of suppliers subject to supplier control audits will be performed as follows:

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

a. After completing the risk management assessment, each PI will identify the number of supplier control audits to be performed by using the guidance described in paragraphs 129a through 129c of this order.

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

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

d. The PI will match the randomly generated numbers to the PAH's or associate facility's supplier control listing. For example, Company ABC was rated as a Group I, Category 1 facility and has 50 suppliers on its supplier control listing. The minimum number of supplier control audits for a Group I, Category 1 facility is four. Using the random number generator method, the PI selects the first four numbers from the generated list of 50 random numbers, which for the purpose of this example would be 5, 8, 14, and 24. The PI will then count down the supplier listing and choose the 5^{th}, 8^{th}, 14^{th}, and 24^{th} suppliers on the list.

e. The PI will screen each of the suppliers selected, taking into consideration the following factors: part complexity or criticality, recipient of a supplier control audit in the previous year, significant service difficulty activity at a supplier, inspectability upon receipt, delegation of major inspections, direct-ship authority, delegation of MRB, or supplier performance. If, based on these factors, the PI decides not to audit a selected supplier, the PI should select the next number on the generated list and screen that supplier against the listed factors. Continue this process until the required number of suppliers is selected.

f. As an alternative to the supplier selection process described above, the PI may apply the screening criteria identified in paragraph 130e of this order to all suppliers on the PAH's supplier listing, thereby compiling a screened list of suppliers suitable for a supplier control audit. The PI will then randomly select the required number of suppliers from the screened list in accordance with the procedures described in paragraphs 130c and 130d of this order.

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

g. There may be reasons such as part complexity or criticality, size of the PAH's or associate facility's supplier base, significant service difficulty activity at a supplier, delegation of major inspections, or supplier performance where the PI may want to do more than the minimum number of supplier control audits. The PI should remember, however, that the purpose of the supplier control audit is to determine that a PAH or associate facility is satisfactorily controlling its suppliers, not to evaluate the performance of the supplier. Specific supplier issues should be evaluated using the product audit described in section 2, part 6 of this chapter.

131. DIRECTORATE SUPPLIER CONTROL AUDIT LIST. Each MIDO/CMO will prepare a supplier control audit list annually to document the results of the selection of suppliers described in paragraph 130 of this order.

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

> **NOTE: When feasible, the MIDO/CMO should schedule the supplier control audit for a time when the supplier has an active purchase order from the PAH or associate facility. A supplier control audit may be scheduled in conjunction with an ACSEP evaluation, provided the audit (1) occurs in the same fiscal year, (2) does not divert resources, and (3) is conducted and reported separately from the ACSEP evaluation.**

b. Each MIDO/CMO will complete a supplier control audit list in accordance with the instructions provided in CMIS, no later than May 15 every year. This list will be used to plan resource allocation in the next fiscal year. The MIO manager will ensure that the lists submitted by each MIDO/CMO are reviewed for completeness and for identification of duplicate suppliers. When the same supplier is selected by different MIDOs or CMOs, the MIO manager should ensure that only one audit is scheduled at that supplier; however, compliance to the requirements of all applicable PAHs or associate facilities should be audited at that supplier. The MIO manager should also determine which MIDO/CMO will conduct the audit, and whether representation from other MIDOs or CMOs is required. When all discrepancies with the lists are resolved, the MIO manager will ensure that a consolidated directorate supplier control audit list is prepared and made available in CMIS.

c. The completed directorate list, described in paragraph 131b of this order, must be available in CMIS to all other MIO managers no later than May 30 every year. All MIO managers should ensure that supplier control audit lists received from other directorates are reviewed to identify duplicate suppliers, potential hand-offs that affect their offices, and supplier control audits to be conducted by the FAA at multiple international suppliers in the same country.

132. COORDINATION OF SUPPLIER CONTROL AUDITS BETWEEN DIRECTORATES. Discussion of duplicate suppliers and hand-offs between directorates should occur during a joint scheduling telcon by June 15 every year.

a. Duplicate Suppliers. Telcon participants should ensure that only one audit is scheduled at a supplier. The participants should determine whether all affected PAHs will be evaluated as part of the audit and identify audit participant(s).

b. Hand-Offs. MIO managers should accept and support hand-offs of supplier control audits that are scheduled within the minimum requirements of paragraph 129 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 before the ACSEP Joint Scheduling Committee meeting. There should be no hand-offs 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 hand-offs, such as those that have significant resource implications, should not be scheduled at this time. Participants should discuss contentious hand-offs and agree on an appropriate solution.

c. Supplier Control Audits to be Conducted by the FAA at Multiple International Suppliers in the Same Country. Telcon participants should identify one FAA office as a lead office to coordinate all audit activities, including notifying the responsible CAA and inviting its participation. The participants should also determine whether representation from other MIOs is required.

133. DOMESTIC HAND-OFF PROCEDURES. After receipt of the finalized Directorate Supplier Control Audit List referenced in paragraphs 131-132 of this order, the following hand-off procedures will be used for suppliers located in the United States:

a. The MIDO/CMO will forward a memorandum to the MIDO/CMO having geographical responsibility of the area in which the supplier is located, no later than 75 days prior to the scheduled audit. The memorandum will indicate the type of audit that should be conducted, i.e., 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), QC or FIS data, technical data, and other pertinent information.

(3) A copy of the PAH's, or supplier's, QC or FIS 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 evaluated, such as a new process or new technology.

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

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

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

(2) Add the audit to the CM plan. Notify the responsible PAH or associate facility in accordance with paragraph 134 of this order.

(3) 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 Form(s) 8100-6, 8100-1, and 8120-14, or printed copies of electronic equivalents. The requesting MIDO/CMO will consider its hand-off 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 hand-off to the geographic MIDO/CMO is appropriate for this purpose, the following hand-off 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), QC or FIS data, technical data, or other pertinent information.

(c) A copy of the PAH's or supplier's QC or FIS 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 Form(s) 8100-6 or 8100-1, or printed copies of electronic equivalents. The requesting MIDO/CMO will consider its hand-off request complete upon receipt of this memorandum.

134. NOTIFYING A PAH OR ASSOCIATE FACILITY. Prior to 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 prior to 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 133b of this order, the office receiving the request will send the notification letter to the PAH or associate facility and provide a copy to the requesting office. Figure 18 contains a sample notification letter.

135. 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 utilizing historical records that are traceable to the PAH's quality flow-down requirements noted on an applicable purchase order.

> **NOTE: The system element standardized evaluation criteria listed in Order 8100.7 should not be utilized as a checklist during supplier control audits. However, for data collection and analysis purposes, the PI must select the most appropriate evaluation criteria number when documenting noncompliances on Form 8100-6.**

FIGURE 18. SAMPLE SUPPLIER CONTROL AUDIT NOTIFICATION LETTER

U.S. Department
of Transportation

Federal Aviation
Administration

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

July 13, 2001

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

Dear Ms. Brown:

The Federal Aviation Administration (FAA), in accordance with its responsibilities under Title 49, United States Code, Subtitle VII, part A, and applicable regulations, has selected Structural Components located in Seattle, Washington, for the conduct of a supplier control audit. The audit is scheduled to be conducted on November 12, 2001, by an FAA representative from the Seattle Manufacturing Inspection District Office (MIDO). This audit will determine that your supplier complies with purchase order and/or quality requirements, including any statistical sampling that may be utilized.

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

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

Sincerely,

Julia Gotta

Julia Gotta
Seattle Manufacturing Inspection
District Office

cc: Fort Worth MIDO

b. A supplier control audit must be recorded on Form 8120-14 by the person conducting the audit. One form will be completed for each supplier control audit conducted. Each hand-off is considered a separate supplier control audit. Prepare the form in accordance with appendix 8 of this order. Document noncompliances on Form 8100-6. Refer to appendix 7 of this order.

136.-138. RESERVED.

PART 4. PRINCIPAL INSPECTOR EVALUATION

139. GENERAL. A PI evaluation is an evaluation 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 evaluation, the PI should advise the MIDO/CMO manager. A PI evaluation will be scheduled using the risk management group and category assignment determined under part 2 of this section. Refer also to figure 16 of this order. ACSEP system element criteria from Order 8100.7 will be used to conduct PI evaluations. The PI evaluation will be scheduled and conducted as follows:

NOTE: The scheduling requirements listed in paragraphs a through d below are considered to be the minimum requirements. A MIDO/CMO may schedule additional PI evaluations at specific facilities when required to ensure continued operational safety.

a. Group I Facility.

(1) Category 1 or 2 Facility.

(a) A PI evaluation will be conducted at each Category 1 or 2 facility at least once every three months.

(b) Evaluation of ALL system elements/subelements APPLICABLE at the specific facility WILL BE completed at least once in the interval between ACSEP evaluations (i.e., 18-24 months and 24-36 months, respectively). A few of the system elements/subelements should be evaluated during each PI evaluation. Initial emphasis should be placed on evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.

(2) Category 3 Facility.

(a) A PI evaluation will be conducted at each Category 3 facility at least once every 12 months.

(b) Evaluation of the top four 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 12-month period.

b. Group II Facility.

(1) Category 1 or 2 Facility.

(a) A PI evaluation will be conducted at each Category 1 or 2 facility at least once every six months.

(b) Evaluation of ALL system elements/subelements APPLICABLE at the specific facility WILL BE completed at least once in the interval between ACSEP evaluations (i.e., 24-36 months and 32-48 months, respectively). A few of the system elements/subelements should be evaluated during each PI evaluation. Initial emphasis should be placed on evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.

(2) Category 3 Facility.

(a) A PI evaluation will be conducted at each Category 3 facility at least once every 12 months.

(b) Evaluation of the top four 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 12-month period.

c. Group III Facility.

(1) Category 1 or 2 Facility.

(a) A PI evaluation will be conducted at each Category 1 or 2 facility at least once every 12 months.

(b) Evaluation of ALL system elements/subelements APPLICABLE at the specific facility WILL BE completed at least once in the interval between ACSEP evaluations (i.e., 32-48 months and 42-60 months, respectively). A few of the system elements/subelements should be evaluated during each PI evaluation. Initial emphasis should be placed on evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data.

(2) Category 3 Facility.

(a) A PI evaluation will be scheduled so as to evaluate one-half of all Group III Category 3 facilities one year, and the other half the following year. This will result in a facility being evaluated at least once every 24 months.

(b) Evaluation of the top four 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-month period.

d. Group IV Category 3 Facility.

NOTE: There are no Category 1 and 2 facilities possible in Group IV using the risk management model software.

(1) A PI evaluation will be scheduled so as to evaluate one-third of all Group IV Category 3 facilities one year, one-third the following year, and the remaining one-third the next year. This will result in a facility being evaluated at least once every 36 months.

(2) Evaluation of the top four 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 36-month period.

140. RECORDING A PI EVALUATION. Record a PI evaluation on Form 8120-14. Complete one form for each PI evaluation conducted. Prepare this form in accordance with appendix 8 of this order. Document noncompliances on Form 8100-6. Refer to appendix 7 of this order.

141.-143. RESERVED.

PART 5. AIRCRAFT CERTIFICATION SYSTEMS EVALUATION PROGRAM EVALUATION

144. GENERAL. An ACSEP evaluation is an integral part of the ongoing CM responsibilities. Specific guidance concerning an ACSEP evaluation is contained in Order 8100.7. Evaluations will be scheduled using the risk management group and category assignment determined under part 2 of this section. Refer also to figure 16 of this order. The ACSEP evaluation will be scheduled as follows:

NOTE: The scheduling requirements listed in paragraphs a through d below are considered to be the minimum requirements. A MIDO/CMO may schedule additional ACSEP evaluations at specific facilities when required to ensure continued operational safety.

a. Group I Facility.

(1) Category 1 Facility. An ACSEP evaluation will be conducted at each Category 1 facility at least once every 18 to 24 months.

(2) Category 2 Facility. An ACSEP evaluation will be conducted at each Category 2 facility at least once every 24 to 36 months.

(3) Category 3 Facility. An ACSEP evaluation is not required.

b. Group II Facility.

(1) Category 1 Facility. An ACSEP evaluation will be conducted at each Category 1 facility at least once every 24 to 36 months.

(2) Category 2 Facility. An ACSEP evaluation will be conducted at each Category 2 facility at least once every 32 to 48 months.

(3) Category 3 Facility. An ACSEP evaluation is not required.

c. Group III Facility.

(1) Category 1 Facility. An ACSEP evaluation will be conducted at each Category 1 facility at least once every 32 to 48 months.

(2) Category 2 Facility. An ACSEP evaluation will be conducted at each Category 2 facility at least once every 42 to 60 months.

(3) **Category 3 Facility.** An ACSEP evaluation is not required.

d. Group IV Facility. An ACSEP evaluation is not required.

145.-147. RESERVED.

PART 6. PRODUCT AUDIT

148. GENERAL. A product audit evaluates the effectiveness of the PAH's or associate facility's quality control or inspection system and the airworthiness of products utilizing 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 production approval holder or associate facility, but may also be conducted at a supplier facility where a product or part(s) thereof 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 hand-off procedures in paragraph 133 of this order. Product audits will be conducted in conjunction with every scheduled ACSEP evaluation. In addition, product audits are conducted in conjunction with scheduled PI evaluations as follows:

NOTE: The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. See also figure 16 of this order. A MIDO/CMO may schedule additional product audits at specific facilities when required to ensure continued operational safety.

a. Group I Facility.

(1) **Category 1 Facility.** Two product audits will be conducted in conjunction with two PI evaluations that are conducted annually. Additionally, a product audit will be conducted in conjunction with each scheduled ACSEP evaluation.

(2) **Category 2 Facility.** A product audit will be conducted in conjunction with one PI evaluation annually. Additionally, a product audit will be conducted in conjunction with each scheduled ACSEP evaluation.

(3) **Category 3 Facility.** A product audit is not required.

b. Group II Facility.

(1) **Category 1 Facility.** A product audit will be conducted in conjunction with one PI evaluation annually. Additionally, a product audit will be conducted in conjunction with each scheduled ACSEP evaluation.

(2) **Category 2 or 3 Facility.** A product audit is not required during a PI evaluation. However, a product audit will be conducted in conjunction with each scheduled ACSEP evaluation at a Category 2 facility only.

c. Group III or IV Facility. A product audit is not required during a PI evaluation. However, a product audit will be conducted in conjunction with each scheduled ACSEP evaluation at a Group III Category 1 and 2 facility only.

149. SELECTION OF PRODUCT AUDIT CHARACTERISTICS. The product audit will be conducted utilizing 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 or part(s) thereof and could cause failure or create an unsafe condition. The selection of the critical characteristics and/or critical process attributes will be governed by utilizing the following:

(1) Known service problem areas, obtained from the Aviation Data Systems Branch, AFS-620, prior to the start of the product audit. Service Difficulty Reports submitted after January 1, 1995, may be accessed at the FAA Web site.

(2) Characteristics/attributes that are operator controlled.

(3) Characteristics/attributes classified as critical as defined by the PAH's or associate facility's Engineering Drawings, Process Specifications, Test Specifications, and Quality Control Procedures.

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, NDI, etc.

150. PRODUCT AUDIT AREAS. The product audit may be divided into one or more of the following areas:

a. Final Product.

b. Subassembly.

c. Detail Parts.

d. Raw Material.

151. 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 19 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 part(s) during the product audit.

a. Operational/functional. Verify that the subassembly or final product conforms to the functional/operational test criteria (e.g., 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 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); e.g., review or revalidate inspection records.

c. Visual. Inspect part for obvious external defects; e.g., corrosion, burrs, handling damage, 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; e.g., part numbers, serial numbers, lot numbers for raw material, inspection stamps. For software revision verification, verify 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; e.g., certificate of conformance, work travelers, blueprints, specifications, first article inspection records.

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

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

FIGURE 19. APPLICABILITY OF PRODUCT AUDIT CRITERIA TO PRODUCT AUDIT AREAS (MINIMUM)

	PRODUCT AUDIT AREAS			
PRODUCT AUDIT CRITERIA	**FINAL PRODUCT**	**SUBASSEMBLY**	**DETAIL PARTS**	**RAW MATERIALS**
Operational/ functional	X	X		
Dimensional	X	X	X	X
Visual	X	X	X	X
Identification	X	X	X	X
Documentation	X	X	X	X
Special processes		X	X	X
Material		X	X	

152. RECORDING PRODUCT AUDIT RESULTS. All product audit results will be recorded on Form 8100-1. When unsatisfactory conditions are identified, prepare Form(s) 8100-6. The PI will retain all applicable objective evidence in accordance with Manual FAA-IR-04-01.

153. RECORDING COMPLETION OF A PRODUCT AUDIT. The completion of a product audit will be recorded on Form 8120-14 by the person conducting the audit. However, Form 8120-14 is not required for an ACSEP evaluation. When a product audit is conducted in conjunction with a PI evaluation 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 8 of this order. The PI will retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. Any corrective action required should be accomplished in accordance with chapter 3, section 3, part 5 of this order.

154.-156. RESERVED.

SECTION 3. RANDOM CM RESPONSIBILITIES

PART 1. INTRODUCTION

157. GENERAL. Parts 2 through 7 of this section provide guidance for accomplishing random CM responsibilities. The tasks discussed below are accomplished on an as-required basis.

158.-159. RESERVED.

PART 2. EVALUATION OF CHANGES TO A PAH'S OR ASSOCIATE FACILITY'S QUALITY OR INSPECTION SYSTEM

160. GENERAL. The cognizant MIDO/CMO must thoroughly review applicable changes to the quality control or inspection system required for the applicable production approval that may affect the inspection, conformity, or airworthiness of the product or part(s) thereof. Refer to appendix 1, paragraph 2, of this order for additional guidance. Any inadequacies in the quality control or inspection system must be identified to the PAH for corrective action.

> **NOTE: The approval or acceptance of changes at an associate facility will remain with the office having CM responsibility for the original PAH. If the original PAH has delegated responsibility to approve changes to the associate facility, the CM office of the associate facility will approve the changes.**

161. PRIORITIZATION OF REVIEW. Review of a facility's changes to its quality control or inspection system should be prioritized according to its risk management grouping. For example, the changes at a facility rated as Group I will be reviewed prior to the changes for a facility rated as Group II, III, or IV. Reviews of changes from facilities in the same risk management group will be prioritized by date of notification or receipt of applicable data.

162. REVIEW OF CHANGES. The cognizant MIDO/CMO should review changes to the quality control or inspection system to ensure that:

a. The quality control or inspection system will continue to adequately provide for the consistent acceptance of only those products or parts thereof which are in conformity with the approved design data and in a condition for safe operation.

b. The quality control or inspection system will continue to meet the intent of the pertinent rules, and can be realistically implemented.

NOTE: The conditions identified in paragraphs 162a and 162b of this order may often be verified through data review alone. In some instances, however, on-site inspection or review may be required.

163. POST-REVIEW ACTIONS. The cognizant MIDO/CMO will:

a. Identify any inadequacies found in the changed quality control or inspection 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 PC or TSO authorization holder, 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 20.

(2) For changes to an inspection system at an APIS or PMA holder, forward a letter to the PAH acknowledging that the changes comply with 14 CFR, including applicable changes to a quality manual submitted by a PAH. The FAA does not approve any quality manual or changes thereto submitted by an APIS or PMA holder since there is no 14 CFR requirement for submittal of data for approval. Refer to the sample letter in figure 21.

(3) The PI should update the CMIS project folder to reflect the current quality control or inspection system.

164.-167. RESERVED.

PART 3. INVESTIGATION OF SERVICE DIFFICULTIES

168. GENERAL. This part provides guidance for conducting/participating in service difficulty investigations. Additional guidance is contained in FAA Order 8010.2, Flight Standards Service Difficulty Program.

a. Source. There are various means by which the FAA obtains information regarding service difficulties in TC products; for example:

(1) Manufacturer's notification of failures, malfunctions, and defects (reference § 21.3 and AC 21-9, Manufacturer's Reporting Failures, Malfunctions, or Defects).

(2) Service Difficulty Report (SDR) (reference §§ 121.703, 121.704, 125.409, 125.410, 135.415, and 135.416).

(3) Mechanical Interruption Summary (MIS) Report (reference §§ 121.705 and 135.417).

(4) Repair station reports of unairworthy conditions (reference §§ 145.63 and 145.79).

(5) Accident and Incident Report (reference 49 U.S.C., subtitle II, chapter 11, subchapter III, sections 1131 through 1136).

FIGURE 20. SAMPLE LETTER OF APPROVAL FOR QUALITY SYSTEM CHANGES BY A PC OR TSO AUTHORIZATION HOLDER

U.S. Department of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
TRANSPORT AIRPLANE DIRECTORATE
SEATTLE MANUFACTURING INSPECTION DISTRICT OFFICE
2500 EAST VALLEY ROAD, SUITE C-2
RENTON, WASHINGTON 98055-4056

August 10, 2000

ABC Aircraft Company
4954 Airport Drive
Renton, Washington 12345

Notification of Quality Control System Change Status

We have completed our review and evaluation of the Quality Control System changes documented in your Quality Management Manual. Your submitted data meets [specify applicable CFR.] The Federal Aviation Administration (FAA) approves the submitted data. The FAA reserves the right to require changes, additions, or clarifications that may become necessary as a result of subsequent inspections and/or evaluations.

This notification should remain on file as evidence of FAA review of your Quality Control System document.

Document Name: Quality Management Manual.

Document Number: 101248

Revision Number: C

Date: June 30, 2000

Dewey Revu

Dewey Revu
[Principal Inspector or Manager]

FIGURE 21. SAMPLE LETTER OF ACKNOWLEDGEMENT FOR INSPECTION SYSTEM CHANGES BY AN APIS OR PMA HOLDER

U.S. Department of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
NEW ENGLAND REGION
ENGINE AND PROPELLER DIRECTORATE
MANUFACTURING INSPECTION DISTRICT OFFICE
CORPORATE AIR BUILDING 85-214
BRADLEY INTERNATIONAL AIRPORT
WINDSOR LOCKS, CT 06096

July 26, 2000

ABC Aircraft Parts Company
4954 Airport Drive
Newington, Connecticut 12345

Notification of Inspection System Change Status

We have completed our review and evaluation of your Inspection System changes, as documented in the submitted data presented to the Federal Aviation Administration (FAA) as evidence of compliance. The submitted data meets [specify applicable CFR.] The FAA reserves the right to require changes, additions, or clarifications that may become necessary as a result of subsequent inspections and/or evaluations.

This notification should remain on file as evidence of FAA review of your Inspection System and submitted data.

Document Name: Inspection System Manual

Document Number: 11204

Revision Number: F

Date: March 15, 2000

Duke E. Season

Duke E. Season
[Principal Inspector or Manager]

(6) User complaints (general public, military, and foreign governments).

(7) Reports and information received from other FAA and government offices.

b. MIO and ACO Investigation. Upon receipt of a service difficulty report, the MIO having CM over the manufacturer of the identified product or part(s) thereof will investigate the information and determine if design or production deficiencies are involved. The cognizant ACO is responsible for corrective action to any design deficiencies.

(1) MIO Responsibilities. When the MIO investigation indicates that the failure, malfunction, or defect is attributable to deficiencies in the manufacturer's quality control/inspection system, the information will be forwarded to the CM DO along with a request for an investigation.

(2) MIDO/CMO Responsibility. The MIDO/CMO will assign a high priority to service difficulty investigations, which must be completed as expeditiously as possible. The identity of a firm or private person reporting service difficulties to the FAA will not be revealed to the manufacturer. The FAA must witness any tear-down inspections or testing to be performed on defective products or parts thereof when such products or parts thereof are flagged (by FAA tags or forms) as requiring the presence of an FAA inspector during the tear-down, inspection, or test, as applicable.

169. INVESTIGATION. The assigned aviation safety inspector (ASI) will make an investigation, independent of that performed by the manufacturer, of reported service difficulties, in accordance with the criteria contained in Order 8010.2. The ASI will also investigate, and include in the report, the results of any investigation conducted by the manufacturer.

170. CORRECTIVE ACTION. The MIDO/CMO will formally request the manufacturer to take corrective action when the investigation discloses unsatisfactory conditions in conformity, QC, or workmanship. In such cases, particular emphasis must be placed on determining by examination or reexamination of all related QC practices, data, records, etc., whether the discrepancy may also involve products and parts thereof in service, in the manufacturing process, or spares, either in storage or shipped to users. If justified, airworthiness directive action should be recommended to the responsible ACO.

171. REPORTING A SERVICE DIFFICULTY INVESTIGATION.

a. Report to MIO. A report of service difficulty investigation will be prepared and submitted to the MIO in accordance with this order, Order 2150.3, and Order 8010.2. The report may be in the form of a memorandum or any other manner acceptable to the MIO and will include as a minimum, the following information:

(1) Name and address of manufacturer.

(2) Type and number of certificates or approvals held.

(3) Make, model, and part number, as appropriate, to positively identify the defective product or part(s) thereof.

(4) Inspector's statement of findings, including an evaluation of any investigation conducted by the manufacturer.

(5) Inspector's conclusion as to the cause of the service difficulty.

(6) All corrective actions requested by the DO and/or taken by the manufacturer including a copy of the DO letter to the manufacturer and the manufacturer's reply.

(7) Effect on products in service.

(8) Recommendations and/or further actions required.

b. Interim Report. In the event that the investigation is delayed for any reason, an interim report of service difficulty investigation outlining the progress of the investigation will be forwarded in a memorandum to the MIO.

c. Violations. When the service difficulty report and the subsequent investigation indicate that a violation exists, the investigating and reporting procedures in Order 2150.3 will also be followed.

d. Delegation Option Authorization (DOA) Reports. Upon notification by the FAA, DOA holders are required by § 21.277 to investigate and report to the FAA the results of their investigation and any action taken or proposed. These reports should be forwarded to the MIO and geographic ACO, which should initiate any actions deemed appropriate for the particular service difficulty involved.

172. FOREIGN MANUFACTURERS. Foreign manufacturers are exempted from the reporting requirements of § 21.3. When foreign manufactured products or articles approved under § 21.29, § 21.502, or § 21.617 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 or article manufacturer is located. Upon receipt and evaluation 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 parts, processes, or methods are involved, airworthiness directives 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.

173.-175. RESERVED.

PART 4. INVESTIGATION OF REGULATORY VIOLATIONS

176. ENFORCEMENT ACTIONS ON SAFETY-RELATED OR SYSTEMIC NONCOMPLIANCES. The performance of CM responsibilities often results in identifying noncompliances by a PAH with 14 CFR or FAA-approved data. These noncompliances may be safety-related, systemic, or isolated. See appendix 7, paragraph 2g(1) through (3). The PI should exercise good judgment in determining whether or not the objective evidence identifies a safety-related or systemic noncompliance to 14 CFR or to FAA-approved data before initiating any enforcement action prescribed in Order 2150.3. Isolated noncompliances do not constitute a quality control or inspection system breakdown. Nevertheless, the PI should evaluate each noncompliance in accordance with Order 2150.3, chapter 2. The initiation of enforcement actions in these instances would only serve to dilute the effectiveness of the FAA compliance and enforcement program. However, when isolated noncompliances are noted, the PI must request prompt corrective action from the PAH using the procedures in part 5 of this section.

177. ENFORCEMENT PROCEDURES. The principal objective of the FAA compliance and enforcement program is to promote aviation safety and to protect the public interest by obtaining compliance with both the statutory and the regulatory requirements. The program ranges from educational and remedial efforts, including administrative action, to punitive legal enforcement remedies, including criminal sanctions in the most serious cases. The PI should follow Order 2150.3 for any safety-related or systemic noncompliances with 14 CFR. The PI should also follow Order 2150.3 when a PAH is found to be in noncompliance with FAA-approved data. Since PC and TSO authorization holders are required by 14 CFR to have data describing the quality system, normally in the form of a manual, the manual is considered part of the approved data. Data deficiencies found after the FAA originally approves the data are not a basis for taking enforcement action. When such deficiencies are found, the PI should send a separate letter to the PAH requesting that appropriate corrective action be taken in a timely manner. If the PAH does not, the PI should then initiate enforcement actions as deemed appropriate.

178. MULTIPLE ENFORCEMENT ACTIONS. When a number of safety-related or systemic noncompliances have been noted at a PAH's facility, such as those resulting from an ACSEP or PI evaluation, the PI should process them as one enforcement action. However, when different types of enforcement actions are involved, the PI should initiate a separate enforcement action for each type of enforcement action to be taken. For example, if an evaluation results in four systemic noncompliances where administrative action is indicated, and three systemic noncompliances where legal action is deemed appropriate, the PI should process two separate enforcement actions.

179. TIMELINESS. To ensure that enforcement actions have the maximum effect as a compliance tool, Order 2150.3 establishes a six month goal for preparing and processing all enforcement investigation reports. This goal includes time for legal processing and preparing of notices when required. Each directorate may elect to use a performance management tool to measure the process and make improvements when necessary.

180. INVALID ALLEGED VIOLATIONS. The PI should advise the PAH when an alleged noncompliance, as cited in a Letter of Investigation (LOI), has been later determined to be invalid. In such cases, a Letter of Notification, Closing of Investigation, should be sent to the PAH.

181. VOLUNTARY DISCLOSURE PROCEDURES. Primary responsibility for monitoring the quality control or inspection system and ensuring compliance with 14 CFR lies with the PAH. The FAA recognizes that the PAH is in the best position to monitor the effectiveness of its own operations and system and that the FAA cannot continuously monitor every aspect of the PAH's quality control or inspection system. The FAA encourages the PAH to monitor its own system and to maintain a reporting and correction policy consistent with the FAA's reporting and correction policy. The FAA should strongly encourage the PAH to implement an internal audit program that will assist the PAH in detecting noncompliances within its system. If the PAH elects to take advantage of the reporting and correction policy, the PI and PAH should develop a definitive agreement that describes how the PAH will implement the reporting and correction policy. The agreement should define the process to be used, and should be referenced within the FAA-approved quality manual for PC and TSO authorization holders. Although the PAH may terminate the agreement at any time, doing so does not relieve it of the responsibility to take appropriate action when it or the FAA discovers noncompliances with products or noncompliances within the quality control or inspection system. If a PAH elects to self-disclose a noncompliance that has left its control, and meets all criteria identified in Order 2150.3, chapter 5, the FAA may mitigate or alleviate civil penalties. Further guidance may be found in AC 00-58, Voluntary Disclosure Reporting Program.

182.-184. RESERVED.

PART 5. CORRECTIVE ACTION

185. GENERAL. The performance of CM responsibilities often results in identifying noncompliances by a PAH, associate facility, or delegated facility (facility) with 14 CFR or FAA-approved data. Refer to part 4 of this section. The facility is responsible for determining and initiating the action needed to correct a noncompliance with 14 CFR or FAA-approved data, and to correct the cause of a noncompliance. For corrective action to be complete after the FAA identifies a systemic noncompliance, the facility must also identify the root cause of the noncompliance to prevent its recurrence. The action taken to correct the immediate noncompliance is not considered satisfactory corrective action for systemic noncompliances. It is important, therefore, that the PI require the facility to focus on the root cause of a systemic noncompliance to prevent its recurrence, and not just on the action to immediately correct it.

186. CORRECTIVE ACTION PROCEDURES. As indicated in paragraph 106 of this order, noncompliances are recorded on Form 8100-6. The PI will review each completed Form 8100-6 as follows to determine the appropriate method to request corrective action:

NOTE: If the noncompliance meets the definition of an SUP, as described in FAA Order 8120.10, Suspected Unapproved Parts Program, the PI must report the SUP in accordance with Order 8120.10.

a. Determine whether the noncompliance is safety-related, systemic, isolated, or certification-related.

b. Determine whether there is a noncompliance with 14 CFR, FAA-approved data, internal procedures, or purchase order requirements.

NOTE: If a facility provides objective evidence, subsequent to the issuance of a Form 8100-6, that justifiably negates the basis of the reported noncompliance, a request for corrective action of that noncompliance will not be required. The PI will retain the Form 8100-6 and all applicable evidence in accordance with Manual FAA-IR-04-01.

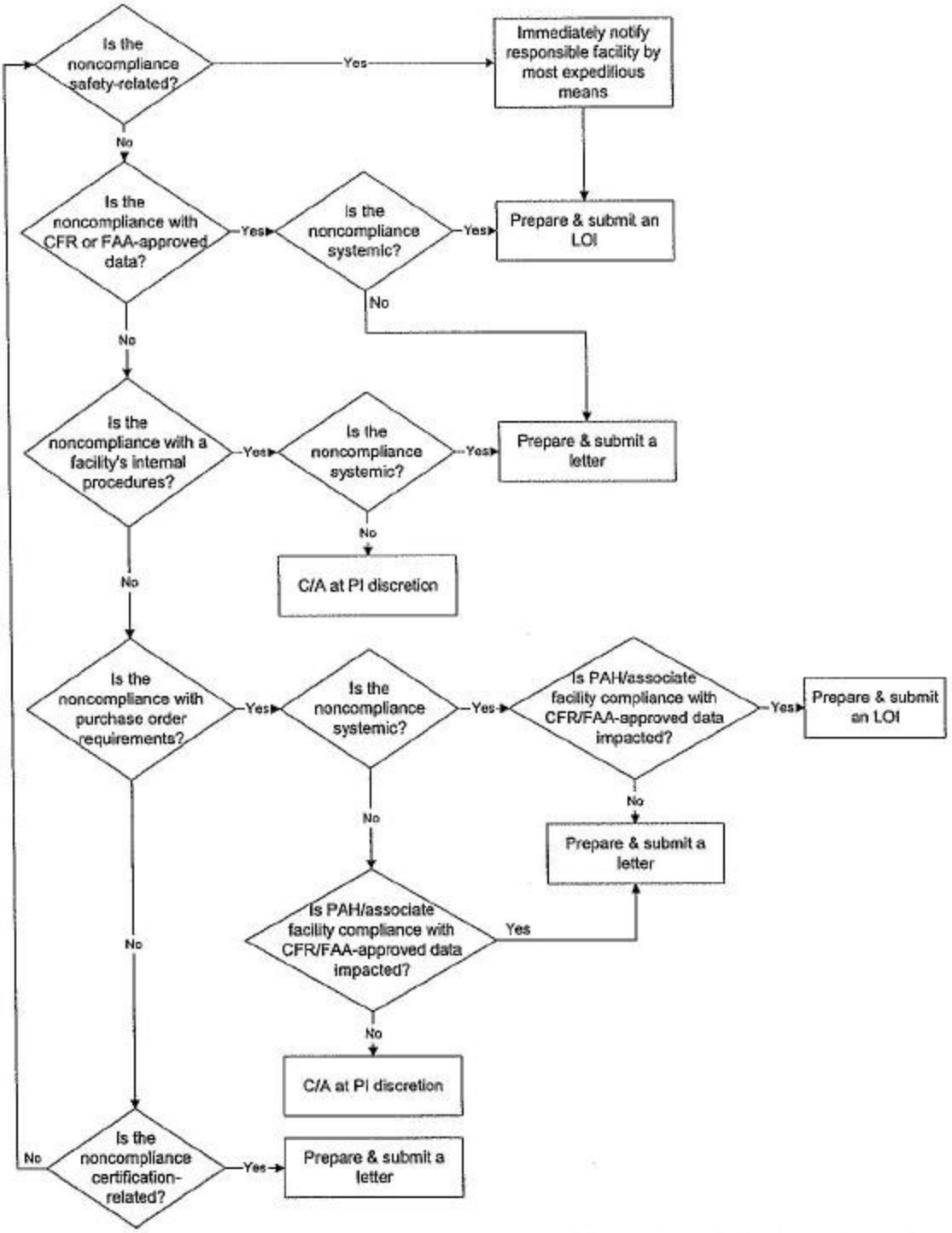
c. Request corrective action as follows (refer to figure 22 for applicable flowchart):

(1) Safety-Related Noncompliance. Immediately notify the responsible facility by the most expeditious means available. Prepare an LOI in accordance with Order 2150.3 and submit it to the responsible facility within 72 hours of discovery. If the noncompliance affects delivered products or services, secure from the responsible facility a list of the end users affected and immediately notify the cognizant ACO, MIO, MIDO, or CMO.

(2) Systemic Noncompliance with 14 CFR or FAA-Approved Data. Prepare and forward an LOI to the responsible facility in accordance with Order 2150.3.

(3) Systemic Noncompliance with Facility's Internal Procedures. Prepare and forward a letter to the responsible facility requesting immediate corrective action.

FIGURE 22. CORRECTIVE ACTION FLOWCHART



(4) Systemic Noncompliance with Purchase Order Requirements (by a Supplier to a PAH or Associate Facility).

(a) Impacts PAH's or Associate Facility's Compliance with 14 CFR or FAA-Approved Data. Prepare and forward an LOI to the PAH in accordance with Order 2150.3.

(b) Impacts PAH's or Associate Facility's Compliance with its Internal Procedures. Prepare and forward a letter to the PAH requesting immediate corrective action.

(5) Isolated Noncompliance with 14 CFR or FAA-Approved Data. Prepare and forward a letter to the responsible facility requesting immediate corrective action.

(6) Isolated Noncompliance with Facility's Internal Procedures. The means of obtaining corrective action is at the discretion of the PI.

(7) Isolated Noncompliance with Purchase Order Requirements (by a Supplier to a PAH or Associate Facility).

(a) Impacts PAH's or Associate Facility's Compliance with 14 CFR or FAA-Approved Data. Prepare and forward a letter to the PAH requesting immediate corrective action.

> **NOTE: Isolated noncompliances identified on Form(s) 8100-6 during a supplier control or product audit conducted as the result of a hand-off will be transmitted to the requesting MIDO/CMO for action with the PAH or associate facility as appropriate.**

(b) Impacts PAH's or Associate Facility's Compliance with its Internal Procedures. The means of obtaining corrective action is at the discretion of the PI.

(8) Certification-Related Noncompliance. Prepare and forward a letter to the responsible facility requesting immediate corrective action.

> **NOTE: Multiple Form(s) 8100-6 applicable to one facility may be grouped into one LOI or letter.**

(9) When a determination is made in accordance with paragraph 125 of this order that a PAH or associate facility is not controlling its suppliers, a request for corrective action should be transmitted after completion of the final supplier control audit scheduled for the fiscal year. The letter of transmittal will factually and concisely summarize the specific noncompliance(s). When it has been determined that the noncompliances constitute a violation of 14 CFR, the transmittal will be prepared as an LOI in accordance with Order 2150.3.

NOTE: Upon completion of a scheduled PI evaluation or supplier control audit, the PI may request corrective action from the PAH or associate facility for specific noncompliances discovered. For example, if a supplier is not maintaining proper tool and gauge calibration as required by the purchase order, corrective action for that noncompliance should be requested from the PAH or associate facility upon completion of the supplier control audit. On the other hand, corrective action for lack of supplier control would not be requested unless there was evidence of a similar system breakdown in tool and gauge calibration at several suppliers to the PAH or associate facility.

(10) Issue an LOI to the PAH or associate facility whenever parts are sold by a supplier outside the scope of the PAH's or associate facility's authority. These are considered to be unauthorized sales by a PAH supplier, and the parts are considered unapproved as described in Order 8120.10. The LOI is needed as part of the investigation into the supplier activity and to fully document and further the related investigation wherever it may lead. However, the PAH or associate facility should not be held accountable for parts produced outside the scope of its approval without its consent and/or knowledge.

187. CORRECTIVE ACTION RESPONSE. The PI with CM responsibility must ensure that the responsible facility identifies and takes corrective action on all systemic noncompliances with 14 CFR or FAA-approved data. It is not unreasonable for the PI to expect the facility to address each of the following items in the corrective action response:

a. Immediate action taken to correct the systemic noncompliance(s) identified in the LOI.

b. Action taken to identify any product or part(s) thereof affected by a systemic noncompliance, and any action required to effect immediate corrective action thereto.

c. Action taken to examine other areas or items that might have a similar systemic noncompliance(s).

d. Identification of the root cause of each systemic noncompliance.

e. Action taken to prevent future recurrence(s) of systemic noncompliances.

f. A schedule for completing immediate and root cause corrective action for each systemic noncompliance, including who will take the action.

NOTE: FAA compliance and enforcement policy considers the effectiveness of a facility's corrective action to be very important in determining the type of enforcement it will pursue and the appropriate sanction.

188. CORRECTIVE ACTION VALIDATION. Corrective action validation should determine that the proposed corrective action was correctly implemented and that the corrective action completely eliminated the noncompliance. The PI should schedule a visit to the responsible facility and/or supplier facility to evaluate corrective action commitments. The PI should schedule the visit far enough in the future to ensure that the facility and/or supplier have fully implemented the corrective action and that the action has become a routine element of the quality control or inspection system, or of a delegated facility's design approval system when applicable. A visit to the facility may coincide with a scheduled audit or evaluation, when appropriate. Occasionally, the PI may be required to validate corrective actions at a supplier facility located outside of the geographical boundary of the responsible CM office. In this case, the PI may elect to visit the supplier facility to validate the corrective action or request the geographic MIDO/CMO where the supplier is located to validate the corrective action. See paragraph 133c of this order. If the facility is located in a bilateral country, the PI may formally request that the responsible CAA validate the corrective action; include the information from paragraph 133c(1) of this order as applicable. Document results of completed corrective action validations in the facility's Enforcement Investigation Report file.

189.-191. RESERVED.

PART 6. UNSCHEDULED AUDITS, EVALUATIONS, OR INVESTIGATIONS

192. GENERAL. Section 2 of this chapter provides for scheduled PI evaluations, product audits, supplier control audits, and ACSEP evaluations. However, any one of these audits or evaluations may be performed on a non-scheduled basis at the discretion of the managing office whenever necessary to ensure continued operational safety. Section 3 of this chapter discusses investigation of service difficulties and regulatory violations. Other random investigations may arise for purposes such as SUP or whistle blower allegations.

193. NON-SCHEDULED CM AUDITS/EVALUATIONS. The managing office will determine the type of audit or evaluation that will provide the best assessment of the applicable situation. A non-scheduled CM audit or evaluation will be planned, conducted, and reported in accordance with section 2 of this chapter to the greatest extent practicable. Appropriate emphasis on planning the audit or evaluation should be provided despite the reduced time that may be available between the decision to conduct the audit or evaluation and the actual conduct of the audit or evaluation. Notification of the non-scheduled audit or evaluation to the PAH or associate facility should be provided as soon as practicable. For a PAH or associate facility located outside the United States, the responsible CAA also should be provided notification as soon as practicable. Situations that may warrant a non-scheduled audit or evaluation may include:

a. Accidents and incidents.

b. Deliberate violations.

c. Repetitive SDRs.

d. SUP investigations.

e. Excessive owner/operator complaints.

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

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

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

i. Relocation of production facility.

j. Surveillance Requests from CAAs. A U.S. manufacturer that has entered into a supplier, subcontractor, or other similar relationship with a foreign manufacturing entity (e.g., a manufacturer of aircraft, aircraft engines, or propellers; a repair station; or an air carrier) may produce, identify and deliver civil aeronautical products and parts thereof to that entity without obtaining an FAA design and production approval under part 21. The purchase order or similar contract/procurement agreement, from the foreign manufacturer to the supplier manufacturer should provide any evidence of the sales relationship to the FAA as needed. These products or parts thereof are to be produced in support of a design approval issued by a CAA, to include modifications made to a type design by repair stations or air carriers (e.g., TC, STC, CAA-approved modification). The regulatory responsibility for control or oversight of a U.S. manufacturer acting strictly as a supplier to a foreign manufacturing entity resides with the CAA having oversight of that design and/or production approval. The FAA assumes no regulatory responsibilities for these programs and will provide assistance only in surveillance of the U.S. supplier through a special written arrangement with the CAA under the provisions of the bilateral agreement.

(1) A CAA 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 requirements of the CAA 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 random CM activities with higher priority.

k. Any other situation as deemed necessary in the interest of safety.

194. OTHER RANDOM INVESTIGATIONS. SUP reports will be investigated in accordance with the current issue of Order 8120.10. Any other investigations that may be required will be conducted in accordance with available specific guidance. In the absence of specific guidance, the managing office will determine the type of investigation that will provide the best assessment of the applicable situation. In some situations, a specific CM audit or evaluation may be appropriate.

195.-197. RESERVED.

PART 7. PROVIDING GUIDANCE TO A PAH OR ASSOCIATE FACILITY

198. GENERAL. The PI should provide guidance to a PAH or associate facility as necessary for the manufacturing of products or parts thereof produced under the approved quality control or inspection system. The guidance provided by the PI may include, but is not limited to, the following:

a. Quality control or inspection system changes.

b. Facility changes.

c. Technical assistance.

d. Updating supplier lists.

e. Service difficulty and corrective action review.

f. Support of ACSEP evaluations.

g. Regulatory requirements, changes to guidance materials, or industry best practices.

h. Understanding of applicable regulations.