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

ORDER 8120.2F

Effective Date:
01/30/2009

SUBJ: Production Approval and Certificate Management Procedures

This order was prepared to provide guidance for Aircraft Certification Service personnel in the accomplishment of certain agency responsibilities. These include the evaluation, approval, and certificate management of the production activities of manufacturers and their suppliers producing products or parts in accordance with Title 14, Code of Federal Regulations.

The guidance in this order relates to the following four types of production approvals issued by the Federal Aviation Administration:

1. Production Certificate.
2. Approved Production Inspection System.
3. Parts Manufacturer Approval.
4. Technical Standard Order authorization.

This order has been organized into two functional areas: procedures for the evaluation and issuance of a production approval and procedures for certificate management of a production approval.

/s/
Frank P. Paskiewicz
Manager, Production and
Airworthiness Division, AIR-200

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Table of Contents

Paragraph *Page*

Paragraph *Page*

Paragraph *Page*

Part 4. Post-PMA Activities

Section 6. Extension of a Production Approval Within the United States

Part 1. General Information

Part 2. Processing a Request for Extension of a Production Approval

Part 3. Approval of the Request for Extension of a Production Approval

Section 7. Non-U.S. Manufacturing Facilities—Determination of Undue Burden and No Undue Burden

Chapter 3. Certificate Management Procedures

Section 1. Introduction

Paragraph *Page*

Paragraph *Page*

Paragraph *Page*

Part 3. Investigation of Service Difficulties

Part 4. Investigation of Regulatory Violations

Part 5. Corrective Action

Part 6. Unscheduled Audits, Evaluations, or Investigations

Part 7. Providing Guidance to a PAH or Associate Facility

Appendix A. Evaluation of a PAH'S Quality or Inspection System

Paragraph *Page*

Paragraph *Page*

Chapter 1. Introduction

1-1. Purpose of This Order. This order contains guidance related to—

a. Production approvals and certificate management (CM) of manufacturers of type-certificated products, technical standard order articles, and replacement and modification parts, to ensure fair and uniform administration of Title 14, Code of Federal Regulations (14 CFR).

b. The Certificate Management Information System (CMIS). In those cases in which activities and work processes are automated by CMIS, aviation safety inspectors, aviation safety engineers, and flight test pilots must use CMIS to perform that work. In the event a manual activity or work process described in this order becomes automated in CMIS, the use of CMIS to perform that activity or work process will take precedence.

1-2. Audience. All Federal Aviation Administration (FAA) employees who provide oversight of the production approval process and are responsible for the CM of production approval holders (PAHs).

1-3. Where Can I Find This Order. You can find this order on the Regulatory and Guidance Library Web site at http://rgl.faa.gov.

1-4. Cancellation. FAA Order 8120.2E, Production Approval and Certificate Management Procedures, dated May 29, 2007, and its associated changes, are canceled.

1-5. Explanation of Policy Changes. This revision—

a. Adopts risk-based resource targeting (RBRT) as a CM tool, replacing the risk management model.

b. Revises figures 3-1 and 3-2 to align with RBRT.

c. Removes AIR Form 8120-9, Risk Management Facility Assessment Sheet.

d. Revises appendix C to include the organizational and technical indicators used in an RBRT facility assessment. In addition, information specific to each indicator is provided as guidance to assist the principal inspector (PI) in completing the assessment.

e. Clarifies where the management plans with the current International Cooperative Supplier Surveillance Program (ICSSP) participants are located.

f. Changes the term “District Office” (DO) to “Manufacturing Inspection District Office” (MIDO).

g. Eliminates the requirement for the MIDO/Certificate Management Office (CMO) to send an electronic copy of certain Parts Manufacturer Approval (PMA) documents to the Aircraft Certification Office (ACO).

h. Incorporates the deviation, dated December 3, 2007, that authorizes the MIDO/CMO to perform initial service difficulty investigations. In addition, several report submission requirements, associated with service difficulty investigations, are now optional.

i. Updates references to suspected unapproved part (SUP) requirements.

j. Clarifies the information required on PMA assist letters.

k. Clarifies information pertaining to ownership and name changes of PMA holders and Technical Standard Order (TSO) authorization holders.

Chapter 2. Procedures for Issuing a Production Approval

Section 1. Introduction

2-1. Chapter Information and Format. This chapter provides guidance relative to the issuance of a production approval. The following sections provide specific guidance for each of the production approval types, including extension of a production approval within the United States. In general, each section describes the applicability of the production approval, the privileges of the approval, the advice that the FAA should be providing to the applicant, processing the application, and issuing the production approval.

Section 2. Production Under a Type Certificate Only (Part 21, Subpart F)

Part 1. General Information

2-2. Applicability. Part 21, subpart F, is applicable to a manufacturer of a product or part(s) without benefit of a production certificate (PC).

2-3. Privileges. A manufacturer of a product or part(s) in accordance with part 21, subpart F, is not granted any privileges. However, upon establishment of an Approved Production Inspection System (APIS), the APIS holder is eligible to have a qualified employee(s) designated as a Designated Manufacturing Inspection Representative (DMIR) in accordance with the provisions of 14 CFR part 183, Representatives of the Administrator (part 183). The APIS holder may also be authorized by part 183 to apply for and obtain an Organization Designation Authorization (ODA). FAA Orders 8100.8, Designee Management Handbook, and 8100.15, Organization Designation Authorization Procedures, contain procedures for the administration of DMIRs and ODAs, respectively.

2-4. Advising the Applicant. When production under the provisions of part 21, subpart F, is indicated, a type certificate (TC) applicant should be advised (during the preliminary TC Board) of the following:

a. Advisory Circular (AC) 21-6, Production Under Type Certificate Only, sets forth an acceptable means of complying with part 21, subpart F. The FAA may approve alternative methods and procedures when the applicant can show the proposed methods or procedures will achieve compliance with part 21, subpart F.

b. The applicant's intentions should be documented with respect to production and submitted to the MIDO/CMO. This will allow the FAA to schedule inspections and evaluations at the earliest stages of establishment of the APIS.

c. The applicant should be encouraged to strive for a PC instead of an APIS. The following advantages of the PC should be emphasized:

(1) No requirement to submit FAA Form 8130-9, Statement of Conformity, for each completed product.

(2) Reduced FAA involvement, relative to conformity inspections and airworthiness certification.

(3) Issuance of airworthiness certificates and approvals for completed products without further showing.

(4) Issuance of export approvals for small aircraft without assembly or flight test.

d. FAA inspectors or authorized designees will conduct inspections and issue all of the necessary airworthiness certificates and approvals for a maximum period of six months, except as otherwise authorized after the date of issue of the TC. The applicant should also be advised that FAA personnel resources are limited and that delays may occur during the six-month period depending on the number of inspections and hours that may be necessary.

e. Subsequent to the six-month period (except as otherwise authorized), an APIS or PC must be obtained in order to continue production of the type-certificated product. Additionally, any products or part(s) manufactured after the deadline date without FAA authorization may result in actions as defined in Order 2150.3, Compliance and Enforcement Program.

f. An APIS is based on compliance with those inspection standards specified in § 21.125. Furthermore, these standards along with any inspection system data submitted form the basis for all FAA CM activity.

g. The APIS holder is required to have process specifications, materials review board records, test procedures, and flight check forms that are acceptable to the FAA. It would be advantageous to the TC applicant to develop these data concurrently with the manufacture, inspection, and testing of prototypes of the product.

h. The TC holder or licensee who produces a completed product under part 21, subpart F, must flight test and/or functional test that product in accordance with the requirements of §§ 21.127, 21.128, or 21.129, as applicable.

(1) Aircraft. Each aircraft, both prior to and subsequent to the issuance of an APIS, must be flight tested in accordance with an approved production flight test procedure and flight checklist form as required by § 21.127.

(2) Engines and Propellers. Each engine or propeller, both prior to and subsequent to the issuance of an APIS, must be subjected to an acceptable test run or functional test in accordance with the requirements of § 21.128 or 21.129, as appropriate.

i. The manufacturer should be encouraged to submit (at the appropriate time) a description of the inspection system as evidence of compliance with § 21.125.

j. The applicant cannot utilize manufacturing facilities located outside the United States unless the FAA has determined that the location of the facilities places no undue burden on the FAA, as specified in § 21.43.

k. TC Holder's Responsibility.

(1) Prior to the issuance of an APIS, a TC holder or licensee who produces a product is responsible for complying with §§ 21.123, 21.127, 21.128, 21.129, and 21.130, as appropriate for the particular product involved.

(2) All products and parts manufactured under the provisions of part 21, subpart F, must be marked in accordance with the requirements of 14 CFR part 45, Identification and Registration Marking (part 45).

> **Note: The holder of a Dealer's Aircraft Registration Certificate is responsible for complying with the requirements of 14 CFR part 47, Aircraft Registration (part 47), regarding the use of temporary registration numbers. Specifically, the temporary registration number must be removed from the aircraft no later than the date on which either title or possession passes to another person.**

(3) A TC holder or licensee is also responsible for reporting any failures, malfunctions, and defects as required by § 21.3.

l. APIS Holder's Responsibility. Upon the establishment of the APIS, the APIS holder is responsible for the actions listed in paragraph 2-4k of this order and the following actions:

(1) The APIS holder must submit a manual to the MIDO that describes the APIS and the means for making the determinations required by § 21.125(b).

(2) The APIS holder is responsible for maintaining the APIS in accordance with § 21.125 to ensure that each product conforms to the type design and is in a condition for safe operation. The APIS holder must also comply with any terms or conditions as prescribed in its APIS approval letter.

(3) The APIS holder is responsible for notifying the FAA of changes in the location of the manufacturing complex approved by the FAA for the particular type certificated product(s).

(a) The APIS is issued to the principal manufacturing facility that controls the design and quality of the product(s) for which the approval was granted. A mailbox address is not acceptable for a facility since the actual location must be identified. Such addresses, however, may be used as supplemental to the actual address when desired for such uses as corresponding to and from FAA offices.

(b) When the APIS holder moves the principal manufacturing facility to a new location, the APIS is no longer effective since an APIS is not transferable. If the APIS holder wants an APIS for the new location, the APIS holder must establish the APIS in accordance with § 21.123.

(c) When the APIS holder adds a new production facility, the FAA must be notified of such changes. The FAA may, if deemed necessary, conduct a MIDO audit at the new production facility. If a MIDO audit is deemed necessary, a satisfactory audit result must be obtained before the production facility can be approved for production.

Part 2. FAA Actions During the Six-Month Period

2-5. FAA Conformity Determinations. Subsequent to the date of issuance of the TC and prior to the issuance of an APIS or PC, the MIDO/CMO has full responsibility for determining whether the product or part(s) conform to the type design and are in a condition for safe operation. The MIDO/CMO has the responsibility for performing inspections of incoming materials (at the source, if necessary), installations, and the completed products. The MIDO/CMO has the responsibility for documenting each inspection on FAA Form 8100-1, Conformity Inspection Record, so that each product or part(s) inspected has a complete inspection record. Refer to figure 2-1 for a sample form.

2-6. Assessing the Applicant's Progress. The MIDO/CMO should periodically assess the applicant's progress in complying with the regulations for obtaining approval of an APIS or PC. If it appears that the applicant is delaying this action or may not be eligible for an APIS or PC by the deadline date, the applicant should be advised in writing of all known deficiencies. Also, the applicant should be cautioned that after the deadline date, the FAA will not issue any airworthiness certificates or any other approvals unless an extension of the time period is authorized by the directorate manager. The MIDO/CMO should keep the directorate office apprised as to the applicant's progress.

2-7. Extension of Six-Month Period. The FAA may grant an extension when there are unusual or extenuating circumstances that preclude the establishment of an APIS or PC within the six-month limitation. The FAA should not grant an extension of the six-month period without giving due consideration to the impact the extension would have on FAA personnel resources and safety. In all instances, the FAA should consider an extension only when the applicant can substantiate the reasons for requesting such an extension. For example, extensions may be justified in those instances where products are in limited or infrequent production and for license and transfer of TCs that were issued more than six months prior to the licensing agreement or transfer. The authorization for extension must be issued to the applicant in writing. Refer to figure 2-2 for a sample extension letter.

2-8. APIS or PC Not Established Within Six-Month Period. When an applicant fails to establish an APIS or PC by the end of the six-month period (except when extended), the FAA will no longer make conformity determinations and will discontinue the issuance of all airworthiness certifications and approvals. However, the FAA should continue to counsel and advise the applicant to the extent necessary to assist in obtaining an APIS or PC as soon as practicable.

Part 3. Processing an Application for an APIS

2-9. Application. When an applicant expresses a desire to apply for an APIS instead of a PC, the applicant should be advised that a formal application is not required by the regulations. However, the applicant may use FAA Form 8110-12, Application for Type Certificate, Production Certificate, or Supplemental Type Certificate, to apply for the APIS since it contains appropriate spaces to indicate whether or not production privileges are desired or whether or not parts will be manufactured for sale. Refer to figure 2-3 for a sample form.

Figure 2-1. Sample FAA Form 8100-1, Conformity Inspection Record (Front)

Conformity Inspection Record

1. Project Number, TIA / Request Date:
2. SHEET of Sheets
3. Applicant/Manufacturer:
4. Beginning Date:
5. Ending Date:
6. Model:
7. Inspected By:

8. Item No.	9. Nomenclature of Item Inspected	10. Drawing, Document, Specification, etc.	11. Revision and Date	12. No. of Items Determined: SAT.	UNSAT.	13. Comments

Sample

FAA Form 8100-1 (5-92) Supersedes Previous Edition (Instruction on page 2)

Figure 2-1. Sample FAA Form 8100-1, Conformity Inspection Record (Back)

INSTRUCTIONS

1. List the FAA assigned number along with date of TIA or Request for Conformity, as applicable.
2. Self-explanatory.
3. List the applicant or the manufacturer, or both. (The manufacturer may be the party producing or responsible for the product).
4. List the date the inspection began.
5. List the date the inspection ended.
6. If inspecting an aircraft, list the make, model, N-number, and serial number. For an engine or propeller, list the make, model, and serial number.
7. Aviation Safety Inspectors must type or print name, sign, and enter office identification. Designees must type or print name, sign, and list their designee identification number.
8. Assign consecutive numbers for each item inspected.
9. List the name or description of the part, appliance, assembly, drawing, document, specification, or name of the process being evaluated.
10. List the technical data that describes the item listed in Block 9. (i.e., drawing number, document number, or name of the process specification number, etc.
11. List the revision level and date of the technical data described in Block 10.
12. List the number of items that were determined satisfactory or unsatisfactory. Do not record individual characteristics. ***NOTE:*** (an item is a single article or unit containing one or more dimensional characteristics or features).
13. Enter comments in this block that will support any information given in Blocks 8 through 12. i.e., unsatisfactory conditions, corrective actions taken, reference to other item numbers listed, serial numbers, type of inspection accomplished, destination of exported products, buyer finished equipment, parts processed through manufacturer's maintenance facility, part new or newly overhauled, condition of part or assembly, etc.
14. To be used for supplementing items 1-13.

NOTE: Unsatisfactory conditions are corrected in one of two ways:

Method 1: If action is presented to correct an unsatisfactory condition, the action is entered in Block 13 and the number in the UNSAT column of Block 12 is lined through and initialed. The number of items now determined satisfactory is entered in the SAT column next to the corrective action entry.

Method 2: If corrective action is not presented, the inspector may continue the inspection by entering the next item inspected. When corrective action to the unsatisfactory condition is eventually presented, assign the item a new number and record the number in Block 8. Complete Blocks 9 and 10, enter a new revision and date if data has changed, and enter the number of items determined satisfactory in Block 12. Record both the corrective action taken and the item number of the unsatisfactory condition in Block 13. Place the item number in parenthesis. Next, line through and initial the number in the UNSAT column located next to Block 13 containing the unsatisfactory condition. Record the corrective action entry item number along with the unsatisfactory condition statement and place the number in parenthesis.

14. Continuation Block

FAA Form 8100-1 (Backer) (5-92)

Sample

Figure 2-2. Sample Letter of Authorization for Extension of § 21.123(c) Six-Month Limitation

U.S. Department
of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
SOUTHWEST REGION
ROTORCRAFT DIRECTORATE
MANUFACTURING INSPECTION OFFICE
2601 MEACHAM BOULEVARD
FORT WORTH, TEXAS 76137-4298

May 10, 1999

Johnson Aircraft Corporation
119 Standards Street
Benbrook, Texas 12345

Attention: Mr. Nelson P. Norman, Vice President

Authorization for Extension of Production Under Type Certificate Only,
Title 14, Code of Federal Regulations (14 CFR),
Part 21, Certification Procedures for Products and Parts (part 21), Section 21.123(c).

Your request, dated April 28, 1999, regarding the subject matter has been reviewed and authorization is hereby granted to extend the period of time products may be manufactured under a Type Certificate Only without an approved production inspection system from June 1, 1999, to October 1, 1999.

This extension of time is based on the fact that you were unable to establish an approved production inspection system within the six-month period as required by Section 21.123(c) due to the four-month labor strike at your facility which ended April 15, 1999. Aircraft produced under the provisions of this authorization will continue to require inspection by FAA personnel at various stages of fabrication, processing, and assembly where detailed inspections can be conducted.

Johnson Aircraft Corporation must also continue to comply with part 21, subpart F, as applicable, including the requirements for a FAA Form 8130-9, Statement of Conformity, with each application for an airworthiness certificate.

Jason P. Hope
Manager, Manufacturing
Inspection Office, ASW-180

Figure 2-3. Sample FAA Form 8110-12, Application for Type Certificate, Production Certificate, or Supplemental Type Certificate

No certificate may be issued unless a completed application form has been received (14 C.F.R.-21)

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

APPLICATION FOR TYPE CERTIFICATE, PRODUCTION CERTIFICATE, OR SUPPLEMENTAL TYPE CERTIFICATE

FORM APPROVED
O.M.B. No. 2120-0018
09/30/2007

1. **Name and address of applicant:**	2. **Application made for:**	3. **Product Involved :**
ABC Aircraft Company 4954 Airport Drive Detroit, Michigan	☐ Type Certificate ☒ Production Certificate ☐ Supplemental Type Certificate	☒ Aircraft ☐ Engine ☐ Propeller

4. **TYPE CERTIFICATE** (Complete item 4a below)

a. **Model designation (s)** *(All models listed are to be completely described in the required technical data, including drawings representing the design, material, specifications, construction, and performance of the aircraft, aircraft engine, propeller which is the subject of this application.)*

5. **PRODUCTION CERTIFICATE:** (*Complete items 5a-c below. Submit with this form, in manual form, one copy of quality control data or changes thereto coveting new products, as required by applicable FAR.)*

a. **Factory address:** *(if different from above)*	b. **Application is for:** ☒ New production certificate ☐ Additions to production Certificate *(Give P.C. No.)*	**P.C. No.**
c. **Applicant is holder of or a licensee under a Type Certificate or a Supplemental Type Certificate:** *(Attach evidence of licensing agreement and give certificate number)* →		**T.C./S.T.C. No.** 1A26

6. **SUPPLEMENTAL TYPE CERTIFICATE:** *(Complete items 6a-d below)*

a. **Make and model designation of product to be modified:**

b. **Description of modification:**

c. **Will data be available for sale or release to other persons ?**	d. **Will parts be manufactured for sale?** *(Ref. FAR 21.303)*
☐ Yes ☐ No	☐ Yes ☐ No

7. **CERTIFICATION - I certify that the above statements are true.**

Signature of Certifying Official	**Title**	**Date**
John J. Smith *John J. Smith*	Director, Quality Assurance	May 10, 2004

FAA Form 8110-12 (4-03) Supersedes Previous Edition

Sample

2-10. Review of Production Inspection System Data. When an APIS applicant submits production inspection system data as evidence of compliance with part 21, subpart F, the cognizant MIDO will evaluate these data in accordance with the criteria contained in appendix A of this order. Any inadequacies in the data submitted must be identified to the applicant for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO will accept the production inspection system data submitted by the applicant. The FAA does not approve these data since there is no part 21 requirement for submittal of these data for approval.

2-11. Provisional Approval Procedures. Evaluation of the applicant's inspection system should be accomplished by the MIDO, concurrent with conducting conformity inspections and making those airworthiness determinations required of the FAA prior to the issuance of an APIS. It is, therefore, to the advantage of the FAA to evaluate and provisionally approve the inspection system on a progressive basis. As portions of the system are determined to meet the regulatory requirements, the MIDO should:

a. Maintain a record of those portions of the system considered satisfactory.

b. Reduce conformity inspections to a spot-check basis for articles covered by the provisionally approved portion of the system.

c. Place increased emphasis on securing corrective actions on the portions of the system where procedural discrepancies have been found or where the system has been found to be inadequate.

2-12. Preliminary MIDO Audit. When the MIDO has determined that the applicant has the capability to comply with § 21.125, the MIDO will conduct a MIDO audit as follows:

a. The MIDO audit evaluates the applicant's production facilities in accordance with the pertinent 14 CFR, the FAA-approved design data, and the production inspection system data accepted in paragraph 2-10 of this order. The cognizant MIDO manager will select a team to conduct this audit. The team may consist of the cognizant PI and at least one other manufacturing inspector or the MIDO manager. It is also recommended that an engineer be selected for the team when deemed necessary by the type and complexity of processes and procedures being utilized at the facility. The standardized evaluation criteria contained in Order 8100.7, Aircraft Certification Systems Evaluation Program, may be used as an aid to evaluate compliance. Team members should be advised, however, that some of the evaluation criteria contained therein may not be related to 14 CFR, and therefore may only be evaluated as a best practice. This audit is not considered an Aircraft Certification Systems Evaluation Program (ACSEP) evaluation. Document noncompliances on FAA Form 8100-6, Noncompliance Record. Refer to appendix F.

b. Notifying the Applicant. Upon completion of the MIDO audit, the MIDO will formally notify the applicant as to any corrective actions necessary to comply with § 21.125. The MIDO should advise the applicant that an APIS Board will be scheduled that could result in a request for additional actions.

c. Reporting. The MIDO will prepare FAA Form 8120-14, Production Approval/Certificate Management Activity Report, upon completion of the MIDO audit, and provisional approval of the applicant's inspection system when applicable. The MIDO will provide notification to the directorate office that the Form 8120-14 may be viewed in CMIS. In addition, the MIDO will provide information to the directorate office concerning the applicant's ability to comply with § 21.125. Refer to appendix G for a sample Form 8120-14.

2-13. APIS Board. Upon receipt of Form 8120-14 and notification by the MIDO that the applicant is in a position to comply with § 21.125, the directorate office should schedule an APIS Board. The primary objective of this board is to make a final determination as to whether or not the applicant has established a production inspection system that complies with § 21.125 and that is capable of producing products and parts in conformity with the type design and in a condition for safe operation.

a. Conduct of the APIS Board. The directorate office will conduct the APIS board in a manner similar to a Production Certification Board (PCB), including the use of a Chairman. Use the PCB procedures contained in chapter 2, section 3, part 3 of this order, as appropriate.

b. APIS Board Minutes. Document the APIS Board minutes in the same manner as a PCB, as applicable to the particular situation. Refer to paragraph 2-25 of this order.

Part 4. Issuance of an APIS

2-14. APIS Approval Letter.

a. Preparation and Delivery. When the APIS Board has determined and documented that the applicant's complete production inspection system complies with the requirements of part 21, subpart F, the directorate office will prepare a letter approving the production inspection system. Refer to figure 2-4 for a sample letter. Electronic signature is not permitted. The approval letter should be delivered to the manufacturer by the MIDO or may be forwarded by certified mail when deemed most expeditious.

b. Additions to the APIS. If the APIS holder desires to add another type-certificated product or a new model to the APIS, the MIDO should evaluate any changes to the APIS that may be involved in the manufacture of the new product. Upon receipt of a completed Form 8120-14 and a satisfactory recommendation from the MIDO, the directorate office may then issue a superseding approval letter. The letter should be issued listing the original and the new product(s) and/or model(s). The APIS holder will be requested to return the original letter. The directorate office will annotate the word "Superseded" on the original letter and retain it in the directorate files.

2-15. Initial Risk-Based Resource Targeting Assessment. Subsequent to the approval of the APIS, the MIDO/CMO will conduct an RBRT assessment of the APIS holder in accordance with chapter 3, section 2 of this order. The results will determine the initial basis for conducting ongoing CM responsibilities, as summarized in figure 3-2 of this order.

2-16. Reserved.

Figure 2-4. Sample Letter for Approving a Manufacturer's Production Inspection System

U.S. Department
of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
SOUTHWEST REGION
ROTORCRAFT DIRECTORATE
MANUFACTURING INSPECTION OFFICE
2601 MEACHAM BOULEVARD
FORT WORTH, TEXAS 76137-4298

November 4, 1999

GEM Aircraft Company
711 Suburban Lane
Oklahoma City, Oklahoma 73064

Production Inspection System Approval

Your production inspection system has been evaluated and found to be in compliance with applicable parts of Title 14, Code of Federal Regulations (14 CFR). Therefore, you are authorized to produce the following products and parts in compliance with the standards contained in 14 CFR part 21, Certification Procedures for Products and Parts, Subpart F, and in conformity with the type design data forming the basis for the following type certificate(s):

Type Certificate/Make/Model

1A25GEM1010	GEM	1020
1A78		

The following terms and conditions are applicable to this approval:

1. GEM Aircraft Company's production approval inspection system, methods, procedures, and manufacturing facilities, including your suppliers, are subject to FAA surveillance or investigations. Accordingly, GEM Aircraft Company must advise its suppliers that its facilities are also subject to FAA surveillance and investigation.

2. GEM Aircraft Company must make available to the FAA, upon request, any pertinent information concerning its suppliers who furnish parts/services, including:

   a. A description of the part or service.

   b. Where, and by whom, the part or service will undergo inspection;

   c. Any delegation of inspection duties.

Figure 2-4. Sample Letter for Approving a Manufacturer's Production Inspection System (Continued)

d. Any delegation of materials-review authority.

e. Name and title of FAA contact at the supplier facility.

f. The inspection procedures required to be implemented.

g. Any direct-shipment authority.

h. Results of GEM Aircraft Company evaluation, audit, and/or surveillance of its suppliers.

i. The purchase/work order number (or equivalent).

j. Any feedback relative to service difficulties originating at GEM Aircraft Company suppliers.

3. Parts or services furnished by suppliers located in a foreign country or jurisdiction may not be used in the production of the products listed in this approval unless:

a. That part or service can and will be completely inspected for conformity at GEM Aircraft Company's facility; or

b. The FAA has determined that the location of the foreign supplier facility places no undue burden on the FAA in administering applicable airworthiness requirements. When the use of such foreign suppliers is contemplated, GEM Aircraft Company must advise the FAA at least 10 days in advance to allow the FAA to make this determination; or

c. The parts/services furnished by the foreign supplier are produced under the "components" provision of U.S. airworthiness bilateral agreements, and approved for import to the U.S. in accordance with Section 21.502.

4. This approval is not transferable to another person or location. In addition, it may be withdrawn for any reason that would preclude its issuance or at anytime the FAA finds that the approved production system is not being maintained. Also, the approval can be withdrawn if unsafe or nonconforming parts are accepted under the approved production inspection system; or if the Statement(s) of Conformity, FAA Form 8130-9, required by Section 21.130, is found to be invalid.

5. Our district office (address of cognizant office) must be notified within 10 days from the date that the address shown in this approval has been changed.

6. GEM Aircraft Company must maintain its approved production inspection system in continuous compliance with the requirements of Section 21.125, and ensure that each product or part(s) conforms with the type design data and is in a condition for safe operation.

Figure 2-4. Sample Letter for Approving a Manufacturer's Production Inspection System (Continued)

7. GEM Aircraft Company is eligible for the appointment of qualified individuals in its employ to represent the FAA as Designated Manufacturing Inspector Representatives for the purpose of issuing Airworthiness Approvals for Class I, II, and III products.

8. GEM Aircraft Company will report to our district office, in a timely manner, information concerning service difficulties on any product(s) or part(s) produced under this approval, in addition to any failures, malfunctions, and defects required to be reported in accordance with Section 21.3.

9. All pertinent technical data for the product(s) or part(s) to be produced under this approval must be readily available to the FAA at the facility in which the parts are being produced.

10. GEM Aircraft will notify our district office immediately in writing of any changes to the APIS that may affect the inspection, conformity, or airworthiness of the product(s) approved in this letter.

11. GEM Aircraft Company will produce all parts in accordance with GEM Aircraft Company Quality Control Manual, Revision G, dated July 17, 1996, which has been presented as evidence of compliance with Section 21.125. Accordingly, any revisions to these data must be submitted and approved by our district office prior to implementation.

Jack M. Safeway
Manager, Manufacturing
Inspection Office, ASW-180

Section 3. Production Certificate (Part 21, Subpart G)

Part 1. General Information

2-17. Applicability.

a. Part 21, subpart G, is applicable to any of the following persons who desire to manufacture a complete product and part(s) with benefit of a PC:

(1) The holder/licensee of a § 21.21 TC.

(2) The United States (U.S.) holder/licensee of a § 21.29 TC, if the licensing agreement clearly provides for the TC holder's and its Civil Aviation Authority's control over any design changes by the licensee. A working arrangement, associated with the respective bilateral agreement, must also be in place between the Civil Aviation Authority (CAA) and the FAA defining their respective responsibilities as State of Design and State of Manufacture.

(3) The holder of a supplemental type certificate (STC) when—

(a) The STC will be incorporated prior to the issuance of an original airworthiness certificate (OAC) to the aircraft; or

(b) The STC will be incorporated after the issuance of an OAC to the aircraft. In this case, the PC would authorize the manufacturing of associated STC parts in accordance with part 21. However, installation of the STC and return to service of the product is accomplished under the provisions of 14 CFR part 43, Maintenance, Preventive Maintenance, Rebuilding, and Alteration (part 43).

(4) The holder/licensee of a § 21.25 TC, provided the TC was issued based on FAA approval of the type design data. The data must have been submitted by the applicant or the licensor and must meet the requirements of § 21.31.

(5) The holder/licensee of a § 21.27 TC, provided that duplicates produced always originate as an aircraft that was designed and constructed in the United States, was accepted for operational use, and was declared surplus by the military. The holder/licensee of a § 21.27 TC also must demonstrate that it has established a quality system that meets the requirements of §§ 21.139 and 21.143 at the product level.

b. A PC may not be issued to the holder of a TC issued under part 21, subpart C (provisional).

c. A PC may not be issued if the manufacturing facilities are located outside the United States, unless it has been determined, in accordance with § 21.137, that such location(s) would place no undue burden on the FAA.

2-18. Privileges. A PC holder has the privileges specified in § 21.163. In addition, a PC holder is eligible to have a qualified employee(s) designated as a DMIR in accordance with the provisions of part 183. The PC holder may also be authorized by part 183 to apply for and obtain an ODA. Orders 8100.8 and 8100.15 contain procedures for the administration of DMIRs and ODAs, respectively.

2-19. Advising the Applicant. The applicant should be advised that:

a. AC 21-1, Production Certificates, sets forth an acceptable means of complying with part 21, subpart G. Alternative methods and procedures may be approved when the applicant can show that the proposed methods and procedures will achieve compliance with part 21, subpart G.

b. The data required to be submitted under § 21.143 should be arranged in the format suggested in AC 21-1. In those instances where an applicant has already established quality control (QC) procedures, e.g., for military contracts, the applicant must identify those portions that comprise the QC data that will be used to show compliance with § 21.143. The data may or may not comprise a lengthy document, depending upon the size of the manufacturing facilities and product complexity. The data must include descriptive material that adequately covers each applicable paragraph of § 21.143. A title should be provided for positive identification and a revision page or similar control is required to ensure that the original approval date and the date of each revision is recorded. A number or letter should identify each revision.

c. The PC holder who produces a completed product under part 21, subpart G, must flight test and/or production test that product in accordance with the requirements of § 21.143(a)(3).

(1) Aircraft. All aircraft must pass an approved production flight test as part of the inspection procedure required for issuance of an airworthiness certificate. A Special Airworthiness Certificate, FAA Form 8130-7, issued for such purposes provides authorization for production flight testing (reference FAA Order 8130.2, Airworthiness Certification of Aircraft and Related Approvals). The exceptions would be small airplanes and gliders manufactured under a PC and being exported without assembly or flight test under the provisions of § 21.325(b). The intent of this rule is to permit shipment of aircraft without assembly or flight test when the extent of disassembly is the same as an aircraft that has been disassembled for shipment purposes. In these instances, the manufacturer must provide FAA-approved assembly and flight test procedures as a condition of shipment.

(2) Periodic FAA Production Flight Tests. FAA production flight tests will be conducted periodically at the PC holder's facility to ensure continued compliance with all parameters as specified in pertinent type certificate data with respect to performance, flight characteristics, operation qualities, equipment operations, etc. The PI, in coordination with the FAA flight test personnel from the appropriate ACO, may arrange these flight tests. In addition, a determination should be made in coordination with FAA flight test personnel that the manufacturer's approved production test pilots are continuing to use approved procedures and that the approved procedures remain adequate.

(3) Engines and Propellers. Engines and propellers must pass a production test approved as part of the QC data required by § 21.143(a)(3).

d. PC Holder's Responsibility.

(1) The PC holder is responsible for maintaining the quality system in conformity with the data and procedures approved for the PC, and for determining that each completed product and part submitted for airworthiness certification or approval conforms to the TC or STC and is in a condition for safe operation.

(2) Section 21.147 requires the holder of a PC to immediately notify the MIDO/CMO in writing of any changes that may affect the inspection, conformity, or airworthiness of the product. These changes would include, but are not limited to:

(a) Relocation of a portion of its facility or addition to existing facilities.

1 A PC holder's manufacturing complex would normally consist of a principal facility and all associate facilities using the same quality system approved by the FAA, for the particular type certificated product(s). Associate facilities are discussed in section 6 of this chapter.

2 The PC is issued to the principal manufacturing facility that controls the design and quality of the product(s) for which the approval was granted. The principal facility address will be listed under the "business address" and all associate facility addresses will be listed under "manufacturing facilities" on FAA Form 8120-4, Production Certificate. A mailbox address is not acceptable for a facility since the actual location must be identified. Such addresses, however, may be used as supplemental to the actual address when desired for such uses as corresponding to and from FAA offices.

3 When a PC holder moves the principal manufacturing facility to a new location, the PC is no longer effective since a PC is not transferable. Refer to § 21.155. If the PC holder wants a PC for the new location, the PC holder must reapply in accordance with § 21.133.

4 When the PC holder moves an associate facility or adds a new production facility, the FAA must be notified of such changes in accordance with § 21.147. The FAA may, if deemed necessary, conduct a preliminary MIDO audit at the new production facility or moved facility. If a MIDO audit is deemed necessary, a satisfactory audit result must be obtained before the facility can be approved for production. The PC also must be amended to reflect this change.

(b) Resumption of production after being discontinued for an extended period of time for other than normal periods of time, such as vacation periods.

(c) Significant curtailment/resumption of production operations.

(d) Significant reduction/reassignment of QC personnel.

(e) Changes or revisions to QC data and related procedures.

(3) All products and parts produced under the provisions of part 21, subpart G, must be marked in accordance with the requirements of part 45, and in accordance with any related FAA-approved QC procedures, as applicable.

Note: The holder of a Dealer's Aircraft Registration Certificate is responsible for complying with the requirements of part 47, regarding the use of temporary registration numbers. Specifically, the temporary registration number must be removed from the aircraft no later than the date on which either title or possession passes to another person.

(4) Identification Plate Requirements for Aircraft, Aircraft Engines, or Propellers Produced Under a Design Data Licensing Agreement Program.

(a) The identification plate requirements for aircraft, aircraft engines, or propellers produced under a design data licensing program (as applicable) are as follows (Refer to § 45.13):

1 The builder's name is the specific name of the licensee as shown on the licensee's PC.

2 The model designation is that model identified on the associated type certificate data sheet (TCDS).

3 The builder's serial number is the serial number(s) dedicated for the use of the licensee as assigned by the TC holder on the associated TCDS.

4 The TC number is the number identified on the associated TCDS and upon which conformity to type design requirements is determined.

5 The PC number is the number that is listed on the licensee's PC.

6 For aircraft engines, the established rating as shown on the TCDS.

7 For aircraft engines manufactured after January 1, 1984, the following information must also be included:

a The date of manufacture as defined in 14 CFR part 34, Fuel Venting and Exhaust Emission Requirements for Turbine Engine Powered Airplanes, § 34.1.

b The status of compliance to applicable exhaust emission provisions, as approved by the Administrator (e.g., COMPLY, EXEMPT, or NON-U.S., as appropriate).

(b) As prescribed under the provisions of § 45.13(a)(8), the Administrator will normally deem it appropriate and necessary to include the following information on the identification plates of products manufactured under a design data licensing agreement between an FAA TC and PC holder: **"Manufactured by *(insert the PC holder's name)* under a licensing agreement with *(insert the TC holder's name).*"**

(c) The FAA requires that only the information in paragraph 2-19d(4)(a) and (b) of this order be included on the identification plates for all products manufactured under a licensing agreement program. However, the FAA would permit a company/corporate logo or registered trademark to be included (after review and approval by the FAA) on the identification plates, if desired by the manufacturer. Aircraft, aircraft engine, and propeller identification plates should be included as part of the product's approved design data and are usually defined in an engineering drawing describing material, size, required information entries, mounting location, etc.

(5) The PC holder must report all failures, malfunctions, and defects as required by § 21.3. The PC holder should be encouraged to establish a procedure for such reporting.

Part 2. Processing an Application for a PC

2-20. Application. Application for a PC is made on Form 8110-12. Refer to figure 2-3 for a sample form. The applicant must submit the application, accompanied by one copy of the QC procedures showing compliance with § 21.143, to the Manager, Manufacturing Inspection Office (MIO), in the directorate in which the applicant's principal manufacturing facility is located. Refer to paragraph 2-19d(2)(a)*1* and *2* of this order. Upon receipt of a properly executed Form 8110-12, the MIO manager will forward a copy to the MIDO/CMO. The MIDO/CMO will prepare a letter of acknowledgement, advising the applicant that it has been authorized to initiate a MIDO audit to determine compliance with applicable regulations. A copy of the letter should be forwarded to the MIO. Refer to figure 2-5 for a sample letter.

2-21. Preliminary MIDO Audit. The MIDO/CMO should make arrangements to conduct a MIDO audit within 30 days after acknowledging the PC application. This audit will be conducted as follows:

a. Evaluate the applicant's QC data for compliance with § 21.143. Additional guidance is provided in appendix A of this order. Any inadequacies in the data submitted must be identified to the applicant for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO/CMO will approve the QC data submitted by the applicant. The approved QC data may be retained in the MIDO/CMO files.

b. Evaluate the applicant's production facilities in accordance with the pertinent 14 CFR, the FAA-approved design data, and the QC data approved in paragraph 2-21a of this order. The cognizant MIDO/CMO manager will select a team to conduct this audit. The team may consist of the cognizant PI and at least one other manufacturing inspector or the MIDO/CMO manager. It is also recommended that an engineer be selected for the team when deemed necessary by the type and complexity of processes and procedures being utilized at the facility. The standardized evaluation criteria contained in Order 8100.7 may be used as an aid to evaluate compliance. Team members should be advised, however, that some of the evaluation criteria contained therein may not be related to 14 CFR, and therefore may only be evaluated as a best practice. This audit is not considered to be an ACSEP evaluation. Noncompliances will be documented on Form 8100-6. Refer to appendix F.

c. Notifying the Applicant. Upon completion of the MIDO audit, the MIDO/CMO will formally notify the applicant as to any corrective actions needed to comply with § 21.135. The applicant should be further advised that these items represent only the result of the FAA's preliminary MIDO audit. Additional requests for corrective actions can be anticipated as a result of subsequent noncompliances, which may be noted during the PCB evaluation activity, as detailed in part 3 of this section.

d. Reporting. The MIDO/CMO will provide notification to the MIO that the "Preliminary" Form(s) 8100-6 may be viewed in CMIS. The "Preliminary" Form(s) 8100-6 should identify any unresolved items requiring corrective action. In addition, letters issued to the applicant requesting corrective action also may be viewed in the CMIS project folder.

Figure 2-5. Sample PC Application Acknowledgement Letter

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

June 10, 1999

ABC Aircraft Company
4954 Airport Drive
Renton, Washington 12345

Production Certification Application Acknowledgement

This will acknowledge receipt of your application dated May 30, 1999, for a Production Certificate. This office has been authorized to initiate a preliminary evaluation of your manufacturing operations, quality system, and testing procedures. The quality control data, required by Title 14, Code of Federal Regulations (14 CFR), part 21, Certification Procedures for Products and Parts (part 21), section 21.143, and submitted with your application, were forwarded to this office for our utilization in determining compliance with applicable regulations.

Accordingly, your quality system and manufacturing facilities (including any supplier facilities, as appropriate) will be evaluated by this office to determine compliance with part 21, subpart G. To preclude any misunderstandings, please notify your suppliers as soon as possible that they are subject to FAA evaluations. We will contact you in the near future to advise you of our evaluation schedule.

Subsequent to our preliminary evaluation, a Production Certification Board will be established to make a final determination as to eligibility for issuance of a Production Certificate. This will be accomplished as soon as practicable following our recommendations to the Manager, Manufacturing Inspection Office, Transport Airplane Directorate. You will be given adequate notice so that a date for convening the Production Certification Board at your principal facility can be mutually agreed upon.

Roger C. Moore
Manager, ANM-108S

Part 3. Production Certification Board

2-22. General PCB Information. The PCB is a high-level FAA evaluation function based directly upon the responsibilities established in Title 49 United States Code (49 USC), §§ 44701, 44702, 44704, and 44709.

a. Purpose. The purpose of the PCB is to evaluate the eligibility of the applicant for issuance of a PC based upon the preliminary findings and recommendations of the MIDO/CMO and the PCB's review of the applicant's facilities and QC data.

b. Applicability. The PCB should be convened only for initial production approvals, or when entire facilities have been relocated or are added to the PC. The PCB should not be convened for the addition of new models to the production limitation record (PLR) or relocation of a portion of the facility. In these instances, the procedures contained in paragraph 2-27b(1) of this order should be followed.

c. PCB Members. PCB members should consist of a group of qualified specialists from Airframe, Systems & Equipment, Propulsion, Manufacturing, and Flight Test functions, as appropriate. These members will assist in evaluating the applicant's production, engineering, flight test procedures, and other related functions. Representatives from Washington, DC, the Aeronautical Center, and/or other directorates may also participate in a PCB, when deemed desirable or necessary.

d. PCB Chairman. The MIO or CMO manager of the directorate where the manufacturing facility to be evaluated is located will act as the Chairman of the Board. When necessary, the MIO or CMO manager may delegate the chairmanship to the MIDO manager or other qualified directorate office personnel.

2-23. PCB Member Responsibilities. Specific PCB member responsibilities are as follows:

a. PCB Chairman. The PCB chairman is responsible for:

(1) Selecting and assigning board members, as deemed appropriate for the particular product, and notifying the members of the PCB in sufficient time to permit adequate planning and preparation.

(2) Notifying the applicant of the PCB schedule and identifying members and their assignments.

(3) Selecting a representative number of the applicant's supplier facilities for evaluation to determine whether or not the applicant's quality system provides for satisfactory supplier control.

(4) Conducting pre/post PCB meetings with the PCB and/or the applicant.

(5) Reviewing and analyzing the PCB findings and ensuring that appropriate corrective actions have or will be taken.

(6) Completing, signing, and distributing the PCB minutes.

b. Principal Inspector. The PI, in coordination with the responsible MIDO/CMO having CM responsibility, and the PCB chairman, is primarily responsible for establishing schedules, making arrangements for meeting rooms, obtaining sufficient copies of QC data, and making all other arrangements necessary for convening and conducting the PCB in the most expeditious manner. The PI is further responsible for ensuring that the applicant has taken all agreed upon corrective actions, for preparing the minutes of the PCB, and for initiating and completing any enforcement actions, when applicable.

c. Propulsion Section/Branch. The propulsion section/branch or its equivalent is responsible for the evaluation and approval of the applicant's production engine/propeller test procedures, as required by § 21.143(a)(3). This effort will be coordinated with the responsible MIDO/CMO. Upon determining that the procedures are acceptable, a letter of approval will be prepared and forwarded to the applicant when a PC is issued. A copy of this approval letter will be included in the PCB minutes.

d. Flight Test Section/Branch. The flight test section/branch or its equivalent is responsible for the evaluation and approval of the applicant's flight test procedures and checklists as required by § 21.143(a)(3). This effort will be coordinated with the responsible MIDO/CMO. Upon determining that the procedures and checklists are acceptable, a letter of approval will be prepared and forwarded to the applicant when a PC is issued. The letter will also include the names of those company pilots designated and authorized by the applicant to conduct production flight tests. A copy of this letter will be included in the PCB minutes.

e. Other PCB Members. Airframe and equipment engineering representatives and all other PCB members are responsible for ensuring that the applicant is in compliance with § 21.139, as appropriate to their particular assignment. Representatives from Washington, DC, the Aeronautical Center, and/or other directorates are responsible for acting in an advisory capacity and/or for the completion of any PCB activity assigned by the PCB chairman.

2-24. Conduct of the Board. A PCB is generally conducted in the following basic phases:

a. Initial FAA Personnel Meeting. Prior to arranging a Pre-Production Board meeting, FAA personnel will hold a meeting to review the results of the MIDO audit, MIDO/CMO recommendations, and related correspondence between the FAA and the applicant. This meeting will also serve to plan the PCB audit, schedule subsequent meetings, and establish agenda items for the Pre-Production Board meetings.

b. Pre-Production Board. A Pre-Production Board meeting with the applicant's representatives should be considered upon receipt of the PC application. This meeting should include the PCB chairman, MIDO/CMO manager, the PI, and others as necessary. The purpose of this meeting is to advise the applicant as to the purpose of the Board and of the FAA's evaluation plans. It should be made clear to the applicant that the board is a fact-finding body convened to determine whether or not the applicant is in compliance with § 21.135. The applicant should also be advised that the PCB is responsible for making a thorough evaluation of the applicant's quality system/data, organization, production facilities, and if deemed necessary, supplier facilities. Also, a determination should be made at this time that the location of the applicant's facilities will pose no undue burden on the FAA as specified in § 21.137.

c. PCB Audit. Following the Pre-Production Board meeting with the applicant, the PCB should evaluate the applicant's QC data and perform an on-site evaluation of the applicant's quality system, organization, production facility, and any suppliers, as deemed appropriate. Refer to paragraph 2-21 of this order for audit procedures.

d. Internal FAA PCB Meetings. Board meetings, attended by all board participants, will be conducted as needed to discuss and evaluate each unsatisfactory condition submitted by each member.

e. Reporting. The PCB will prepare Form 8120-14 upon completion of the PCB. All unsatisfactory conditions will be recorded on Form(s) 8100-6 and 8120-14. Refer to appendixes F and G of this order.

f. Final PCB Meeting. A final meeting, attended by all PCB members and representatives of the applicant, will be held to advise the applicant of the PCB findings. Each unsatisfactory condition should be presented and discussed briefly.

(1) Corrective Action. In those instances where a product is being produced under a TC only, the PC applicant must be requested to commence immediate corrective action on those items that directly involve the product and related QC practices. A reasonable time may be allowed for correcting deficiencies in the QC data. However, the applicant must be advised that the PCB cannot recommend that a PC be issued unless all applicable regulations are complied with and until the MIDO/CMO has evaluated all corrective actions and found them to be satisfactory.

(2) Formal Confirmation. The applicant must also be advised that an official letter will be sent confirming the verbal presentation of the list of unsatisfactory conditions. This formal notification should be prepared by the PI for the signature of the Chairman of the Board, within ten working days following the final meeting with the manufacturer.

(3) Violations. If the PC applicant is manufacturing a product under a TC only, and any of the unsatisfactory conditions are determined to be violations to part 21, subpart F, appropriate enforcement actions should be initiated by the MIDO/CMO in accordance with FAA Order 2150.3.

g. Final Phase of PCB. The final phase of a PCB is the evaluation by the MIDO/CMO of the corrective action taken by the applicant. The results of the re-inspection should be reported to the Chairman of the Board using Form 8120-14. Refer to appendix G of this order.

h. PCB Conclusion. The MIDO/CMO will formally advise the applicant in writing, as soon as practicable, that a PC will be issued based on a showing of compliance to § 21.135, or that a PC will not be issued if there is failure to show compliance with § 21.135. The MIDO/CMO will provide notification to the MIO that the letter has been issued and may be viewed in the CMIS project folder.

2-25. PCB Minutes. The MIDO/CMO will prepare the PCB minutes for the signature of the Chairman. The minutes should encompass a concise record of the entire PCB proceedings, including the names and titles of all participants.

a. All correspondence relating to the PCB, including letters to the applicant, replies, etc., are considered to be part of the minutes and should be attached as appendixes.

b. All Form(s) 8100-6 and 8120-14, or printed copy of electronic equivalent, should also be attached to the PCB minutes as a separate appendix.

c. Distribution of PCB Minutes. The PCB minutes should be distributed as follows:

(1) Original to the directorate office involved. In accordance with Manual FAA-IR-04-01, Aircraft Certification Service Records Management Requirements Manual, destruction of the original is not authorized.

(2) One copy to the cognizant MIDO/CMO that participated in the PCB.

2-26. PCB Adjournment. The PCB will be adjourned when the PCB minutes are accepted by the Chairman and distributed to the board members.

Part 4. Issuance of Production Certificate and Production Limitation Record

2-27. Preparation and Delivery of PC and PLR. Upon a finding by the PCB that the PC applicant's QC data/system, organization, and facilities comply with § 21.135, the MIDO/CMO will prepare Form 8120-4 and FAA Form 8120-3, Production Limitation Record, for the signature of the MIO Manager. Refer to figures 2-6 and 2-7 for sample forms. Signature authority for the PC and PLR may be delegated to the PCB Chairman. Electronic signature is not permitted. Delivery of the PC and PLR should be in person by the PI; however, if this procedure will result in an undue delay, the PC and PLR may be sent to the PC holder by certified mail. Whichever method of delivery is used, it is essential that the PC holder be advised of the PC display requirements and of the PC responsibilities by a letter. Refer to figure 2-8 for a sample letter.

a. PC. The PC will be consecutively numbered within each directorate; e.g., PC-6CE would indicate that the PC was the sixth one issued by the Small Airplane Directorate. Each directorate should establish and maintain a summary of PCs issued and a listing of changes made thereto.

> **Note: When a PC is issued based on a licensing agreement that is for a specific period of time, it must be indicated on Form 8120-4 under "Duration."**

b. PLR. The PLR will include the TC and model number of each product authorized for production, and the date that production was authorized. When a PC is issued for an STC, the PLR will include the STC number, the model number of each product on which the STC is eligible, and the date that production was authorized.

Figure 2-6. Sample FAA Form 8120-4, Production Certificate

This form is a representation of the original form and not to be construed as the original certificate.

NOT FOR OFFICIAL USE

Federal Aviation Administration

The United States of America
Department of Transportation
Federal Aviation Administration
Washington D.C.

No._____

Production Certificate

This certificate, issued to:

whose business address is:

and whose manufacturing facilities are located at:

Sample

authorizes the production, at the facilities listed above, of reasonable duplicates of which are manufactured in conformity with authenticated data, including, drawings, for which Type Certificates specified in the pertinent and currently effective Production Limitation Record were issued. The facilities, methods, and procedures of this manufacturer were demonstrated as being adequate for the production of such duplicates on date of

Duration:
This certificate shall continue in effect indefinitely, provided, the manufacturer continuously complies with the requirements for original issuance of certificate, or until the certificate is canceled, suspended, or revoked.

Date issued: **By direction of the Administrator**

_____ _____
Manager, Manufacturing Inspection Office

This Certificate is not Transferable, AND ANY MAJOR CHANGE IN THE BASIC FACILITIES, OR IN THE LOCATION THEREOF, SHALL BE IMMEDIATELY REPORTED TO THE APPROPRIATE REGIONAL OFFICE OF THE FEDERAL AVIATION ADMINISTRATION

Any alteration of this certificate is punishable by a fine of not exceeding $1,000, or imprisonment not exceeding 3 years or both

FAA FORM 8120-4 (07-07) SUPERSEDES PREVIOUS EDITION

HQ-O19007.indd

Figure 2-7. Sample FAA Form 8120-3, Production Limitation Record

This form is a representation of the original form and not to be construed as the original certificate.

NOT FOR OFFICIAL USE

The United States of America
Department of Transportation

Federal Aviation Administration

Production Limitation Record

The holder of
Production Certificate No. **6CE**
may receive the benefits incidental to the possession of such certificate with respect to

AIRCRAFT
(OR AIRCRAFT PROPELLERS, AIRCRAFT ENGINES, AS APPLICABLE)

manufactured in accordance with the data forming the basis for the following Type Certificate(s) No.

Type Certificate	Model	Date Production Authorized
5A25	ABC 258D	August 10, 1999

Sample

(Note: Any number of columns may be used provided the material is neat and legible. Additional PLRs may be used when necessary. Additional PLRs shall be numbered "1 of 2," "2 of 2," as appropriate to the number of pages involved.)

LIMITATIONS:

(if any)

August 10, 1999
Date of issuance

By Direction of the Administrator
J. J. Jones
J. J. Jones
Manager, Manufacturing Inspection

FAA FORM 8120-3 (7-67)

Figure 2-8. Sample PC Transmittal Letter

U.S. Department
of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
SMALL AIRPLANE DIRECTORATE
MANUFACTURING INSPECTION OFFICE
901 LOCUST STREET, ROOM 301
KANSAS CITY, MISSOURI 64106-2641

August 12, 1999

ABC Aircraft Company
4954 Airport Drive
Kansas City, Missouri 12345

Production Certificate Transmittal

We are pleased to forward Production Certificate No. 6CE, dated August 10, 1999, together with its Production Limitation Record listing Type Certificate No. 5A25. These documents must be prominently displayed in the main office of your factory, as required by Title 14, Code of Federal Regulations (14 CFR), part 21, Certification Procedures for Products and Parts (part 21), Section 21.161.

A Production Certificate authorizes the production of duplicates of specific type-certificated products and entitles the holder to certain privileges, including the option to obtain the appointment of a Designated Manufacturing Inspection Representative to issue airworthiness certificates and other related approvals. It should be noted that the issuance of a Production Certificate also places basic responsibilities upon the holder, as prescribed by 49 United States Code, Sections 44702(a) and 44704(b). The related rules are contained in part 21 and 14 CFR part 45, Identification and Registration Marking. We suggest that copies of the aforementioned be made available to the appropriate personnel in your organization.

If at any time you have questions concerning your privileges or responsibilities relative to your Production Certificate, please contact either this office or our Manufacturing Inspection District Office (number and address).

James C. Grace
Manager, Manufacturing Inspection
Office, ACE-180

(NOTE: When the PC and PLR are delivered in person, this letter should be suitably revised to reflect such delivery.)

(1) Additions to the PLR. If a PC holder desires to add a new TC or new model under an existing TC to the PLR, the PC holder must make application in the same manner as for the original issuance. In this instance, it is not normally necessary to establish a PCB. In place of the PCB, the MIDO/CMO should conduct an audit using the guidelines in paragraph 2-21, as appropriate, to determine whether the quality system is adequate or has been appropriately changed to ensure positive control of the product to be added to the PLR. When changes to the quality system are substantial, the PI may elect to request a nonscheduled ACSEP evaluation to make this determination. Refer to Order 8100.7. The MIDO/CMO having CM responsibility may issue revisions to the PLR to include new products or models, when authorized.

(2) Deletions from the PLR. Where production of a type-certificated product has been discontinued, and more than one TC is listed on the PLR, the following applies:

(a) If neither the complete product nor spare parts are being produced, the discontinued product or model should be deleted from the PLR. Upon issuance of the revised PLR, the MIDO/CMO will request that the PC holder return the superseded PLR, which will be marked "Superseded" and retained in the files. If no other products, models, or spare parts are covered by the PC, the PC holder will be requested to return both the PC and PLR for cancellation. The MIDO/CMO will retain the canceled PC and PLR.

(b) If production of the complete product has ceased, but spare parts are still being produced, the PLR should be revised to reflect this. The MIDO/CMO should ensure that the PC holder remains in compliance with § 21.147 and will continue to advise the FAA of any changes in its organization, systems, procedures, or processes.

(3) STC Modifications Incorporated by a TC/PC Holder.

(a) When the holder of the TC seeks and obtains its own STC, or is licensed to use another person's STC data, the TC holder may amend the TC to incorporate the STC approval by reference. Another party's STC that is incorporated during production and is referenced in and becomes a part of the TC need not be shown on the PLR. When a TC is amended to incorporate data approved under an STC, only the TC should continue to be shown on the PLR.

(b) When the PC holder of a TC obtains an STC, or related licensing agreement, but does not make the STC an integral part of the TC, the PC holder may incorporate the STC in production products prior to OAC approval, provided that:

1 The PC holder makes application to the FAA to add the STC to its PLR.

2 The QC data are revised as necessary.

3 The engineering data submitted for the STC approval provide all the details necessary for manufacture and for making conformity determinations.

(c) When a PC holder elects not to use either of the foregoing methods, the TC holder may incorporate an STC modification into production products only after OAC, in accordance with the provisions of part 43.

2-28. Initial Risk-Based Resource Targeting Assessment. Subsequent to the issuance of the PC, the MIDO/CMO will conduct an RBRT assessment of the PC holder in accordance with chapter 3, section 2 of this order. The results will determine the initial basis for conducting ongoing CM responsibilities, as summarized in figure 3-2 of this order.

2-29. Reserved.

Section 4. Technical Standard Order Authorization (Part 21, Subpart O)

Part 1. General Information

2-30. Applicability. Part 21, subpart O, is applicable to a person who desires to manufacture an article that meets a specific TSO. The TSO authorization system does not apply to parts produced under a PMA, TC only, or a PC.

2-31. Privileges. A TSO authorization holder has the privileges specified in § 21.603. In addition, a TSO authorization holder is eligible to have a qualified employee(s) designated as a DMIR in accordance with the provisions of part 183. The TSO authorization holder may also be authorized by part 183 to apply for and obtain an ODA. Orders 8100.8 and 8100.15 contain procedures for the administration of DMIRs and ODAs, respectively.

2-32. Advising the Applicant. The applicant will be advised that:

a. Section 21.605(a)(3) establishes the need for a quality system. AC 21-1 sets forth an acceptable means of compliance with § 21.605(a)(3). The FAA may approve alternative methods and procedures when the applicant can show that the proposed methods and procedures will achieve compliance with § 21.605(a)(3).

b. The applicant should arrange the data required for submittal to the FAA under § 21.605(a)(3) in the format suggested by AC 21-1. In those instances where an applicant has already established QC procedures, e.g., for military contracts, the applicant must identify those portions that comprise the QC data that the applicant will use to show compliance with § 21.605. The data may or may not comprise a lengthy document, depending upon the size of the manufacturing facilities and product complexity. The data must include descriptive material that adequately covers each applicable paragraph of § 21.605. A title should be provided for positive identification and a revision page or similar control is recommended to ensure that the original approval date and the date of each revision is recorded. A number or letter should identify each revision.

c. A TSO authorization holder is a manufacturer who controls the design and quality of an article produced under the TSO system. The TSO authorization holder's control extends to all related parts, processes, or services, including all related parts, processes, or services procured from outside sources.

d. A TSO design approval can be obtained only for the applicable TSO that is in effect on the date of application for that article.

e. A TSO authorization does not imply installation eligibility on a type-certificated product.

f. TSO Authorization Holder's Responsibility.

(1) The TSO authorization holder is responsible for maintaining the quality system in conformity with the data and procedures approved for the TSO authorization, and for determining that each completed article and parts produced conforms to the TSO and any terms or conditions prescribed in the TSO letter of authorization.

(2) The holder of a TSO authorization should notify the MIDO in writing prior to any changes that may affect the inspection, conformity, or airworthiness of the product. These changes would include:

(a) Relocation of a portion of its facility or addition to existing facilities.

1 A TSO authorization holder's manufacturing complex would normally consist of a principal facility and all associate facilities using the same quality system approved by the FAA, for the particular TSO article(s). Associate facilities are discussed in section 6 of this chapter.

2 The TSO authorization is issued to the principal manufacturing facility that controls the design and quality of the article(s) for which the approval was granted. A mailbox address is not acceptable for a facility since the actual location must be identified. Such addresses, however, may be used as supplemental to the actual address when desired for such uses as corresponding to and from FAA offices.

3 When a TSO authorization holder moves the principal manufacturing facility to a new location, the TSO authorization is no longer effective. In accordance with FAA Order 8150.1, Technical Standard Order Procedures, the responsible MIDO will evaluate the TSO holder's quality system to determine the TSO holder's ability to comply with § 21.143. If the MIDO finds no change to the TSO holder's ability to comply with § 21.143, the TSO holder may be eligible for the reissuance of its TSO authorization(s). The ACO must notify the TSO holder that no new articles may be shipped from its new facility until the TSO authorization has been reissued.

4 When the TSO authorization holder moves an associate facility or adds a new production facility, the FAA should be notified of such changes. The FAA may, if deemed necessary, conduct a preliminary MIDO audit at the new production facility or moved facility. If a MIDO audit is deemed necessary, a satisfactory audit result must be obtained before the facility can be approved for production.

(b) Resumption of production after being discontinued for an extended period of time for other than normal periods of time, such as vacation periods.

(c) Significant curtailment/resumption of production operations.

(d) Significant reduction/reassignment of QC personnel.

(e) Changes or revisions to QC data and related procedures.

(3) The TSO authorization holder must report all failures, malfunctions, and defects as required by § 21.3. The TSO authorization holder should be encouraged to establish a procedure for such reporting.

(4) Identification Marking. A TSO authorization holder is responsible for ensuring that only those articles that meet the applicable TSO performance standards are identified as required by § 21.603. Section 21.603(a) states in part that "...no person may identify an article with a TSO marking unless that person holds a TSO authorization and the article meets applicable TSO performance standards." The intent of § 21.603 is to address the identification of an article with its original TSO identification marking as required by § 21.607(d) at the time of manufacture.

> **Note: The address identification marking required by § 21.607(d)(1) will be the location of (1) the principal manufacturing facility, (2) the associate facility, or (3) the supplier that manufactures the complete article.**

(a) Supplier Marking. Suppliers to TSO authorization holders can identify parts with TSO markings provided the TSO approval holder adequately controls those suppliers as part of its quality system. Suppliers that mark parts should be treated the same as any other supplier furnishing parts or services, using supplier control procedures as part of the quality system. MIDOs may require that specific part marking controls be included in these procedures, along with any additional conditions that may be necessary for suppliers with direct-ship authorization.

(b) Detail Parts and Invoice Identification. When detail parts are produced for installation in a TSO article, individual detail parts of the TSO article sold separately must be accompanied by a shipping document containing the information required by § 21.607(d) and must identify the detail part as a subcomponent of a TSO article.

(c) Detail Parts and Design Data Identification. TSO article markings required by §§ 21.603 and 21.607(d) are applied to the top-level assembly for which the original TSO authorization was granted, not subassemblies or individual detail parts. It is not required that each individual subassembly or detail part within the TSO article be marked. The TSO marking requirements for detail parts, which are sold by the original TSO authorization holder for installation into its related TSO articles, may be found within the applicable design data for the TSO article. This provides traceability of the individual detail parts to their related TSO articles.

(5) Reidentifying Marking. Section 21.603 does not prohibit a certificated person, authorized under § 43.3, from modifying or replacing the original TSO identification marking in accordance with the TSO authorization holder's instructions (e.g., service letters, service bulletins, airworthiness directives, etc.) resulting from an FAA-approved design change. The following guidance applies to the incorporation of design changes to TSO articles that have left the manufacturer's quality system that require reidentifying of the TSO articles.

(a) There are instances when the holder of a TSO authorization, or a letter of TSO design approval, changes a design and provides data so that these changes may be incorporated into articles in service, through alteration. Service bulletins, service letters, and airworthiness directives are common nomenclature for these types of data, but the data may be transmitted in any appropriate form. Regardless of whether the change is major or minor, as defined in § 21.611, it may be necessary and/or appropriate to reidentify the article.

(b) The reidentification procedure indicated in paragraph 2-32f(5)(a) of this order must be part of the FAA-approved data for the entire alteration. The identification markings must comply with the requirements of § 21.607 and the applicable TSO. Some of the reidentification methods expected include the following: making additional marks; making new marks and obliterating the old; installing a new data plate or label provided by the TSO authorization holder; or a combination thereof. Consideration should be given to minimizing confusion as to the status of the article and maximizing traceability to the maintenance and alteration records.

(c) Design changes introduced by persons other than the TSO authorization holder are permissible under § 21.611(c). Order 8150.1 addresses the identification/marking requirements of TSO articles that are modified by persons other than the TSO manufacturer.

(6) Identification Marking of Replacement and Modification Parts Produced Pursuant to the Enhanced Enforcement Program (EEP) as Published in Federal Register Notice of February 27, 1995. Parts produced under the EEP that subsequently were issued TSO authorizations were not eligible at the time of production and are ineligible for marking in accordance with § 21.607(d). Although parts produced under the authority of the EEP are not eligible for part marking, these parts were considered acceptable for sale/installation under the provisions of § 21.305(d). Section 21.305(d) allows parts to be approved in any manner approved by the FAA Administrator. Parts produced under the authority of the EEP continue to be acceptable subsequent to the expiration of the EEP.

Part 2. Processing an Application for a TSO Authorization

2-33. Application.

a. A U.S. applicant (or an applicant's authorized agent) must submit an application for a TSO authorization by letter to the Manager, Aircraft Certification Office (ACO), having geographical responsibility for the area in which the applicant's principal manufacturing facility is located. The applicant must submit, along with the application, those documents required by § 21.605, which includes:

(1) A statement of conformance.

(2) A copy of the technical data.

(3) A description of the quality system in the detail specified in § 21.143.

b. A foreign manufacturer who desires to obtain a TSO letter of design approval (as provided for in § 21.617) must submit an application through its CAA to the ACO (or equivalent) that has cognizance over the geographical area in which the foreign manufacturer is located. A foreign manufacturer located in a member state of the European Union who desires to obtain a TSO letter of design approval must submit an application through the European Aviation Safety Agency to the Boston ACO.

2-34. Design Approval. The regulations and requirements concerning TSO design approval methods are contained in part 21, subpart O, and the applicable TSO. Policy covering TSO design approval methods is contained in Order 8150.1.

2-35. Preliminary MIDO Audit. At the request of the ACO, the MIDO should make arrangements to conduct a MIDO audit, within the deadline established by the ACO. This audit will be conducted as follows:

a. Evaluate the applicant's QC data for compliance with § 21.143 using the criteria contained in appendix A of this order. The data must include an acceptable test procedure to which each production article will be tested. Any inadequacies in the data submitted must be identified to the applicant for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO will approve the quality control data submitted by the applicant. The approved QC data may be retained in the MIDO files.

b. Evaluate the applicant's production facilities in accordance with the pertinent 14 CFR, the FAA-approved design data, and the QC data approved in paragraph 2-35a of this order. The cognizant MIDO manager will select either an individual or a team to conduct this audit. The team may consist of the cognizant PI and at least one other manufacturing inspector or the MIDO manager. It is also recommended that an engineer be selected for the team when deemed necessary by the type and complexity of processes and procedures being utilized at the facility. The standardized evaluation criteria contained in Order 8100.7 may be used as an aid to evaluate compliance. Team members should be advised, however, that some of the evaluation criteria contained therein may not be related to 14 CFR, and therefore may only be evaluated as a best practice. This audit is not considered to be an ACSEP evaluation. Record all noncompliances on Form(s) 8100-6 and 8120-14. Refer to appendixes F and G of this order.

c. Reporting. The MIDO will advise the ACO concerning the results of the MIDO audit. Any unresolved items requiring corrective action should be identified and copies of letters to the applicant requesting corrective action will be provided.

Part 3. Issuance of a TSO Authorization or Letter of TSO Design Approval

2-36. TSO Letter of Authorization. Upon a showing of compliance with part 21, subpart O, the cognizant ACO will issue a letter in accordance with established procedures. Electronic signature is not permitted. This letter should be amended, as appropriate, to reflect subsequent additions to a manufacturer's original TSO authorization, after appropriate coordination between the ACO and MIDO in determining the need for a MIDO audit.

2-37. Letter of TSO Design Approval. The cognizant ACO may issue a letter of TSO design approval for an import appliance to a foreign manufacturer located in a country with which the United States has an agreement that provides for the reciprocal acceptance of appliances, provided the following criteria are met:

a. The CAA of the country in which the appliance will be manufactured certifies to the FAA that the design of the particular appliance meets the pertinent design requirements of the specific TSO.

b. The CAA is advised that each appliance produced under the provisions of the TSO design approval and exported to the United States must be accompanied by a certificate of airworthiness for export as specified in § 21.502.

2-38. Transferability.

a. A TSO authorization is not transferable. However, a TSO authorization holder undergoing a name change is not considered a transfer. A sale of ownership resulting in a change in the legal status of the TSO authorization holder or the sale of TSO design rights is considered a transfer and will require the new owners to submit an application for exemption to retain the TSO authorization.

b. In the event a TSO authorization holder is acquired by another company, with no resulting change in the legal status of the TSO authorization holder, the acquiring company will not be required to apply for a new TSO authorization. However, the TSO authorization holder must:

(1) Retain possession of the production approval.

(2) Retain the same quality system.

(3) Continue to operate at the same location with the same core management officials.

c. The PI should conduct an on-site visit to ensure that the TSO authorization holder has complied with the requirements in paragraph 2-38b of this order. In addition, the acquiring company should provide a letter to the MIDO indicating its status as the new owner of the TSO authorization holder and any future plans affecting the status of the TSO authorization holder. The PI should update the project files to include documentation indicating the acquisition.

d. In the event the status of the TSO authorization changes (e.g., the TSO authorization holder is disbanded or absorbed into the acquiring company) or the TSO authorization holder transfers or relinquishes its production approval, the ACO will ensure a new application for TSO authorization is submitted for processing by the FAA.

2-39. Initial Risk-Based Resource Targeting Assessment. Subsequent to the issuance of the TSO authorization, the MIDO/CMO will conduct an RBRT assessment of the TSO authorization holder in accordance with chapter 3, section 2 of this order. The results will determine the initial basis for conducting ongoing CM responsibilities, as summarized in figure 3-2 of this order.

2-40. Reserved.

Section 5. Parts Manufacturer Approval (Part 21, Subpart K)

Part 1. General Information

2-41. Applicability.

a. Section 21.303 requires any person producing replacement or modification parts for sale for installation on a type-certificated product to obtain a PMA or to produce such parts in accordance with one of the exceptions in § 21.303(b).

b. A PMA may be obtained for replacement parts for TSO articles that are approved as part of a product type design, provided that installation eligibility to that product can be shown. However, approval of a part that would constitute a major design change to the TSO article cannot be done under a PMA and would require a new TSO authorization. An applicant's design that could meet the identicality provisions of § 21.303 would normally not be considered a major design change.

c. A PMA may not be issued if the manufacturing facilities for the part are located outside the United States, unless it has been determined, in accordance with § 21.303, that such location(s) would place no undue burden on the FAA.

d. Exceptions. A PMA is required except, as described below:

(1) Manufacturing inspection procedures, materials, and/or special processes, such as hardening, plating, or shot-peening are not in and of themselves eligible for PMA. However, if a person participates in controlling the design, manufacture, or quality of a part by performing such procedures or processes and does so with the intent that the part be sold for installation on a type-certificated product, that person must do so as an approved supplier to another's FAA-approved production system.

(2) A PMA cannot be issued on the basis of a "one-time-only" STC or FAA Form 337, Major Repair and Alteration, approval. The applicant would have to reapply for a new STC, which constitutes a "multiple approval," before a PMA could be considered.

(3) Other PAHs (PC, APIS, or TSO authorization) may produce replacement parts for their products or articles under their existing design and production approvals. A supplier to a PAH may not produce replacement or modification parts for sale for installation on a type-certificated product, unless the PAH authorizes major inspection and grants direct-ship authority (with FAA approval) to that supplier or that supplier has a PMA for the replacement or modification parts.

(4) An aircraft owner or operator may produce parts for installation on its own product without a PMA. The installation of those parts must comply with part 43 and other applicable airworthiness standards.

(5) An air carrier, operating under 14 CFR part 121, Operating Requirements: Domestic, Flag, and Supplemental Operations, or 14 CFR part 135, Operating Requirements: Commuter and On Demand Operations and Rules Governing Persons On Board Such Aircraft, may produce parts for installation on its own product without a PMA, provided the installation of those parts is approved in accordance with part 43 and complies with the air carrier's accepted maintenance procedures manual and instructions.

(6) An FAA-certificated repair station may produce a part for installation on a type-certificated product for current and anticipated in-house repairs or modifications. Further guidance may be found in AC 43-18, Fabrication of Aircraft Parts by Maintenance Personnel.

(7) The FAA does not require a PMA for production of standard parts produced for sale for installation on a type-certificated product. A PAH may purchase standard parts and subject them to more restrictive inspection criteria prior to approval for installation. When a question arises as to whether a part is a standard part, the certificating ACO and/or MIDO should be contacted to determine whether the design of the part meets the criteria for a standard part.

(8) In accordance with § 21.502, replacement or modification parts produced and imported to the United States under the provisions of an agreement with a foreign country do not require a PMA. The scope of the agreement must specifically include the approval and acceptance of replacement and modification parts. Acceptable replacement and modification parts may include:

(a) Parts produced under the provisions of a bilateral agreement by the foreign holder of an FAA TC issued in accordance with § 21.21 or § 21.29, an STC, or a letter of TSO design approval; or

(b) Parts produced by a foreign manufacturer and approved by their local CAA as specified in a bilateral agreement. (Depending on the scope of the bilateral agreement, such parts may include those designed as replacements for U.S. State of Design products.)

> **Note: In both of these cases, the parts are accepted for import under § 21.502, only when accompanied by an appropriate airworthiness approval for export.**

2-42. Privileges. A PMA holder has the privileges specified within the PMA letter and supplement. In addition, a PMA holder is eligible to have a qualified employee(s) designated as a DMIR in accordance with the provisions of part 183. The PMA holder may also be authorized by part 183 to apply for and obtain an ODA. Orders 8100.8 and 8100.15 contain procedures for the administration of DMIRs and ODAs, respectively.

2-43. Advising the Applicant. Approval of an application for PMA requires an approval of the design by the ACO and a production system approval by the MIDO. The applicant should be advised of the following:

a. PMA Holder's Responsibility.

(1) Reporting Failures, Malfunctions, and Defects. The PMA holder should establish a procedure to report to the FAA any failure, malfunction, or defect of a PMA part that has left its quality system. This reporting requirement applies to failures, malfunctions, or defects that may result in or have resulted in one of the occurrences listed in § 21.3(c).

(2) Maintaining FIS. The PMA holder must maintain the FIS to comply with § 21.303. The PMA holder should notify the MIDO in writing prior to any changes to the FIS that may affect the inspection, conformity, or airworthiness of the parts.

(3) Additional Part Approvals. If a PMA holder wishes to produce additional parts under the existing approved production system, an application must be made and the holder must show compliance with § 21.303(d). The MIDO will then issue a PMA supplement that adds the new parts to the original approval. If the new parts production constitutes a significant change in the operation or capabilities of the PMA holder, the MIDO will conduct a review the holder's FIS.

(4) Relationship Changes. The PMA holder may not produce parts if any change, in its relationship to the design approval holder (licensor) or otherwise, prevents it from meeting its PMA responsibilities.

b. Part Marking Requirements. Section 45.15 specifies the marking requirements for PMA parts produced for installation on TC products, STC products, and TSO articles. In accordance with § 45.15, parts produced under a PMA must be permanently and legibly marked in a manner that will enable persons to identify that it is a PMA part, the manufacturer, the part number, and the type certificated product(s) on which it may be installed. In the case of a PMA part based on an STC, the identification of installation-eligible type-certificated products must include reference to the STC on the shipping document. The same protocols should be followed in the case of a PMA part to be installed on a TSO article. The installation eligibility marking identifies the name and model of each applicable type-certificated product. Listing TSO identification information (i.e., TSO-C149, TSO-C63C, TSO-C85A, etc.) in lieu of installation eligibility information (i.e., A310-200 series, B737-300 series, etc.) does not meet the requirements of § 45.15. The issuance of the PMA letter authorizes and requires the holder to mark parts as prescribed in § 45.15.

(1) Marking Critical PMA Parts. In addition to the marking requirements of § 45.15, a PMA part with a critical characteristic(s), as described in § 45.14, must be permanently and legibly marked with a serial number. The FAA must confirm that the marking location and the associated process will not affect airworthiness.

(2) Marking Detail Parts of PMA Assemblies. PMA part markings required by § 45.15 are applied to the top-level assembly of the approved replacement or modification part. Marking subassemblies or individual detail parts is not required. For example, if the PMA were approved for a hydraulic pump, the PMA marking would be affixed to the completed assembly. It is not required that each individual subassembly or detail part within the assembly be marked with "FAA-PMA," unless it is being produced under its own PMA. If a PMA is granted for an assembly, individual detail parts of the assembly sold separately, except those produced under their own PMA, must be accompanied by a shipping document containing the information required by § 45.15(a)(1) through (3) and must identify the detail part as a subcomponent of a PMA assembly. The part marking requirements for detail parts that are sold by the original PMA holder for installation into its related PMA assemblies may be found within the applicable design data for the assembly. This provides traceability of the individual detail parts to their related PMA assemblies.

> **Note: There is no need to reissue previously issued PMA letters that require detail parts of an assembly sold separately to be marked in accordance with § 45.15.**

(3) Part Numbering. Except as provided in paragraphs 2-43b(3)(a) and 2-43b(3)(b) of this order, the applicant's part should be numbered such that it is distinguishable from the corresponding TC holder's part number. The TC holder's part number with a prefix or suffix is sufficient for this purpose, as long as use of such a prefix or suffix will not cause confusion with the part marking practices of the TC holder. The requirement of § 45.15(a)(2) (to mark with the name, trademark, or symbol of the applicant) may be satisfied by the use of a prefix or suffix, if the prefix or suffix is consistent across the applicant's product line. Each part also must be marked with "FAA-PMA" to meet the requirement of § 45.15(a)(1).

(a) Supplier Part Number. Some applicants are suppliers to PAHs. Often these PAHs use the supplier part numbers in their approved designs. When these suppliers later apply for PMA, they may continue to use their original part numbers, provided they also meet the requirements of § 45.15.

(b) Parts Manufactured Under License. When the PMA is based on the applicant showing evidence of a licensing agreement, the PMA part may have the same number as the type-certificated part, provided the applicant also meets the requirements of § 45.15.

(4) Parts Impractical to Mark. If the FAA finds the part too small or impractical (because of characteristics) to mark all (or any) of the information on the part, the information not marked on the part must appear on an attached tag or the part's container label. Often the number of type-certificated products on which the part is eligible for installation is too long to include with the part or the list is likely to change over time. In such cases, the attached tag or container label may refer to the applicant's publicly available manual or catalog for part eligibility information. Section 45.15(b) requires the PMA holder to make the manual or catalog "readily available" for part eligibility information. Providing a manual or catalog via the Internet meets the intent of "readily available." However, because access to the Internet is not universal, the PMA holder must have an alternative means of providing the manual or catalog.

(5) Supplier Marking of PMA Parts. Suppliers to PMA holders may identify parts with PMA markings provided the PMA approval holder adequately controls those suppliers as part of its quality system. Suppliers that mark parts should be treated the same as any other supplier furnishing parts or services, using supplier control procedures as part of the quality system. MIDOs may require that specific part marking controls be included in these procedures, along with any additional conditions that may be necessary for suppliers with direct-ship authorization.

(6) Identification Marking of Replacement and Modification Parts Produced Pursuant to the Enhanced Enforcement Program (EEP) as Published in Federal Register Notice of February 27, 1995. Section 45.15 states that each person who produces a replacement or modification part under a PMA issued under § 21.303 will permanently and legibly mark the part. Parts produced without a PMA, such as parts produced under the EEP, were not produced under § 21.303 and therefore are not eligible for marking in accordance with § 45.15. Although parts produced under the authority of the EEP are not eligible for part marking, these parts were considered acceptable for sale/installation under the provisions of § 21.305(d). Section 21.305(d) allows parts to be approved in any manner approved by the FAA Administrator. Parts produced under the authority of the EEP continue to be acceptable subsequent to the expiration of the EEP.

Part 2. Processing an Application for a PMA

2-44. Applicant Responsibilities.

a. Application Letter. The applicant must submit a letter of application to an ACO or MIDO, depending on the design approval basis. If the applicant is applying on the basis of an STC or identicality by licensing agreement, the application will be submitted to the MIDO having geographical responsibility for the area in which the applicant's manufacturing facility is located. Refer to figure 2-9 for a sample letter of application. If the design approval basis is other than an STC or identicality by licensing agreement, the application will be submitted to the ACO having geographical responsibility for the area in which the applicant's manufacturing facility is located. The application should include the following information:

(1) The name and address of the manufacturing facility that will be covered by the FIS of the applicant.

(2) The identity of the part for which PMA application is being made, including:

(a) The type-certificated product identified by make, model, series, and if appropriate, serial number, on which the part is to be installed.

(b) The TC holder's part number and if known, the drawing number and revision level that the PMA part would replace or modify.

(3) A statement that certifies the applicant has established a FIS in compliance with § 21.303(h).

Figure 2-9. Sample PMA Letter of Application

The ABC Tool Company
3000 Hill St.
Randolph, MA 02368
(781) 555-1212

FAA - New England Region
12 New England Executive Park
Burlington, MA 01803
(781) 238-7199

Attention: Mr. Mark Steale
Manager, Boston Manufacturing Inspection
District Office, ANE-MIDO-42

Subject: Request for New FAA-PMA Approval

Mr. Steale:

The ABC Tool Company is submitting an application for Parts Manufacturer Approval for our part number (P/N) ABC 13579. We request your review of the enclosed data being submitted in support of this application. Part number ABC 13579 is a bushing assembly eligible on PS PT9D-1, -7, -9 series engines. Approval is requested based on (STC #/Licensing Agreement #, dated) under 14 CFR § 21.303(c). Part number ABC 13579 replaces PS bushing assembly P/N 13579, drawing no. 13579, revision level C.

The part will be manufactured at ABC Tool Company, 3000 Hill Street, Randolph, MA 02368. ABC Tool Company hereby certifies that a fabrication inspection system that is in accordance with 14 CFR § 21.303(h) has been established and the above part is manufactured in accordance with that system.

Your efforts in support of this request are most appreciated.

Very truly yours,

PMA Administrator,
ABC Tool Company

Enclosures:
1 copy STC or PMA Assist Letter
1 copy Unnumbered PMA Supplement

(4) A brief description of the method by which design approval will be sought:

(a) Identicality by Showing Evidence of a Licensing Agreement. The applicant should submit an appropriate document from the TC, STC, or TSO authorization holder authorizing use of its FAA-approved data. Evidence of a licensing agreement is not a separate approval method, but merely a way to show identicality. The evidence of a licensing agreement is used by the applicant to show that the data submitted are FAA-approved and are therefore identical. For FAA purposes, the licensing agreement, in whatever form it takes, need only to authorize the applicant to use the type design data specified. The current industry practice of TC holders preparing "assist letters" for applicants to submit to the FAA sufficiently meets the requirements of showing evidence of a licensing agreement under § 21.303(c)(4). The MIDO should ensure the "PMA assist letter" includes the information specified in paragraph 2-45f(1) of this order.

(b) Identicality Without a Licensing Agreement. The applicant should submit a statement certifying that the design is identical in all respects to the design of the part covered under an approved design (e.g., TC, STC, or TSO authorization). In addition, the applicant should summarize the data that support the identicality assertion. Identicality to another PMA is unacceptable.

(c) Test and Computation. The applicant should submit a data package that includes a statement that all design, materials, processes, test specifications, system compatibility, and interchangeability are supported by an appropriate test and substantiation plan for FAA review and approval.

(d) STC. The applicant should submit a statement that references the STC number and present evidence of a written permission statement from the STC holder.

b. Unnumbered PMA Supplement. The applicant must prepare an unnumbered PMA supplement. Refer to figure 2-10 for a sample PMA supplement. Because some PMA supplements are quite long, an electronic copy on a disk or an e-mail will expedite processing.

c. Establishment of the Fabrication Inspection System. In accordance with § 21.303(h), the applicant must establish and maintain a FIS. Refer to appendix B of this order.

2-45. MIDO Responsibility. The MIDO confirms that the applicant has the capability to produce the proposed part in accordance with the approved design. The MIDO will conduct the production approval process upon receipt of the PMA supplement evidencing approval of the design by the ACO, or upon receipt of an application based on identicality by licensing agreement or STC. The production approval process includes the following:

a. Conformity Inspections. The MIDO will perform or delegate conformity inspections at the request of the ACO or other MIDOs.

Figure 2-10. Sample PMA Supplement for Licensing Agreement and STC

U.S. Department of Transportation
Federal Aviation Administration

FEDERAL AVIATION ADMINISTRATION - PARTS MANUFACTURER APPROVAL

Smith Engineering Corporation
10 Main Street
Los Angeles, CA 90012

PMA NO._____
SUPPLEMENT NO._____
DATE_____

Part Name	Part Number	Approved Replacement for Part Number	Approval Basis and Approved Design Data	Make Eligibility	Model Eligibility
Galley	SE101001-101	101001-101	Identicality per 14 CFR, § 21.303, licensing agreement between Smith Engineering Corp. and Ace Aircraft, File No. 5-1034-89-RMS 769, dated 9/12/89 DWG No: AA 25207 Rev: None Date: 3/31/88 or later FAA-approved revisions	Ace Aircraft	A-700, -710
Wing Kit	MDL 660	Modification Part	STC SA1234NM DWG No: MDL 660 Rev: None Date: 3/31/88 or later FAA-approved revisions	General Air	CP6-6, -30

----------End of Listing----------

NOTE: The procedures that have been accepted by the type certificate or TSO authorization holder and their cognizant FAA Aircraft Certification Office, for minor changes to original parts used on type-certificated products, are also acceptable for incorporating the same minor changes on identical PMA replacement parts. The PMA holder must be able to show traceability relating to the TC, STC, or TSO authorization holder on all minor changes incorporated by this procedure. When these procedures are no longer applicable because of completion of the production contract, or termination of the licensing agreement or business relationship, all subsequent minor design changes to the PMA parts must be submitted in a manner as determined by the ACO. Major design changes (reference 14 CFR §§ 21.93 and 21.97) to drawings and specifications are to be handled in the same manner as that for an original PMA.

_____
Manager, Manufacturing
Inspection District Office

b. FIS Statement. The MIDO will ensure the applicant has submitted a statement certifying that the FIS required by § 21.303(h) has been established. Data submitted as evidence of compliance with part 21, subpart K, should be evaluated in accordance with the criteria contained in FAA Order 8110.42, Parts Manufacturer Approval Procedures, and in Order 8100.7. The ACO should be involved in evaluating technical data such as design data control, software control, and material review board (MRB), etc. When the data have been found to be acceptable, an additional statement, similar to the following, must be included in the initial PMA letter: "(*Applicant name*) shall produce all parts in accordance with (*Applicant name*), Quality Manual, Revision (*manual's revision*), dated (*manual's date*) or a later FAA-accepted revision." Refer to figure 2-11, condition 13, of this order.

c. Preliminary MIDO Audit. Prior to the original issuance of a PMA, the MIDO will conduct a MIDO audit of the applicant's facility, including supplier facilities, as appropriate, to determine whether the applicant is in compliance with part 21, subpart K. The MIDO should decide whether to perform a conformity inspection (1) within 30 days of receiving the PMA supplement from the ACO or (2) prior to issuing a PMA based on an STC or identicality by licensing agreement. This determination should be made based on part criticality, the history of the applicant, part complexity, supplier control issues, etc. When applicable, the MIDO will verify the applicant's manufacturing critical processes required to achieve the approved design characteristics.

d. Principal Inspector. When deemed necessary, the PI should conduct or make arrangements for a part conformity or a MIDO audit when additional parts are approved by a supplement to the original PMA approval letter, or when the manufacturer expands or relocates its facility.

e. Design Change Issues. The MIDO should ensure the applicant has the proper authority and/or FIS processes to implement minor design changes and MRB dispositions. The MIDO should coordinate with the ACO to evaluate the FIS controls that detail the design change and MRB disposition processes.

f. PMA Assist Letter. The evidence of a licensing agreement from the TC, STC, or TSO authorization holder must include written permission for the applicant to use the design data to apply for a PMA. A "PMA assist letter" or similar evidence authorized by the TC, STC, or TSO authorization holder is sufficient for showing evidence of a licensing agreement. Refer to figure 2-12 for a sample "PMA assist letter." A licensing agreement alone is insufficient to issue a PMA. The applicant must meet all the requirements of § 21.303.

(1) The "PMA assist letter" must include the following information:

(a) Product model, name, and TC/STC number.

(b) A statement that the PMA applicant is authorized to use the design data as identified by part name and drawing number.

(c) Information describing the authority of the PMA applicant to use the TC or STC holder's part number and other part marking information, if applicable.

Figure 2-11. Sample PMA Letter

U.S. Department of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Kansas City Manufacturing Inspection District Office
250 Richards Road
Kansas City, Missouri 64116

February 12, 2005

Aero-Parts, Inc.
3212 Newton Street
St. Louis, Missouri 63044

FEDERAL AVIATION ADMINISTRATION - PARTS MANUFACTURER APPROVAL

In accordance with Title14, Code of Federal Regulations (14 CFR), part 21, Certification Procedures for Products and Parts, subpart K, the FAA has found that the design data, as submitted by Aero-Parts, Inc., (hereinafter referred to as "the Manufacturer") on September 16, 2004, meet the airworthiness requirements of 14 CFR applicable to the product(s) on which the part(s) is to be installed. Additionally, the FAA has determined that the Manufacturer has established the fabrication inspection system (FIS) required by § 21.303(h) at 3212 Newton Street, St. Louis, Missouri 63044. Accordingly, Parts Manufacturer Approval (PMA) is hereby granted to the Manufacturer to produce the replacement parts (or modification parts, as applicable) listed in the enclosed supplement(s) in conformity with the FAA-approved design data. Subsequent changes to these design data must be approved in a manner acceptable to the FAA.

The following terms and conditions apply to this approval:

1. The Manufacturer's FIS, methods, procedures, and manufacturing facilities, including suppliers, are subject to FAA surveillance and investigations. Accordingly, the Manufacturer must advise its suppliers that their facilities are also subject to FAA surveillance and investigations.

2. The Manufacturer must notify the Kansas City Manufacturing Inspection District Office (MIDO) in writing within ten working days from the date the manufacturing facilities, at which parts are manufactured, are relocated or expanded, to include additional facilities at other locations. This requirement also applies to the Manufacturer's suppliers with major inspection authorization, and those suppliers who furnish parts or related services where a determination of safety and conformance to the approved design cannot or will not be made upon receipt at the approved receiving facility.

Figure 2-11. Sample PMA Letter (Continued)

3. Upon request, the Manufacturer must make available to the FAA any pertinent information concerning their suppliers who furnish parts/services. This includes:

a. A description of the part or service;

b. Where and by whom the part or service will undergo inspection;

c. Any delegation of inspection duties;

d. Any delegation of materials review authority;

e. The name and title of the FAA contact at the supplier facility;

f. The inspection procedures required to be implemented;

g. Any direct-shipment authority;

h. Results of the Manufacturer's evaluation, audit, and/or surveillance of their suppliers;

i. The purchase/work order number (or equivalent); and

j. Any feedback relative to service difficulties originating at the Manufacturer's suppliers.

4. Parts, appliances, or manufacturing services furnished by any suppliers located in a foreign country may not be used in the production of any part or appliance listed in the enclosed supplement unless:

a. That part or service can and will be completely inspected for conformity at the Manufacturer's U.S. facility; or

b. The FAA has determined that the location of the foreign supplier facility places no undue burden on the FAA in administering applicable airworthiness requirements. The Manufacturer must advise the FAA at least ten working days in advance when the use of such foreign suppliers is contemplated. This will allow the FAA time to make this determination.

5. Parts produced under the terms of this approval must be permanently marked with the identification information as required by 14 CFR part 45, Identification and Registration Marking, § 45.15. Use the letters "FAA-PMA," the name, trademark, or symbol of the company, the part number, and the name and model designation of each type-certificated product on which the part is eligible for installation. If the part is too small or impractical to mark, the FAA must approve alternate means of identification. For a part based on an STC, the identification of installation-eligible type-certificated products must refer to the STC on the shipping document.

Figure 2-11. Sample PMA Letter (Continued)

6. This approval is not transferable and it may be withdrawn for any reason that precludes its issuance or whenever the FAA finds that the FIS is not being maintained. A withdrawal may occur if unsafe or nonconforming parts are accepted under the FIS.

7. The Kansas City MIDO must be notified within ten working days from the date that the address shown in this approval has been changed.

8. The Manufacturer must maintain its FIS in continuous compliance with the requirements of § 21.303(h). The Manufacturer also must ensure that each part conforms to the approved design data and is safe for installation on type-certificated products.

9. The Manufacturer is eligible for the appointment of qualified individuals in its employ to represent the FAA as Designated Manufacturing Inspection Representatives (DMIRs). The DMIRs may issue an export airworthiness approval for Class II and Class III products.

10. The Manufacturer must report in a timely manner, to the Kansas City MIDO, information concerning service difficulties on any part produced under this approval. The Manufacturer also must report any failures, malfunctions, and defects that are required to be reported in accordance with § 21.3.

11. All technical data required by § 21.303(c)(3), for the parts to be produced in accordance with this approval, must be readily available to the FAA at the facility where the parts are being produced.

12. The Manufacturer must notify the Kansas City MIDO immediately in writing of any changes to the FIS that may affect the inspection, conformity, or airworthiness of the parts approved in this letter.

13. **This condition should only be prescribed when the applicant voluntarily submits inspection system data/procedures as evidence of compliance with § 21.303(h).** The Manufacturer must produce all parts in accordance with Aero-Parts, Inc., Quality Assurance Manual, Revision B, dated August 7, 1997, that has been presented as evidence of compliance with § 21.303(h). Accordingly, any revisions to these data must be submitted to the Kansas City MIDO for approval prior to implementation.

G Jones

G. Jones
Manager, Kansas City Manufacturing
Inspection District Office

Enclosure:
Parts Manufacturer Approval Listing
Supplement No. 1

Figure 2-12. Sample TC, STC, or TSO Authorization Holder's PMA Assist Letter

SUPPORTING DATA
PARTS MANUFACTURER APPROVAL

Smith Engineering Corporation
10 Main Street
Los Angeles, CA 90012 FILE
NO._____

(1) Manufacturer Part Name and Part No.	(2) Approved Replacement For	(3) TC/STC/TSO Approval and Design Data	(4) Model Eligibility
Part Name: Spring P/N: SE24689	General Air P/N: 24689	TC: E9NM DWG. No: GA25206 Rev: None Date: 3/31/88	General Air CP6-6, -30
Part Name: Pin P/N: SE24695	General Air P/N: 24695	TC: E9NM DWG. No: GA25207 Rev: None Date: 3/31/88	General Air CP6-6, -30

It is hereby certified that the components listed herein are included as a part of the type design/ approved design data for General Air models as specified in the fourth column herein.

Approved:
General Air Corp.

_____
J. Doe, Manager Date
(Engineering Manager, Q. A. Manager, Corporate Officer, or FAA Liaison)

The above-named manufacturer is hereby authorized to use the approved (type design) data noted in the third column herein to manufacture replacement components noted in column 1. This certification may be used as part of the application for PMA (14 CFR § 21.303).

PAGE 1 OF 1

(d) Information on the part's eligibility for installation (product make, series, model, and if appropriate, the serial number per the type certificate data sheet).

(2) Applicants must provide sufficient data to support discretionary conformity inspections in their application letters. Holders of the TC, STC, or TSO authorization may add this information to their assist letters. These data include:

(a) The revision level of the part's drawing to baseline the design for future approved changes.

(b) A statement as to whether design changes to the part and disposition of nonconforming parts will be controlled through the TC, STC, or TSO authorization holder's quality assurance process. The statement also should describe how design change information will flow to the applicant, and consequently, to the FAA.

(c) Information that establishes the life limits or airworthiness limitations of the part.

g. Identicality Finding. Based on the review of the "PMA assist letter" that contains the information specified in paragraph 2-44a(4)(a) of this order, the MIDO will make a finding of identicality by showing evidence of a licensing agreement. The MIDO also will review the PMA supplement prepared by the applicant. Refer to figure 2-10 for a sample PMA supplement for licensing agreement and STC.

h. Life-Limited Parts. The MIDO will forward PMA applications for life-limited parts to the certificating ACO to verify completeness of design data. The MIDO should ensure the application includes a continued operational safety plan.

Part 3. Issuance of a PMA

2-46. Assignment of the PMA Number. The MIDO will assign a PMA number to all original PMA letters in accordance with the existing project assignment number procedures. The PMA number should be unique to each PMA holder and be carried forth on subsequent approved supplements for that PMA. The MIDO will sign the PMA supplements affirming production approval after completing validation of the FIS.

2-47. PMA Letter.

a. The MIDO will prepare the following PMA documents:

(1) A PMA letter for the initial issuance of the PMA. Refer to figure 2-11 for a sample PMA letter.

(2) A transmittal letter for all subsequent issuances of PMA, including all supplements. Refer to figure 2-13 for a sample transmittal letter.

b. The original(s) should be presented to the manufacturer, and the MIDO should retain one copy. The information on the PMA supplement will be forwarded to the Aircraft Engineering Division, Delegation and Airworthiness Programs Branch (AIR-140).

> **Note: At the request of the applicant, information on the PMA supplement considered proprietary (e.g., drawing revision level), may be excluded from publication on the FAA Web site.**

2-48. Initial Risk-Based Resource Targeting Assessment. Subsequent to the issuance of the PMA, the MIDO/CMO will conduct an RBRT assessment of the PMA holder in accordance with chapter 3, section 2 of this order. The results will determine the initial basis for conducting ongoing CM responsibilities, as summarized in figure 3-2 of this order.

Part 4. Post-PMA Activities

2-49. Change in Location of the Manufacturing Facility. When a manufacturer relocates or expands, including suppliers with delegated major inspection functions, the FAA may, if deemed necessary, conduct a reevaluation of the FIS at the new or expanded facilities. In accordance with § 21.303(j), the PMA holder must notify the FAA in writing within ten days (working) from the date such action takes place. This notification requirement also applies to supplier facilities where a determination as to the safety and conformance to the approved design is not made at the approved receiving facility. The PMA holder should take special care to preserve the inspection status of parts that are to be moved to the new location.

2-50. Transferability.

a. A PMA is not transferable to another person, company, or location. The regulations do not preclude revising approval letters to show a change in name only of the holder, provided there is no change in the FIS, management, ownership, or location of the principal facility. However, the design portion of a PMA based on an STC may be sold, licensed, or otherwise transferred. If the STC holder or a licensee intends to manufacture parts, it must apply for a new PMA.

b. In the event a PMA holder is acquired by another company, with no resulting change in the legal status of the PMA holder, the acquiring company will not be required to apply for a new PMA. However, the PMA holder must:

(1) Retain possession of the production approval.

(2) Retain the same FIS.

(3) Continue to operate at the same location with the same core management officials.

c. The PI should conduct an on-site visit to ensure that the PMA holder has complied with the requirements in paragraph 2-50b of this order. In addition, the acquiring company should provide a letter to the MIDO indicating its status as the new owner of the PMA holder and any future plans affecting the status of the PMA holder. The PI should update the project files to include documentation indicating the acquisition.

Figure 2-13. Sample Transmittal Letter of Subsequent PMA Supplement

U.S. Department of Transportation
Federal Aviation Administration

DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION
Kansas City Manufacturing Inspection District Office
250 Richards Road
Kansas City, Missouri 64116

February 28, 2005

Aero-Parts, Inc.
3212 Newton Street
St. Louis, Missouri 63044

FEDERAL AVIATION ADMINISTRATION - PARTS MANUFACTURER APPROVAL

In accordance with the provisions of Title 14, Code of Federal Regulations (14 CFR), Part 21, Certification Procedures for Products and Parts, subpart K, the FAA has found that the design data, based on a licensing agreement submitted by Jet Parts Engineering, Inc., with your letter dated September 10, 2004, meet the airworthiness requirements of the regulations applicable to the products on which the parts are to be installed. Additionally, the FAA has determined that Aero-Parts, Inc., has established the fabrication inspection system required by § 21.303(h) at 3212 Newton Street, St. Louis, Missouri 63044. Accordingly, Parts Manufacturer Approval (PMA) is hereby granted for production of the replacement parts listed in the enclosed Supplement No. 2.

You are reminded that the provisions of 14 CFR, Parts 21 and 45, noted in our PMA letter of approval dated September 22, 2004, also apply to the enclosed PMA Listing-Supplement No. 2. The enclosed supplement should be retained with the original PMA letter as evidence of approval to produce the parts concerned.

Sincerely,

G Jones
G. Jones
Manager, Kansas City Manufacturing
Inspection District Office

Enclosure:
PMA Listing-Supplement No. 2

d. In the event the status of the PMA changes (e.g., the PMA holder is disbanded or absorbed into the acquiring company) or the PMA holder transfers or relinquishes its production approval, the ACO or MIDO will ensure a new application for PMA is submitted for processing by the FAA.

2-51. Reuse of PMA Design Data. Although a PMA itself is not transferable, the design and substantiating data approved under a PMA may be used by another person to apply for a new PMA. The applicant must show compliance with the regulations and may submit previously approved substantiating data to meet (partially or fully) this requirement.

2-52. Changes to the FIS. Whenever a PMA applicant has submitted data as evidence of compliance with part 21, subpart K, and the MIDO has found the data acceptable, any subsequent revisions to these data should be accepted by the PI prior to implementation. Revisions that affect the design (e.g., MRB, design data control, service difficulty reporting) should be coordinated with the ACO. The MIDO should notify the PMA holder in writing as to the acceptability of the data submitted. Refer to the sample letter in figure 3-6.

2-53. Export Considerations. Many countries have additional requirements regarding their acceptance of PMA parts. In particular, the European Union Member States require special statements on FAA Form 8130-3, Airworthiness Approval Tag, regarding whether a part is critical or non-critical. For more information see FAA Order 8130.21, Procedures for Completion and Use of the Authorized Release Certificate, FAA Form 8130-3, Airworthiness Approval Tag.

2-54. Reserved.

Section 6. Extension of a Production Approval Within the United States

Part 1. General Information

2-55. Applicability. The procedures in this section are applicable to a PAH who desires to extend its production approval to another facility, referred to herein as an associate facility. An APIS holder may extend its production approval to an associate facility after the FAA has determined, by a MIDO evaluation, that such extension would place no undue burden upon the FAA.

2-56. Privileges. An associate facility has the same privileges as the original PAH, unless the original PAH or the FAA withholds specific privileges. If authorized by the original PAH, the associate facility can request from its MIDO/CMO the appointment of DMIRs. In addition, if authorized by the original PAH, the associate facility may apply for and obtain an ODA. Orders 8100.8 and 8100.15 contain procedures for the administration of DMIRs and ODAs, respectively.

2-57. Advising the Original PAH and the Associate Facility.

a. A PAH can request the FAA to extend its production approval to an associate facility. To be approved, the associate facility must:

(1) Be located within the United States.

(2) Be owned and controlled by the original PAH that controls the design and quality of the product or part(s), except for companies participating in joint-production and/or co-production business agreements.

(3) Use a quality control or inspection system that has been approved by the original PAH.

(4) For a PMA or TSO authorization holder, produce the same part and to the same extent as the original PAH.

b. When the associate facility produces the complete product or part(s) and meets 14 CFR eligibility requirements for the type of production approval, it should be encouraged to obtain a separate production approval. The PAH would benefit from a separate approval because the FAA offices would not need to coordinate production approval extensions.

c. All FAA correspondence intended for the original PAH will be from or routed through the MIDO/CMO that has CM of the original PAH.

d. Original PAH's Responsibilities.

(1) Implement its quality system or fabrication inspection system (FIS) at the associate facility or approve the quality system or FIS used by the associate facility.

(2) If the approval or acceptance of changes is retained by the original PAH, the associate facility should be required to submit all proposed changes to the originally approved FIS or QC manual to the PAH for acceptance or approval.

e. Associate Facility's Responsibilities.

(1) Communication with the FAA will be with the MIDO having geographical responsibility of the area in which the associate facility is located.

(2) The associate facility will comply with the quality system or FIS of the original PAH or the quality system or FIS approved by the original PAH.

(3) If the approval of changes to the QC or FIS manual is retained by the original PAH, the associate facility will submit proposed changes to the original PAH for approval.

(4) If the approval of changes to the QC or FIS data is delegated to the associate facility, the associate facility should submit changes to its geographic MIDO.

Part 2. Processing a Request for Extension of a Production Approval

2-58. Request for Extension of a Production Approval. The original PAH can request an extension of its production approval to an associate facility. The extension application will be submitted to the original PAH's MIDO/CMO. The request must contain the following information:

a. The location of the associate facility.

b. The type and extent of activities to be performed at the associate facility.

c. Any special conditions of the request, such as the delegation or withholding of delegation of MRB authority or designee privileges.

d. A point of contact at the associate facility.

2-59. Evaluating the Request. The MIDO/CMO of the original PAH will evaluate the request for extension and determine if:

a. The location of the associate facility is adequately described.

b. The PAH's quality system or FIS is adequate to control the design and quality of the products and parts produced at the associate facility, or the original PAH has reviewed and approved the associate facility's quality system or FIS.

c. The request states explicitly the type and extent of production to be accomplished at the associate facility.

d. Any special conditions of the extension apply (e.g., delegation or nondelegations of MRB authority).

2-60. Coordination with the Geographic MIDO. Following the evaluation of the request from the original PAH, the MIDO/CMO will contact the MIDO having geographical responsibility of the area in which the associate facility is located. The MIDO/CMO will:

a. Submit a hand-off memorandum to the geographic MIDO informing it of the request, a copy of the extension request, and the evaluation results. Refer to figure 2-14 for a sample memorandum.

b. Request the geographic MIDO to perform a MIDO audit.

c. At a minimum, arrange for the following to be addressed:

(1) Reporting of MIDO audit findings.

(2) Reviewing changes to QC or FIS manual.

(3) Compliance and enforcement actions.

(4) Submittal of correspondence.

Part 3. Approval of the Request for Extension of a Production Approval

2-61. Approval of the Request. After satisfactory completion of the MIDO audit and any applicable corrective actions taken, the MIDO/CMO will approve the request. The MIDO/CMO will ensure the original PAH provides the MIDO of the associate facility a copy of the QC or FIS data to be used if not available at the associate facility. The MIDO/CMO will issue to the original PAH an amended PC, an amended PMA approval letter, or an amended APIS approval letter. For a TSO authorization holder, the MIDO will request that the ACO issue a revised TSO authorization letter. The amended production approval authorization letter will list the associate facility as a manufacturing location. A copy of the amended production approval authorization letter will be sent to the MIDO of the associate facility.

2-62. Geographic MIDO Responsibility After Approval of the Request for Extension. The geographic MIDO/CMO will perform CM at the associate facility in accordance with chapter 3 of this order.

Section 7. Non-U.S. Manufacturing Facilities—Determination of Undue Burden and No Undue Burden

2-63. Undue Burden and No Undue Burden. The Administrator does not issue type certificates or production approvals if the manufacturing facilities are located outside the United States, unless the Administrator finds that the location of the manufacturer's facilities places no undue burden on the FAA.

a. When an initial production approval application involving non-U.S. manufacturing facilities is reviewed by the FAA, an "undue burden or no undue burden" decision must be made and the FAA is required to prepare a decision paper in accordance with FAA Order 8100.11, Developing Undue Burden and No Undue Burden Decision Papers Under 14 CFR Part 21.

b. If a new or existing PAH proposes to use non-U.S. suppliers, the criteria for supplier selection in this order must be applied to determine whether the supplier would likely be selected for a supplier control audit. If the supplier would not be selected, there is no burden. If the supplier could be selected, the FAA is required to prepare a decision paper in accordance with Order 8100.11.

c. Any subsequent changes to an approval holder's manufacturing programs involving non-U.S. facilities will cause the initial undue burden or no undue burden decision to be reevaluated by the FAA.

d. Order 8100.11 provides general instructions on what to consider during decision paper development. It also contains the general content requirements of decision papers that include a specific list of required decision paper elements.

2-64. Reserved.

Figure 2-14. Sample Hand-Off Memo for Requesting a MIDO Audit and CM

Federal Aviation Administration

Memorandum

Date: December 18, 2007

To: Manager, Fort Worth Manufacturing Inspection District Office, SW-MIDO-42

From: Duke E. Season, Manager, Cleveland Manufacturing Inspection District Office, CE47

Prepared by: Amanda Dickens

Subject: **ACTION:** Request for MIDO Audit and Certificate Management at ABC Company

This office has received a letter from Airplane Aircraft Company, dated December 6, 2007 (attached), requesting an extension of its production approval to the ABC Company.

In accordance with FAA Order 8120.2F, paragraph 2-59, we have evaluated Airplane Aircraft Company's request for extension and concur with its request. Since ABC Company is located in your geographic area, we are requesting your office conduct a MIDO audit at ABC Company, utilizing the following information:

Facility Name/Address:
ABC Company
2500 West Canyon Road
Fort Worth, TX, USA 91355

Point of Contact for ABC Company:
Mr. Jim Blender, Director of Quality Assurance
Phone: (817) 555-1222

Point of Contact for Airplane Aircraft Company:
Mr. Scott Clemons, Airplane Aircraft QA Director
Phone: (216) 333-1212

Q.C. Procedures Applicable to this Associate Facility:
Airplane Aircraft Company's Quality Manual, Revision C

Part Name and/or Part Number: Flight Deck LRU's, Warning Electronics, Cabin Entertainment LRU's Black Box Avionics

Figure 2-14. Sample Hand-Off Memo for Requesting a MIDO Audit and CM (Continued)

MRB Delegation/Authorization: Yes

Design Approval and/or Change Authorization: Yes

DER Authorization: Yes

Direct Ship Authorization: Yes

DMIR Authorization: Yes

We request the following activities be conducted by your office:

Pre-Approval

A. MIDO Audit
- ☒ Respond to Requesting MIDO Acknowledging Receipt of Request
- ☒ Review and Evaluate the Capability of Associate Facility Utilizing ACSEP Criteria
- ☒ Verify Supplier Approval Process
- ☒ Review and Report Any Compliance and Enforcement Actions
- ☒ Record and Report the Results of the MIDO Audit to the Requesting MIDO

Post-Approval

A. Certificate Management
- ☒ Establish Project Number
- ☒ Special Evaluation when requested
- ☒ Risk Management Assessment
- ☒ Corrective Action Follow-Up
- ☐ ACSEP Evaluations
- ☒ PI Evaluation (Including Any Quality Processes and Special Manufacturing Processes to Approved PAH Requirements)
- ☒ Review and Evaluate Changes to Quality Manual
- ☒ Product Audits
- ☐ Supplier Control Audits

B. Designee Management (Order 8100.8)
- ☐ Monitor Activity
- ☐ Perform Annual Review
- ☐ Maintain Designee File
- ☐ Conduct Supervision and Complete Form 8130-14
- ☐ Delegate DMIR(s) to Perform Authorized Functions

C. ☐ Other/Remarks

Figure 2-14. Sample Hand-Off Memo for Requesting a MIDO Audit and CM (Continued)

Document Certificate Management Activity in CMIS

After your satisfactory completion of the MIDO audit, this office will notify Airplane Aircraft Company that its request to add ABC Company as an associate facility has been approved. In addition, we will amend or have its production approval(s) (i.e., PC, PMA, or TSO authorization) amended to reflect the addition of this associate facility. A copy will be forwarded to your office.

After the extension is granted and you receive a copy of the amended production approval, we request that your office conduct certificate management activities in accordance with chapter 3 of Order 8120.2F. Please coordinate your certificate management visits with this office, so that we can provide you with applicable information/data needed for corrective action follow-up, special evaluations, etc. We would also like to have copies of all noncompliances, service difficulties, concerns, or items of interest identified during the conduct of certificate management activities.

Attachment
Letter from Airplane Aircraft Company

Chapter 3. Certificate Management Procedures

Section 1. Introduction

3-1. Chapter Information and Format. 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, 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 3-1 of this chapter depicts the CM life cycle process.

a. Ongoing CM Responsibilities. The MIDO/CMO responsible for a specific PAH or associate facility within its geographical boundaries accomplishes the following tasks on a continuing basis. Any tasks required to be scheduled and conducted at a supplier facility located in another U.S. geographical area should be handled in accordance with paragraph 3-26 of this order. For tasks required to be scheduled and conducted outside the United States, refer also to paragraph 3-7 of this chapter.

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

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

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

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

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 3-26 of this order.

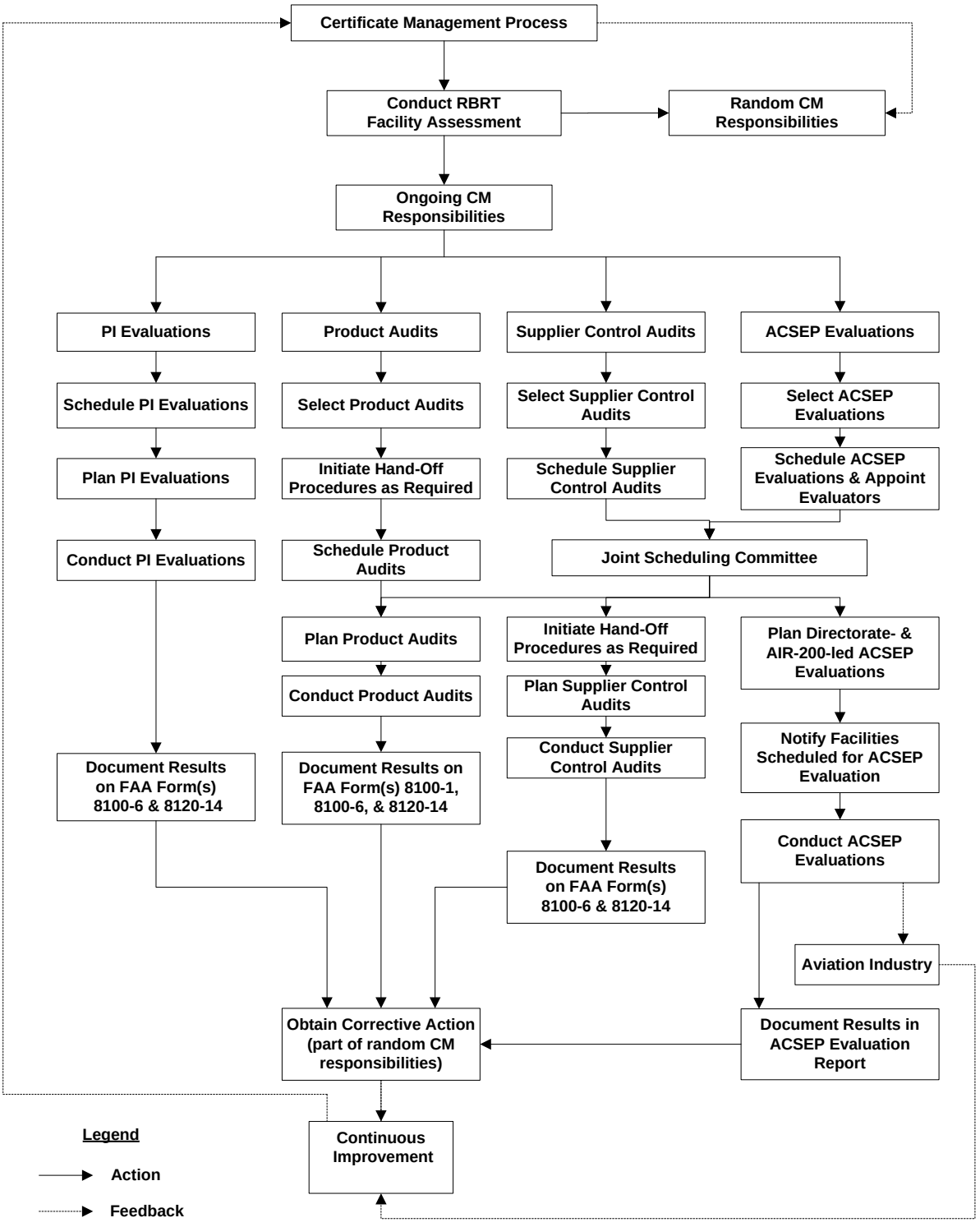
(1) Evaluate changes to a PAH's or associate facility's quality control or inspection system that may affect the inspection, conformity, or airworthiness of the product or part(s).

(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.

Figure 3-1. Certificate Management Life Cycle Process



(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.

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

3-2. 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.

3-3. 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.

3-4. Reserved.

Section 2. Ongoing CM Responsibilities

Part 1. Introduction

3-5. CM Tasks. Parts 2 through 6 of this section provide detailed guidance for accomplishing ongoing CM responsibilities. Figure 3-2 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. Additional CM tasks may be performed at the discretion of the managing office.

Figure 3-2. Certificate Management Responsibilities (Ongoing) Minimum Requirements

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

General Note: Functions associated with shaded blocks are optional based on justified need (e.g., evaluation results, history, investigation, or service difficulties).
Note 1: 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.
Note 2: For PAHs having a screened supplier listing > 50 ≤ 100, conduct 6 supplier control audits annually. For PAHs having a screened supplier listing > 100, conduct 9 supplier control audits annually.

3-6. Certificate Management Plan. A CM plan assists the PI in planning and tracking the performance of ongoing CM responsibilities. Within a timeframe established by the MIO, each MIDO/CMO may prepare a CM plan annually for each PAH and associate facility after RBRT assessments have been completed. The MIDO/CMO may subsequently amend the CM plan as necessary to include additional or reduced requirements and schedule changes. As a minimum, the CM plan should include the following:

a. Name of PAH or associate facility.

b. Current RBRT risk level.

c. Schedules for PI 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.

> **Note: The scheduling function in CMIS is intended to provide a starting point in the development of the CM plan. Should an inconsistency develop between the CMIS-generated number, frequencies, or scheduled dates of CM activities and the requirements in figure 3-2 of this order, figure 3-2 shall take precedence.**

3-7. Coordination of Requests for Supplier Surveillance Assistance with Other CAAs. When a supplier to a U.S. PAH is located in a country or jurisdiction having an applicable bilateral agreement with the United States, the FAA may seek supplier surveillance assistance from the bilateral CAA. Such assistance requests may take various forms at the PAH's supplier (e.g., ongoing surveillance, supplier control audits, product audits, etc.), and may or may not be agreed to by the CAA, depending upon its availability of resources, common production approval facilities, etc. Requests for supplier surveillance assistance should be transmitted from the MIO manager of the directorate in which the PAH is located to a counterpart CAA production contact. If the CAA agrees to the request and the assistance is recurring, a management plan must be formulated between the FAA and the supporting CAA. The management plan must outline the details of the type of support requested, the methodology by which it will be performed (this is usually the normal surveillance system, procedures, and documentation of the local CAA), the frequency of the surveillance activity, documentation expectations, etc.

a. AIR-200 has established management plans with certain European CAAs that permit those CAAs to conduct supplier surveillance activity on the FAA's behalf, in accordance with FAA Order 8120.13, International Cooperative Supplier Surveillance Program Procedures. The management plans with the current International Cooperative Supplier Surveillance Program (ICSSP) participants may be found at the AIR Work Tools page on the FAA Employees' Web site. Supplier surveillance activity conducted outside the United States will be handled in accordance with Order 8120.13 when the local authority is a program participant.

b. If the FAA must conduct the supplier surveillance activity itself in another country or jurisdiction, for whatever reason(s), the PI will perform the following activities:

(1) Notify the responsible CAA and invite CAA participation as an observer through a formal letter signed by the directorate MIO manager, or delegated signatory. The letter should be addressed to the Production contact for the CAA. A list of CAAs and respective contacts is available from the International Policy Office, AIR-40. Send an electronic facsimile (FAX) of the letter 45 days prior to the audit, followed by mailing the formal letter. Notify the CAA of any changes in the audit's schedule. The CAA's participation in the audit is not mandatory, and the choice to provide an observer is at its discretion. The letter should include the following information, as a minimum:

(a) Identity of the facility to be audited.

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

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

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

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

(2) Provide the PAH's certificate managing office with details of any noncompliance encountered during the surveillance activity. For example, if there is a trend showing recurring test failures or nonconforming articles, it may be evidence of a system breakdown or a compliance problem at that facility. The PAH's certificate managing office will determine if there are any system issues or major problems that should be forwarded to the applicable CAA for its consideration because the PAH's supplier may coincidentally hold a local production approval.

3-8. 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 the guidelines listed in appendix F 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 FAA Order 1270.1, Freedom of Information Act Program.

3-9. Reserved.

Part 2. Risk-Based Resource Targeting

3-10. Risk-Based Resource Targeting Assessment Tool. In the interest of safety and effective resource allocation, a risk-based assessment tool has been developed to identify facilities according to their potential for producing nonconforming products or parts. The FAA will assess annually each facility subject to an RBRT assessment. As a result, the RBRT assessment tool assigns each facility a risk level according to the potential for producing nonconforming products or parts. Each directorate will use the RBRT assessment tool and its application procedures to provide a rational and justifiable basis for effective deployment of FAA resources for ongoing CM responsibilities.

3-11. Scope. Holders of an APIS, PC, PMA, and/or TSO authorization and their associate facilities are subject to an RBRT assessment. Suppliers, delegated facilities, holders of a letter of TSO design approval, and PAHs in an inactive status are not subject to an RBRT assessment.

3-12. Risk-Based Resource Targeting Risk Levels. The RBRT assessment of each applicable facility is based on organizational and technical indicators that demonstrate a facility's potential for producing nonconforming products or parts. See appendix C of this order. The RBRT assessment results in assigning a facility one of the following risk levels:

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

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

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

3-13. Risk-Based Resource Targeting Assessment of Facilities. The FAA will assess facilities annually, using the RBRT assessment tool.

a. The assessment of facilities will be completed annually, no later than April 30.

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

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

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

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

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

3-14. Modification of Risk-Based Resource Targeting Assessment. Circumstances may arise following the annual identification of RBRT risk levels that may challenge the assigned risk level for a specific facility. When any of the following conditions occur at a facility after a risk level has been assigned, the PI should complete a new RBRT assessment in accordance with the instructions provided in CMIS. Refer to appendix C for assistance in determining the significance of the following conditions:

a. Changes in unit criticality.

b. Significant quality or inspection system changes.

c. Significant change in key management.

d. Significant turnover of critical staff.

e. Significant increase or reduction in workforce.

f. Deliberate non-responsiveness to corrective action requests.

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

h. Addition of a complex manufacturing process.

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

j. Significant change in the use of suppliers/outsourcing.

k. Significant increase in the use of foreign suppliers.

l. Movement or shift of production location or volume.

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

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

3-15. Risk-Based Resource Targeting Assessment Validation Plan. For CM purposes, the objective of RBRT is to effectively deploy FAA resources to those facilities that have the greatest potential to produce nonconforming products or parts. The FAA has planned several validation tasks to ensure that this objective remains viable. Appendix E describes the details of the validation plan.

3-16. Modification of Risk-Based Resource Targeting Assessment Tool. The RBRT assessment tool is comprised of several quantitative factors that result in the identification of facilities according to their potential to produce nonconforming products or parts. The RBRT assessment validation plan periodically reviews many of these factors. Any proposed modifications to the RBRT assessment tool as a result of validation, or other source (i.e., changes to indicator assessment criteria, indicator point weights, factor level rating scales, and RBRT risk level assignment decision rules), require formal Aircraft Certification Management Team approval. AIR-200 will coordinate the implementation of any changes to the RBRT assessment tool, including development and dissemination of revised program guidance, updated CMIS programming, and revised RBRT assessment training materials.

3-17. Reserved.

Part 3. Supplier Control

Subpart A. Determining Supplier Control by a PAH or Associate Facility

3-18. General PAH Supplier Control Responsibilities. 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) 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.

3-19. 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 subpart B of this part. 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.

3-20. 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 will prepare Form 8100-6 and retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. The PI will request corrective action for a system breakdown in accordance with section 3, part 5, of this chapter.

3-21. Reserved.

Subpart B. Supplier Control Audit

3-22. Scheduling. A supplier control audit is conducted as part of the CM of the PAH or associate facility, that evaluates the system established to control the 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 3-26 of this order. A supplier control audit is applicable to suppliers of a PAH or associate facility as determined by the selection process identified in paragraph 3-23 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 in accordance with the results of the latest RBRT assessment as follows:

Note: The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. Refer also to figure 3-2 of this order. A MIDO/CMO may schedule additional supplier control audits at specific facilities when required to ensure continued operational safety.

a. High Risk Facility. For PAHs having a screened supplier listing, as described in paragraphs 3-23e and 3-23f of this order, of:

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

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

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

b. Medium Risk Facility.

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

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

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

3-23. Supplier Selection. Selection of suppliers subject to supplier control audits will be performed as follows:

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

a. After completing the RBRT assessment, each PI will identify the number of supplier control audits to be performed by using the guidance described in paragraphs 3-22a through 3-22c 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 High Risk facility and has 40 suppliers on its supplier control listing. The minimum number of supplier control audits for a High Risk facility with 40 suppliers is three. Using the random number generator method, the PI selects the first three numbers from the generated list of 40 random numbers, which for the purpose of this example would be 5, 8, and 24. The PI will then count down the supplier listing and choose the 5^{th}, 8^{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 3-23e of this order to all suppliers on the PAH's supplier listing, thereby compiling a screened list of suppliers suitable for a supplier control audit. The PI will then randomly select the required number of suppliers from the screened list in accordance with the procedures described in paragraphs 3-23c and 3-23d 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.

3-24. 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 3-23 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 3-24b 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.

3-25. 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 3-22 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.

3-26. Domestic Hand-Off Procedures. After receipt of the finalized Directorate Supplier Control Audit List referenced in paragraphs 3-24 to 3-25 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) 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 3-27 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.

Figure 3-3. 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

3-27. 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 3-26b of this order, the office receiving the request will send the notification letter to the PAH or associate facility and provide a copy to the requesting office. Figure 3-3 contains a sample notification letter.

3-28. 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.**

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 G of this order. Document noncompliances on Form 8100-6. Refer to appendix F of this order.

3-29. Reserved.

Part 4. Principal Inspector Evaluation

3-30. Scheduling. 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 in accordance with the results of the latest RBRT assessment. Refer also to figure 3-2 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 c 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. High Risk Facility.

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

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

b. Medium Risk Facility.

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

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

c. Low Risk Facility.

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

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

3-31. 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 G of this order. Document noncompliances on Form 8100-6. Refer to appendix F of this order.

3-32. Reserved.

Part 5. Aircraft Certification Systems Evaluation Program Evaluation

3-33. Scheduling. 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 in accordance with the results of the latest RBRT assessment. Refer also to figure 3-2 of this order. The ACSEP evaluation will be scheduled as follows:

> **Note: The scheduling requirements listed in paragraphs a through c 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. High Risk Facility. An ACSEP evaluation will be conducted at each High Risk facility at least once every 24 months.

b. Medium Risk Facility. An ACSEP evaluation will be conducted at each Medium Risk facility at least once every 32 to 48 months.

c. Low Risk Facility. An ACSEP evaluation is not required.

3-34. Reserved.

Part 6. Product Audit

3-35. Scheduling. 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) 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 3-26 of this order. A product audit will be scheduled in accordance with the results of the latest RBRT assessment as follows:

> **Note: The scheduling requirements listed in paragraphs a through c below are considered to be the minimum requirements. See also figure 3-2 of this order. A MIDO/CMO may schedule additional product audits at specific facilities when required to ensure continued operational safety.**

a. High Risk Facility. A product audit will be conducted in conjunction with PI evaluations at each High Risk facility at least twice every 12 months.

b. Medium Risk Facility. A product audit will be conducted during every scheduled ACSEP evaluation at each Medium Risk facility.

c. Low Risk Facility. A product audit is not required.

3-36. 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) and could cause failure or create an unsafe condition. The selection of the critical characteristics and/or critical process attributes is determined by reviewing the following (this review does not need to be documented):

(1) Known service problem areas.

(2) Characteristics/attributes that are operator controlled.

(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.

(4) Service Difficulty Reports (SDRs). Information related to SDRs can be found on the FAA Flight Standards Service Aviation Information Web site, located at http://av-info.faa.gov/sdrx/.

b. In addition to critical characteristics and/or critical processing attributes, the PI may select certain non-critical characteristics and/or non-critical processing attributes, such as radiuses, surface finishes, machine to cast features, cad plating, NDI, etc.

3-37. 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.

3-38. Product Audit Criteria. The audit criteria used in the performance of a product audit to establish conformity to approved type design are listed below. This audit criteria is a minimum and not all-inclusive. Figure 3-4 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 3-4. Applicability of Product Audit Criteria to Product Audit Areas (Minimum)

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

3-39. 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.

3-40. 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 G 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 section 3, part 5 of this chapter.

3-41. Reserved.

Section 3. Random CM Responsibilities

Part 1. Introduction

3-42. Section Information. 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.

3-43. Reserved.

Part 2. Evaluation of Changes to a PAH's or Associate Facility's Quality or Inspection System

3-44. General MIDO/CMO Responsibilities. 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). Refer to appendix A, 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.**

3-45. Prioritization of Review. Review of a facility's changes to its quality control or inspection system should be prioritized according to its RBRT risk level. For example, the changes at a facility rated as High Risk will be reviewed prior to the changes for a facility rated as Medium Risk. Reviews of changes from facilities rated the same RBRT risk level will be prioritized by date of notification or receipt of applicable data.

3-46. 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 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 3-46a and 3-46b of this order may often be verified through data review alone. In some instances, however, on-site inspection or review may be required.**

3-47. 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 3-5.

(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 3-6.

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

3-48. Reserved.

Part 3. Investigation of Service Difficulties

3-49. General Service Difficulties Information. 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, 125.409, and 135.415).

Figure 3-5. 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 3-6. 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]

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

(4) Repair station reports of unairworthy conditions.

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

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

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

b. MIDO/CMO and ACO Investigation. Upon receipt of a service difficulty report, the MIDO/CMO having CM over the manufacturer of the identified product or part(s) 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.

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

3-50. 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.

3-51. 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 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.

3-52. Reporting a Service Difficulty Investigation.

a. Service Difficulty Investigation Report. The MIDO/CMO will prepare and process a report of service difficulty investigation in accordance with this order, Order 2150.3, and Order 8010.2. The report may be in the form of a memorandum or any other acceptable manner and will include as a minimum, the following information:

(1) Name and address of manufacturer.

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

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

(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 MIDO and/or taken by the manufacturer including a copy of the MIDO letter to the manufacturer and the manufacturer's reply.

(7) Effect on products in service.

(8) Recommendations and/or further actions required.

b. Interim Report. In the event that the investigation is delayed for any reason, and if requested by the MIO, the MIDO/CMO will prepare an interim report of service difficulty investigation outlining the progress of the investigation.

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) and ODA Reports. Upon notification by the FAA, DOA and ODA holders are required by § 21.277 and § 183.63, respectively, 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.

3-53. 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.

3-54. Reserved.

Part 4. Investigation of Regulatory Violations

3-55. 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 F, 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.

3-56. 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.

3-57. 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.

3-58. Timeliness. To ensure that enforcement actions have the maximum effect as a compliance tool, Order 2150.3 establishes a 75-day goal for FAA investigative personnel in field offices to complete an investigation and the associated enforcement investigation reports. Regional program office personnel should complete their review of an enforcement investigation report within 15 days.

3-59. 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.

3-60. 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.

3-61. Reserved.

Part 5. Corrective Action

3-62. General Corrective Action Information. 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.

3-63. Corrective Action Procedures. As indicated in paragraph 3-8 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 a SUP, as described in FAA Order 8120.16, Processing Reports of Suspected Unapproved Parts, the PI must report the SUP in accordance with Order 8120.16.**

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. When a determination is made in accordance with appendix F of this order, subsequent to the finalization of an audit or evaluation, that the type of noncompliance recorded on Form 8100-6 is incorrect and should be changed, the PI will:

(1) Prepare a memorandum providing justification for changing the type of noncompliance.

(2) Obtain written concurrence (signature) on the memorandum from their manager.

(3) Inform the ACSEP team leader or principal evaluator of the change, if applicable.

(4) Complete a revised Form 8100-6, corresponding to the changed type of noncompliance.

(5) Retain the original Form 8100-6, the signed justification memorandum, the revised Form 8100-6, and any applicable objective evidence, in the office project folder.

d. Request corrective action as follows (refer to figure 3-7 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.

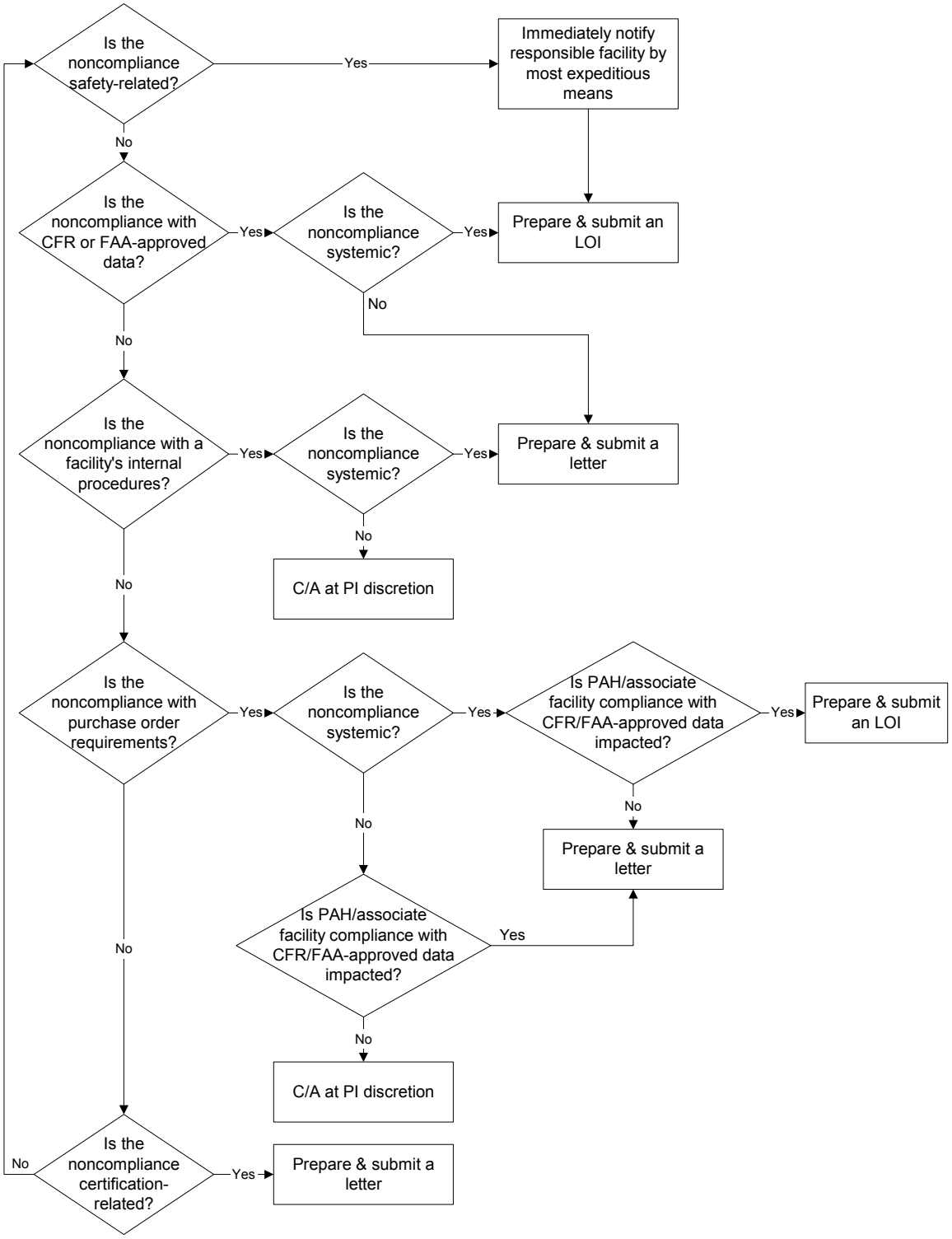
(3) Systemic Noncompliance with Facility's Internal Procedures. Prepare and forward a letter to the responsible facility requesting immediate corrective action.

(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.

Figure 3-7. Corrective Action Flowchart



(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 3-20 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 8120.16. 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.

3-64. 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) 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.**

3-65. 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 3-26c 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 3-26c(1) of this order as applicable. Document results of completed corrective action validations in the facility's Enforcement Investigation Report file.

3-66. Reserved.

Part 6. Unscheduled Audits, Evaluations, or Investigations

3-67. General Unscheduled Audit and Evaluation Information. 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.

3-68. 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 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 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.

3-69. Other Random Investigations. SUP reports will be investigated in accordance with Order 8120.16. 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.

3-70. Reserved.

Part 7. Providing Guidance to a PAH or Associate Facility

3-71. Guidance. The PI should provide guidance to a PAH or associate facility as necessary for the manufacturing of products or parts 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.

Appendix A. Evaluation of a PAH'S Quality or Inspection System

1. Purpose. This appendix, in conjunction with the applicable 14 CFR requirements, provides guidance to thoroughly review all data submitted by a PAH that describe the quality control or inspection system required for the applicable production approval. These data may include a quality manual, procedures, policies, standards, instructions, and/or processes. Any inadequacies in the data submitted must be identified to the PAH for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO/CMO will approve or accept the data, as applicable.

2. Data Review. All quality control or inspection system data submitted to the cognizant MIDO/CMO must be reviewed to ensure that:

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

b. The quality control or inspection system is adequately described, meets the intent of the pertinent rules, and can be realistically implemented. Be wary of data that are overly descriptive, since such data may often be difficult to implement.

c. The data are identified by title, revision, and date, and contain the signature of the appropriately authorized person in the PAH's organization.

d. The data are well organized, unambiguous, and not subject to misinterpretation.

e. Inspection procedures are well organized and easy to understand and implement.

f. The quality control or inspection system adequately defines when a product or part(s) has officially left the control of the quality or inspection system.

g. The quality control or inspection system adequately describes the process of re-introducing, back into the quality control or inspection system, new products or parts that have left a PAH's quality system. The process must ensure the following criteria are met:

(1) The products or parts are traceable to the PAH that manufactured them.

(2) The products or parts meet the type design and are in a condition for safe operation.

Note: Depending on their complexity, a visual inspection may be adequate for determining that the products or parts meet their type design. When a determination cannot be made by a visual inspection, the products or parts must be re-introduced to the quality control or inspection system at a point where functional testing is possible.

h. New products and parts that leave the control of a PAH and fail on initial installation and/or testing are considered to be nonconforming. Those nonconforming products and parts that are returned to the PAH must be processed utilizing the PAH's quality control or inspection system.

i. Statistical sampling plans are clearly documented. The ASI must ensure that sampling plans based on valid consensus standards do in fact comply with those standards (e.g., MIL-HDBK-683, Statistical Process Control (SPC) Implementation and Evaluation Aid; MIL-HDBK-1916, Companion Document to MIL-STD-1916; "Zero Acceptance Number Sampling Plans," by Nicholas Squeglia, ASQ Quality Press). Sampling plans that are not based on valid consensus standards should be closely examined to determine their statistical validity (Juran & Gryna, *Quality Control Handbook*, may be used as an aid in determining this validity). Regardless of the basis of the sampling plans utilized, the PAH is responsible to ensure that all products or parts conform to the approved design data. Therefore, the ASI should ensure that the acceptance/rejection criteria will not allow for acceptance of nonconforming product or parts. If specific experience or expertise is required to review sampling plans, the PI should advise the MIDO/CMO manager. Additional information is available on the FAA Web site via the Statistical Quality Control (SQC) Best Practice. The following should be considered when reviewing sampling plans:

(1) Controlled process. Prior to implementing a sampling plan, objective evidence must exist that demonstrates and ensures that the process(es) used to manufacture sampled characteristics are documented, controlled, repeatable, and consistent.

(2) Characteristics classified. Each characteristic that will be part of the sample plan must be identified, evaluated, and properly classified. Characteristics are classified based upon the effect they may have on safety or usability of the product.

(3) Proper and reasonable sample sizes. Specific sample sizes should be chosen based upon the lot/batch size, the characteristic classification and criticality, the design tolerances being measured, and the probability of accepting nonconforming products or parts.

(4) Unbiased sample selection. The plan should fully describe how samples are selected. The sample method must be unbiased; that is, the sample selection method does not unfairly weight a particular timeframe, production sequence, tooling configuration, operator(s), batch, etc. To ensure an unbiased representative sample, the lot, batch, or group should be homogeneous (i.e., consisting of the same characteristics, type, grade, class, composition, and manufactured under the same data and conditions, and manufactured at approximately the same time).

(5) Samples are controlled. When sampling is used, the results of the selected sample apply to the entire lot, batch, or grouping. The lot, batch, or group should be clearly identified and segregated throughout the entire sampling, inspection , and possible disposition process. In the event that any characteristics are found to be nonconforming in the sample, the entire lot, batch, or grouping must be withheld pending additional analysis, ensuring that there are no other nonconforming parts. Should this analysis indicate the possible existence of additional nonconforming parts, the entire lot, batch or grouping must be dispositioned in accordance with the PAH's approved material review procedures. In all cases, the PAH is responsible to ensure that all products and parts conform to the approved design data.

3. Data Approval/Acceptance Standards.

a. PC or TSO Authorization Holder. The cognizant MIDO/CMO will determine the adequacy of the data reviewed in accordance with paragraph 2 of this appendix. Any inadequacies in the data submitted must be identified to the PAH for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO/CMO will prepare a letter approving the PAH's quality control data and forward it to the PAH. The cognizant MIDO/CMO also should send a copy of the approval letter to the cognizant ACO. These data, 14 CFR, and the FAA-approved design data comprise the standards with which the PAH must show continued compliance.

b. APIS or PMA Holder. The cognizant MIDO will determine the adequacy of the data reviewed in accordance with paragraph 2 of this appendix. Any inadequacies in the data submitted must be identified to the PAH for corrective action. After the data have been reviewed, and any applicable corrective actions taken, the MIDO will accept the inspection system data submitted by the APIS or PMA holder. The FAA does not approve these data since there is no part 21 requirement for submittal of these data for approval. These data, 14 CFR, and the FAA-approved design data comprise the standards that will be used when performing CM activities at the APIS or PMA holder.

Appendix B. Fabrication Inspection System

1. Establishment of the Fabrication Inspection System (FIS). In accordance with § 21.303(h), the applicant must establish and maintain an FIS. The description of the FIS may be in any form acceptable to the FAA. However, for durability and easy reference, it is suggested that this description be in the form of a manual, indexed as necessary, describing the methods, procedures, inspections, and tests that the applicant and its suppliers intend to use to meet the requirements of § 21.303(h)(1) through (9). This also should apply to meeting the requirements for reporting under § 21.3 and for identifying the product in accordance with § 45.15. The description may or may not comprise a lengthy document, depending upon the size of the manufacturing facilities, and the number and complexity of parts being manufactured. In describing the FIS, references to other documents or data maintained by the applicant may be utilized in lieu of a detailed description of a particular procedure, provided a brief description is included in the manual and the referenced documents provide a complete description of the system. All referenced documents must be submitted for acceptance as part of the FIS description. If procedures or data are kept at or controlled by the original design/PAH under a contractual arrangement with the applicant, the applicant must demonstrate contractual provisions or provide other appropriate written assurance of the procedure for communicating design and manufacturing changes to the applicant. The applicant should demonstrate that termination of the contractual relationship would not affect the applicant's ability to maintain compliance with the established FIS. For record purposes, the description also should include a facsimile of the applicant's symbol, trademark, or prefix/suffix. The following paragraphs, headed by the applicable 14 CFR section to which they apply, provide an example of the material usually found in an acceptable description.

2. Section 21.303(h)(1). The portion of the FIS established to comply with this section would usually include the procedures that ensure conformity to approved design data of all supplier-furnished materials and services. Generally, this part of the FIS description would describe how the applicant ensures that:

a. All incoming materials conform to approved design data prior to their acceptance and release to production.

b. Provisions are made for the evaluation and surveillance of suppliers by the applicant when it relies to any degree upon a supplier's inspection system. The surveillance of suppliers of proprietary parts must enable the applicant to determine that incoming materials conform and that supplier services are performed correctly.

c. Suppliers, including suppliers of proprietary parts upon whom an applicant relies for controlling conformity and quality, are formally advised that their inspection system and materials being supplied are subject to inspection by the FAA. When a supplier from a foreign country is involved, the FAA will determine whether the performance of any FAA duties at the supplier's facilities would result in an undue burden on the FAA. If such FAA duties would be required, a means acceptable to the FAA of relieving any undue burden must be found, or it will be necessary for the applicant to perform all required functions in the United States.

d. Positive control is exercised over the design configuration and condition of all parts obtained from suppliers. The fact that the supplier does not hold a production approval for the part reemphasizes the PMA holder's responsibilities for the design configuration of the part.

e. All material review actions and design changes made by suppliers, including suppliers of proprietary parts over which the applicant does not exercise direct design control, are evaluated by the applicant and approved, if applicable, in accordance with § 21.303(d) and part 21, subpart D.

f. Records are maintained of all inspections and tests performed by or for the applicant in controlling the conformity of all supplier-furnished materials.

g. All incoming materials and services, including related inspection and test records, are identified with appropriate acceptance, rejection, or rework stamps, as applicable.

3. Section 21.303(h)(2). The FIS description will include the system the applicant will utilize, with respect to compliance with this section, to ensure that the physical and chemical properties of incoming material are as specified in the approved design data.

4. Section 21.303(h)(3). An acceptable description of the storage and issuance system established by the applicant would include the procedures that ensure:

a. Identification, segregation, and protection of materials in storage.

b. Periodic re-inspection and disposition of materials subject to deterioration from prolonged storage.

c. Protection of materials and components from handling damage while en route and stored in fabrication and shipping areas.

d. Incorporation of all applicable design changes prior to release of stored components for installation in the part.

e. Receipt into and issuance from storage of only those materials and components that are identified as having passed receipt inspection criteria.

5. Section 21.303(h)(4). The integrity of processes and services utilized in the manufacture of parts is dependent upon the skill with which the work is performed, the capabilities of the equipment used, and close control of critical factors such as temperatures, solutions, curing time, special tools, etc. A system to control processes and services, such as welding, brazing, heat treatment, plating, and radiographic, ultrasonic, or magnetic particle inspection, etc., requires that each process be performed by trained and qualified personnel, in accordance with approved specifications. The specifications should contain definitive standards of quality, and ensure that the periodic inspection of gauges, solutions, or any critical equipment is controlled and documented. The description with respect to this section in the FIS manual should explain the procedure by which the applicant will qualify personnel and control processes performed at the approved facilities, as well as suppliers. The description should generally include a listing of manufacturing processes that are relied upon to ensure the quality, conformity, and safety of the completed parts.

6. Section 21.303(h)(5). Compliance with this section requires that procedures be established by the applicant to control all phases of inspection of the part. Therefore, the FIS description should provide descriptions of all procedures established by the applicant to ensure that all inspections and tests will be conducted in the proper sequence, when components and processes are in an inspectable condition (e.g., prior to painting or closures). This is achieved through use of inspection instructions, shop travelers, checklists, or similar media. The following are examples of inspection functions that would be described to the extent applicable to the complexity of the parts or size of the manufacturer's facilities:

a. Planning Procedures. These procedures ensure that each component used in the part is adequately inspected for conformity with the approved design. This function of the planning system would be facilitated if it provided for:

(1) Classifying design characteristics and related manufacturing defects to determine their critical nature so that the most effective fabrication inspection methods and process controls will be used with respect to critical and major characteristics, and defect detection. Acceptable statistical processes may be found in SAE Aerospace Recommended Practice 9013, Statistical Product Acceptance Requirements.

(2) Selecting appropriate inspection methods and plans for each classification. This will ensure that all characteristics affecting safety will be inspected and re-inspected, as appropriate, to conform to approved design data and to eliminate discrepancies from in-process and completed parts.

b. Inspection Status. This system would ensure that appropriate stamps or marks are placed on components or other means are used to indicate their inspection status. It would be helpful if this portion of the description also contains copies of all inspection forms, checklists, and imprints of the various inspection and process stamps, along with their meanings. Procedures should call for the applicant to use suitable acceptance, rework, or rejection stamps, particularly on life-limited, critical, or nonconforming (MRB) parts, materials, and components that:

(1) Have been subjected to a process such as heat treatment, welding, bonding, etc., or testing and inspection that may include hardness tests, laboratory analysis, magnetic particle inspection, or similar functions.

(2) Have been inspected at the specified point in production and are found in conformity with the approved design.

(3) Are rejected as being unusable or scrap, so as to preclude their installation.

c. Tool and Gauge Control. This system should provide control over periodic inspection and calibration of inspection tools, gauges, testing equipment, production jigs, fixtures, templates, etc., which are depended upon as media for inspection product acceptance. The description of the means utilized for tool and gauge control should include a schedule of periodic or usage inspection and calibration intervals. This will ensure that tools, gauges, etc., are inspected, adjusted, repaired, and/or replaced before they become inaccurate. The inspection system description also should include the procedures for implementing the tool and gauge control schedules. Such procedures would basically ensure that each piece of equipment is:

(1) Checked prior to first usage and at the proper periodic interval.

(2) Marked to indicate it is under calibration control and indicates the next inspection due date.

(3) Removed from inspection and shop areas or conspicuously identified to prohibit usage after expiration of the inspection due date.

d. Final Inspection. This function of the inspection system would ensure that each completed part is subjected to a final inspection to determine conformity with approved design data. The inspection system also would ensure compliance with applicable FAA airworthiness directives and safety of the part for installation on type-certificated products. Such a system would usually incorporate procedures to ensure that:

(1) Each part is inspected for completeness, adjustments, safety, calibration, markings, placards, etc., as applicable to the complexity of the part.

(2) If applicable, each completed part or appropriate sample is subjected to a functional test to ensure that the operating characteristics meet the approved design provisions.

7. Section 21.303(h)(6). The description of the system established for compliance with this rule includes the procedures utilized to ensure that:

a. Current design drawings are readily available to manufacturing and inspection personnel, and used when necessary, and

b. Obsolete drawings and data, or those affected by superseding data or FAA airworthiness directives, are promptly removed from production and inspection areas, or otherwise controlled, to prevent their improper use.

8. Section 21.303(h)(7). The description of the drawing change controls required by this regulation should include procedures to ensure that, prior to final acceptance of articles and completed parts, all changes required to be FAA-approved have been approved and are incorporated in the applicable drawings or covered by change notices attached to such drawings. The FIS manual would, therefore, include a section describing or referring to the drawing change control system. If the drawing change control system refers to or relies upon the original design approval holder's system through a contractual relationship, the applicant should demonstrate contractual provisions or provide other appropriate written assurance sufficient to ensure that all changes will be incorporated into the finished part(s) manufactured by the applicant. In such a case, the applicant also should indicate how it would establish a new system to maintain the FIS, should the contractual relationship with the original design approval holder or PAH be changed or terminated.

9. Section 21.303(h)(8). The description of the procedures established for compliance with this regulation include provisions for the evaluation of rejected materials and articles to determine whether they can be reworked, repaired, or accepted "as is" without affecting the airworthiness of the part. The MRB procedure should describe engineering, quality, and production involvement in MRB activities. Approval for the PMA applicant to use this provision will depend upon the ability of the applicant to substantiate the effects of nonconformance or repair on the safe performance of the part and its parent system(s). If the procedures proposed by the applicant to demonstrate compliance with 14 CFR rely upon a contractual relationship with the original design approval holder, the applicant must demonstrate contractual provisions or provide other appropriate written assurance indicating how the applicant's compliance with applicable requirements will be ensured. In such a case, the applicant also should indicate whether it would need to establish a new system to maintain the FIS should this aspect of the contractual relationship with the original design approval holder or PAH be changed or terminated.

10. Section 21.303(h)(9). Compliance with this section requires that procedures be established for maintaining inspection records. This includes all inspections accomplished on the parts from raw materials to finished parts. A procedure should be established for identifying inspection records where practicable with parts, such as serial numbers, dates, codes, etc. The applicant must file and retain the inspection records for at least 2 years after the part has been completed.

Appendix C. Risk-Based Resource Targeting Organizational and Technical Indicators

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

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

Figure C-1. RBRT Indicators

ORGANIZATIONAL INDICATORS

Quality System

1. ISO 9001/AS9100 Quality System

2. Supplier Control Processes/Procedures

3. Nonconforming Material Processes/Procedures

4. Corrective and Preventive Action

5. Product/Part Configuration Control

Supplier/Outsourcing

6. Manufacture/Inspection Outsourcing

7. Design/Configuration Outsourcing

8. Testing/Validation Outsourcing

9. Stability of Suppliers

10. Suppliers of Flight Critical Parts

11. Supplier Audit History

Organizational Stability

12. Workforce Reduction/Growth/Turnover

13. Turnover of Critical Staff

14. Change in Key Management

15. Company Merger or Takeover

Relationship with FAA

16. Documented Agreement with FAA

17. Constructive Relationship with FAA

Compliance History

18. Applicant/PAH-Identified Noncompliances

19. FAA-Identified Noncompliances

20. Enforcement Action History

21. Demonstrated Independent Show Compliance

Safety Culture

22. SMS in Place

23. Employee Safety Training

24. Accident/Incident Investigation Program

25. Continued Operational Safety

26. Continuous Improvement

TECHNICAL INDICATORS

Complexity

27. Complex Part/Product/Assembly

28. Complex Manufacturing Process

29. Complex Testing Program

Service Experience

30. Injury/Fatal Accident Design Factor

31. AD/SAIB Design Factor

32. SUP/SDR History

Applicant/PAH Experience

33. Level of Experience

New/Emerging Technology

34. New/Emerging Technology

No. 1	**ISO 9001/AS9100 Quality System**				
	Is the applicant/PAH ISO 9001 certified or do they have an AS9100 quality system?				
Possible Ratings	Yes, ISO 9001 certified for 2 years or more	Yes, ISO 9001 certified for less than 2 years	Not ISO 9001 certified, but they have an AS9100 quality system in place	Not ISO 9001 certified, but they have some elements of an AS9100 quality system in place	Not ISO 9001 certified and no elements of a AS9100 quality system in place
Score	**1**	**2**	**3**	**4**	**5**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The following should be considered when assessing this indicator:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- Critical staff turnover generally has a greater impact on small companies than on large companies, all other things being equal. Critical staff may include people such as quality inspectors, foremen, engineers, test technicians, audit staff; any one-of-a-kind specialty (e.g., level III NDT) or any key FAA contact.
- If losses are replaced or backfilled, consider the background of the new staff. Internal selections may provide more familiarity with the organization than external hires, although a solid aviation or product background may compensate. Similarly, civil experience is generally better than military, due to CFR/FAA familiarity. Technical expertise, however, is paramount for individuals in these key positions.
- If losses are not replaced or backfilled, consider the context. If the company is downsizing, streamlining, or reorganizing, losses of this type will almost always impact the stability of the organization. If, on the other hand, the changes result from the end of a major project or program, there may be less of an impact to the organization.
- In any event, consider the strength of the company's organization. If it's well established, with fully documented procedures, then it may be able to absorb the loss of critical staff without significantly affecting the organization. Consider whether the organization's ability to perform remains intact, and is not being reduced as these individuals leave.

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

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

- Management changes generally have a greater impact on small companies than on large companies, all other things being equal. Key managers may include people such as the director of quality/quality manager, facility manager, chief engineer, section or line managers, company FAA focal points, or company president/CEO.
- The background of new management personnel is extremely important. In general, internal selections may provide more familiarity with the organization and may be less problematic than external hires, although a solid aviation or product background may compensate. Similarly, civil experience is often preferable to a military aviation background, since knowledge of the CFR and experience with the FAA are important.
- The reason behind any change(s) is also important. If it's performance-based, then the change may be an improvement. On the other hand, downsizing, streamlining, and reorganizations can reduce the stability of an organization.
- Consider the impact of new programs or product lines that may alter existing lines of authority and supervision and lead to organizational instability without anyone leaving the company.
- Management changes can also affect overall company philosophy or operational priorities. A shift to a more aggressive sales focus may lead to reduced emphasis on compliance to the CFR and on quality. Cost-cutting and greater "bottom line" pressure can undermine or dilute a company's focus on safety.

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

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

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

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

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

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

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

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

When evaluating this indicator, you may want to consider:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Safety management system **requirements** include the following:

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

Safety culture **attributes** include the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- The degree to which the design deviates from conventional or traditional practices may be considered. If the design involves revolutionary design concepts, it may be considered more complex, even for simple components. Additionally, traditional designs used in new applications should also be considered. This may be particularly true for technology that has been used for years in one category of aircraft, but has migrated to other categories where it has not been widely used.
- The number of components, subsystems, or subassemblies in the end item often drives its complexity. Any dynamic or rotating parts or assemblies, as well as if the item or any of its elements is life-limited, are also strongly linked to complexity. Similarly, the more functions the item performs, and/or the more failure modes it has, the greater its complexity.
- For airborne software, the DO-178 “level of software” correlates to complexity. The functionality and integration of the software drives complexity. Accordingly, complexity of designing Level A through E software should be assessed as Highly complex through Not complex respectively.
- The degree of integration and/or interdependence of the end item with other parts or systems is also a complexity driver. In general, clear functional boundaries between the item and other components or systems create less complexity than overlapping or integrated relationships. If any other systems are dependent on the end item, that typically increases overall complexity.
- The materials used in the end item are also relevant to complexity. Incorporation of any nontraditional, exotic, or revolutionary materials, and/or material(s) that haven’t been used in this way before, increase complexity. Limited knowledge or expertise can make simple things complicated.

For TSO authorization applications, the incorporation of non-TSO functions should also be considered. (Reference Notice 8150.4)

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

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

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

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

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

- The number and type of steps involved in a process often drive complexity. Generally, the more things that must be tracked, controlled, and/or sequenced, and the more special processes involved, the more complex the process. In particular, the number of process elements that must be critically controlled is a complexity driver.
- The latitude,or lack thereof, afforded to system operators is also frequently linked to complexity. Other characteristics to look for include detailed and intricate process specifications, and/or frozen or limited process changes subject to engineering source approval. Similarly, the more frequently the process is audited or validated, the greater its probable complexity.

- Multiple, in-depth, and expensive testing requirements for the end item or product can also be a reflection of manufacturing process complexity. Intricate and sophisticated test procedures are sometimes, but not always, required based on how the product was manufactured.
- Outsourcing of manufacturing processes, both production and testing, is also an element to consider. Outsourcing of these processes to highly expert firms is sometimes, but not always, necessary due to the complexity of the process.

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

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

- Complexity of testing is many times a question of program scope. A new design would most likely require a larger scope of testing than a derivative or follow-on design. For any certification program, the suite of tests is largely defined by the scope of the design changes, and, for a derivative, the specific changes made to the airplane. As the program scope increases, so does the array and complexity of testing that becomes necessary. On the other hand, it is important to keep in mind that small design changes can sometime result in large and complex testing programs.
- It is also important to note that when analysis techniques are used to show compliance, this is often an indication that the testing methods are not complex. Analysis is usually permitted only when the method has been shown to be reliable, usually supported by testing that has been validated. If a combination of testing and analysis is used, then this should also be considered when making the evaluation.
- Testing done in support of production may be an integral part of establishing the airworthiness of the product or part. In some instances, this testing can be very complex, and therefore, should not be overlooked.
- Consideration should also be given to the uniqueness of the testing. Some testing programs may be complex, but are well understood over years of application.

- The number and variety of tests in a program should be considered. Some standards require many different types of tests. Others require a single type of test to be run several times.
- Consideration should be given to the ease of the test(s), as well as the general understanding of how to successfully complete the test(s). Some testing programs are relatively simple to complete, but improper selection of test articles is common. Therefore, these standards should be rated higher. Conversely, some tests are very complex, but test procedures and proper selection of test articles are well defined.
- Another consideration is whether specialized equipment and training is needed to perform the testing. If specialized equipment is needed, it generally follows that special qualifications to operate and maintain the equipment are needed. If either special equipment or training is needed to perform the testing, this should be taken into consideration.

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

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

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

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

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

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

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

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

No. 32	**SUP/SDR History**				
	Have similar designs been the subject of Suspected Unapproved Part (SUP) reports or Service Difficulty Reports (SDR)?				
Possible Ratings	None		Some		Numerous
Score	**1**	**2**	**3**	**4**	**5**

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

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

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

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

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

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

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

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

Other items to consider include:

- Generally, the more experience an applicant/PAH has using a technology, designing, manufacturing, or testing a part, similar products or similar modifications, the less need for concern. When evaluating an applicant/PAH's experience, you should ask "have they done this before?" and "how recently have they done this?" Relevancy of experience should definitely be considered. New applicant/PAHs that have assembled a staff with relevant and recent experience might be considered more experienced than a well established company.
- For established companies, evidence that skill levels are being maintained or upgraded is also important. Even a simple, well-established process can be complex to those who aren't experienced in or knowledgeable of the technology involved. If a company has experience, but it has not produced a part, modification, or product in some time, then it is important to consider if the company has retained its experience over the design or production lull.

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

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

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

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

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

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

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

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

Appendix D. Category Parts List

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

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

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

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

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

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

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

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

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

Figure D-1. Sample Category Parts List

Revision F dated 7/01/04 **AIRCRAFT CERTIFICATION SERVICE CATEGORY PARTS LIST**

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

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

(3) Describe the reason for adding the assembly or part, for changing the category of an existing assembly or part, or for removing an existing assembly or part.

(4) Provide all applicable supporting data. This may include service difficulty information, airworthiness directives, or any other data to support the request.

(5) Identify where on the CPL a new assembly or part should be added. Omit this data for a change or removal request.

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

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

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

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

(2) Part 25: ANM-108.

(3) Parts 27 and 29: ASW-180

(4) Parts 33 and 35: ANE-180

d. The 14 CFR part MIO manager forwards the memo to a directorate specialist. The directorate specialist will investigate and coordinate the data described in the memo with the appropriate ACO. The directorate specialist will then complete the "Coordination" section of the Part Categorization memo as follows:

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

(2) If the action is to accept either a request to add an assembly or part or to change an existing category, assigns the appropriate category to the assembly or part.

(3) If the action is to accept a request to remove an assembly or part from the CPL, goes to paragraph e.

(4) If the action is to deny the request, indicates the reason it was denied.

e. On completion of the actions in paragraph 4d of this appendix, the directorate specialist forwards the memo to the 14 CFR part MIO manager. The 14 CFR part MIO manager will sign the completed memo and forward it to the originating MIO manager. The 14 CFR part MIO manager will retain a copy of the memo as a reference for future request reviews.

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

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

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

Figure D-2. CPL Revision Process Flowchart

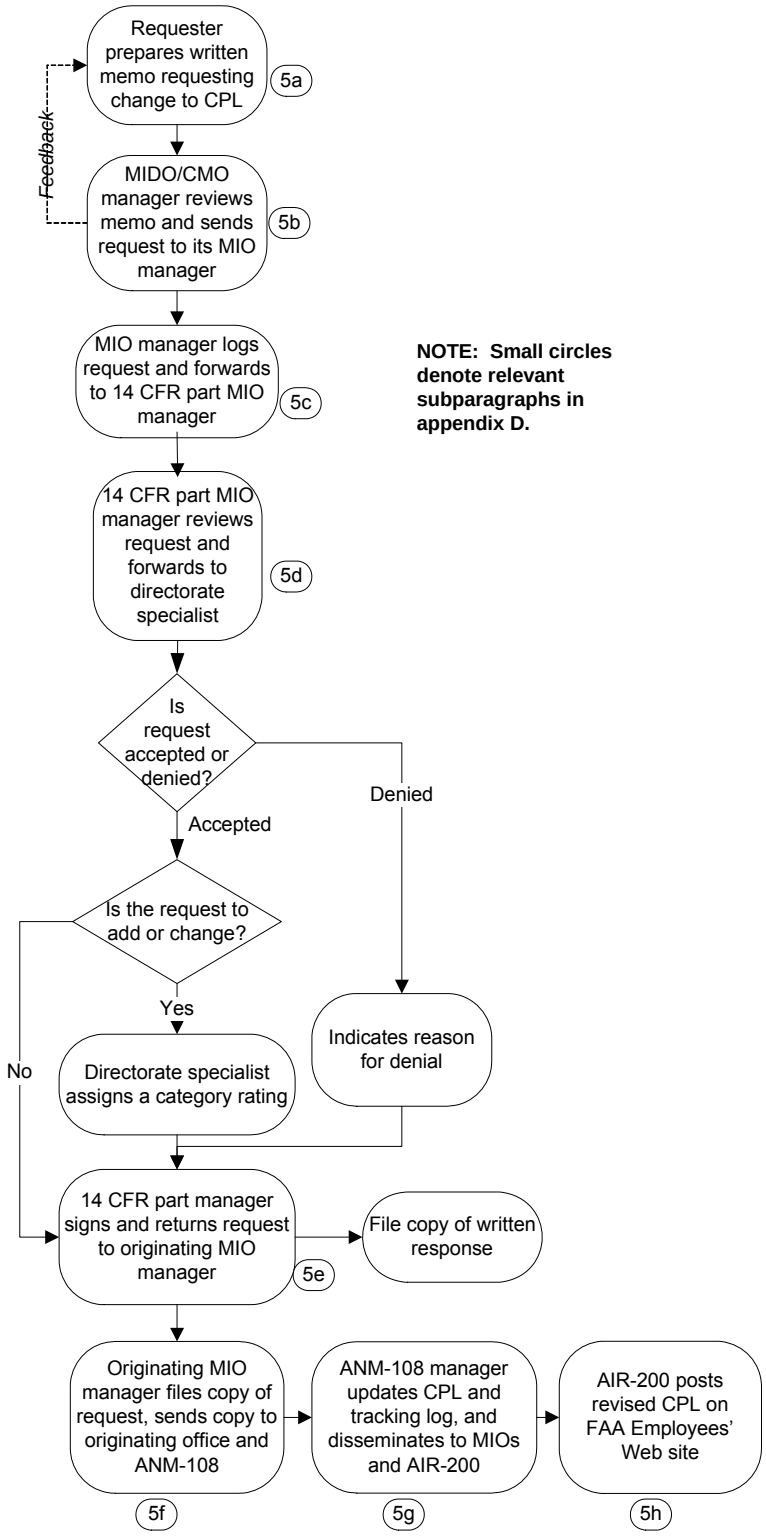


Figure D-3. Sample Part Categorization Memo for Requesting an Addition to the CPL

Federal Aviation Administration

Memorandum

Date: March 6, 2002

To: Manager, ANM-108

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

Prepared by: James Staney

Subject: **ACTION:** Part Categorization

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

1. Part name: Fuel cell door.

2. 14 CFR part affected: 25.

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

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

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

Attachment
AD #2001-15-01

COORDINATION

Action on request: Accept

Category assigned: 2

C.P. Ells Date: April 3, 2002

C.P. Ells

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

Federal Aviation Administration

Memorandum

Date: March 26, 2002

To: Manager, ACE-180

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

Prepared by: Ronald Reynolds

Subject: **ACTION:** Part Categorization

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

1. Part name: Flight compartment window.

2. 14 CFR part affected: 23.

3. Reason for changing existing category: Category 1 is not appropriate for a Cessna 150 aircraft.

4. The following applicable supporting data are attached: Cessna 150 performance data.

5. Placement of part on CPL: Systems and Equipment, Window-Windshield System.

6. Current category: 1.

Attachment
Cessna 150 performance data

COORDINATION

Action on request: Accept

Category assigned: 2

V. Small Date: April 23, 2002

V. Small

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

Federal Aviation Administration

Memorandum

Date: April 26, 2002

To: Manager, ANM-108

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

Prepared by: Molly Gale

Subject: **ACTION:** Part Categorization

We request to remove the following part from the Category Parts List (CPL).

1. Part name: Brake deboost valve.

2. 14 CFR part affected: 25.

3. Reason for removing part: The only PAH manufacturing brake deboost valves is no longer in business.

4. The following applicable supporting data are attached: Letter from ASW MIDO-42 canceling project. Cover letter from PAH containing the returned PMA letter.

5. Placement of part on CPL: Systems and Equipment, Brake System and Assembly Components.

6. Current category: 2.

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

COORDINATION

Action on request: Deny

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

C.P. Ells Date: May 23, 2002

C.P. Ells

Appendix E. Risk-Based Resource Targeting Assessment Validation Plan

1. Purpose. This appendix explains the structure and application of the RBRT assessment validation plan. The objective of the plan is to ensure that RBRT assessments consistently and accurately identify those PAHs and associate facilities having the greatest potential to produce nonconforming products or parts. It also defines a basis for continually refining and modifying the RBRT assessment tool as required to achieve this objective. The plan utilizes several validations to accomplish these objectives.

2. RBRT Assessment Validations. Each validation listed below identifies the data source(s) required for each validation element, the individuals or groups responsible for validating the element, and a brief description of the process for each validation element.

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

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

(2) Parties Responsible for Validation: Facility PI and MIDO/CMO manager.

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

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

b. Validation of the Continued Relevance of the RBRT Assessment Indicators. This validation is conducted annually following the completion of all scheduled ongoing CM responsibilities for the fiscal year. Since this validation is data-driven, and aimed at the adequacy of the RBRT assessment tool elements, detailed planning for analysis and reporting will be required.

(1) Data Source(s): The RBRT assessment tool within CMIS is the data source for this validation.

(2) Parties Responsible for Validation: Directorates.

(3) Description: Each directorate will collect the relevant data and design, and perform the required analyses.

(4) Expected Outcome: This validation seeks to identify the RBRT assessment indicators that do not significantly contribute to the identification of RBRT risk level assignments.

c. Validation of the RBRT Assessment Tool's Ability to Reflect PI Experience and Judgment. This validation is conducted every three years, beginning three years from the date of RBRT implementation. The individual RBRT assessment indicators and the relative weights assigned to each were based on input from managers, PIs, and engineers, and this input reflects their combined knowledge, experience, and judgment. It is necessary to periodically revalidate this basis to ensure that the RBRT assessment tool continues to reflect this experience and judgment. Since this validation is data-driven, and aimed at the adequacy of the RBRT assessment tool elements, detailed planning for analysis and reporting will be required.

(1) Data Source(s): The RBRT assessment reports are the primary data sources for this validation. In addition, each directorate will use an RBRT assessment questionnaire to assess the validity of the risk levels assigned.

(2) Parties Responsible for Validation: Directorates.

(3) Description: Each directorate will collect the relevant data and design, and perform the required analyses.

(4) Expected Outcome: This validation seeks to determine the degree to which the rating plan for the RBRT assessment indicators reflects the experience and judgment of the PIs. Once every three years, following assignment of the RBRT risk levels, each directorate will provide a questionnaire to its PIs to assess the validity of the assignments. The questionnaire will request PIs and their managers to mutually review the RBRT Assessment Office Reports, identify any RBRT risk level assignments they disagree with, and provide written justification for their opinion. The differences identified with the RBRT risk levels assigned and the written justifications will be analyzed to detect any patterns or trends in the data attributable to inadequacies in the RBRT assessment tool. A small number of justifiable changes to the RBRT risk level is a strong nominal indicator of RBRT assessment tool validity; i.e., if a large majority of the RBRT risk level assignments are accepted, then the knowledge and experience of the directorate staff is adequately reflected in the RBRT assessment tool.

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

1. Purpose. This appendix provides instructions for completing Form 8100-6 for all audit and evaluation activities.

2. Specific Guidance. Figure F-1 shows Form 8100-6 with numbered blocks. The form will be prepared as a stand-alone document. WRITE THE NONCOMPLIANCE AGAINST THE RESPONSIBLE PAH or ASSOCIATE FACILITY. Prepare the form by inserting in:

a. Block 1. When the activity is an ACSEP evaluation, enter the ACSEP Number/Report Number. For all other activity, enter "N/A."

b. Block 2. The project number(s) applicable to the production approval(s) activity.

c. Block 3. A check mark in the appropriate box to indicate the type of activity that was conducted.

d. Block 4. Under "System Element Evaluated," enter the name of the system element in Order 8100.7 to which the noncompliance is relevant. Under "Evaluation Criteria Number," enter the evaluation criteria number from Order 8100.7, appendix 5. For new criteria, insert the system element number assigned by Order 8100.7, appendix 5. Do NOT insert more than one number.

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

e. Block 5. The reference controlling document. The controlling document is defined as the FAA-approved or accepted data, purchase order/quality requirements from a PAH or associate facility, or internal procedures used in producing the product or part(s). Enter the complete reference number, or, as a minimum, the document title and effective date. (Examples: ABC Company Quality Manual dated March 5, 1976; XYZ QOI 32-6 dated June 23, 1990; BCD Drawing No. 9825333-2 dated May 20, 1989.) Insert a check in the "Yes" or "No" block, as appropriate, to indicate whether the controlling document is FAA-approved.

Note: If an APIS or PMA holder's quality manual is submitted to the FAA as evidence of compliance to part 21, it is not considered to be FAA-approved data. The "NO" block should always be checked for these documents. Purchase orders and/or quality requirements flowed down to a supplier by a PAH or associate facility are generally not considered to be FAA-approved data. In some cases, quality requirements for use at a supplier facility are specifically approved by the FAA prior to use. Determine the approval status of any referenced PAH supplier quality requirement before checking the "YES" or "NO" block.

f. Block 6. The applicable 14 CFR part or section that establishes the responsibility of the PAH (i.e., § 21.165 or § 21.607). For an APIS or PMA facility, insert the specific paragraph reference from § 21.125 or § 21.303(a), (h), (h)(1) through (h)(9), (j), or (k), or other applicable 14 CFR sections (e.g., § 45.15) to which the observed condition is directly traceable. If the observed condition is not directly traceable to one of these requirements, leave the block blank. Insert the applicable 14 CFR reference for each approval type affected.

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

g. Block 7. A check mark in the appropriate box to indicate the type of noncompliance found. A noncompliance is indicated when it is discovered that a PAH's or associate facility's operating practices are inconsistent with 14 CFR, FAA-approved data, or internal procedures. Internal procedures refer to a PAH's or associate facility's procedures that are not included as part of the FAA-approved data. A supplier's operating practices found to be inconsistent with a PAH's or associate facility's purchase order requirements are considered to be noncompliances by the PAH or associate facility. A noncompliance is classified into one of the following four categories:

(1) Safety-Related Noncompliance: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that compromises immediate continued operational safety and requires immediate corrective action. This includes any noncompliance to § 21.3, including an isolated noncompliance. For an ACSEP evaluation, record a safety-related noncompliance only when the responsible PI determines that immediate action is required.

Note: The PI should formally submit any safety-related noncompliance to the responsible PAH or associate facility in writing within 72 hours of discovery. If the noncompliance affects delivered products or services, the PI will secure from the responsible PAH or associate facility a list of the end users affected and immediately notify the cognizant ACO, MIO, MIDO, or CMO.

(2) Systemic Noncompliance: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is not safety-related and is systemic in nature, i.e., is pervasive, repeatable, and represents a breakdown in the quality control or inspection system.

(3) Isolated Noncompliance: a noncompliance to 14 CFR, FAA-approved data, the facility's internal procedures, or purchase order requirements that is not safety-related and is of an isolated or nonsystemic nature, i.e., is not pervasive or repeatable, and does not represent a breakdown in the quality control or inspection system. However, an isolated noncompliance with § 21.3 is considered a safety-related noncompliance when it meets the definition in paragraph 2g(1) of this appendix.

(4) Certification-Related Noncompliance: a noncompliance to 14 CFR that is discovered in FAA-approved data and that is not safety-related.

Note: Number noncompliances sequentially beginning with the number "1."

h. Block 8. The condition required by the controlling document, applicable supporting documents, or the applicable 14 CFR part or section. Use the same wording as the controlling document, the applicable supporting document, or the applicable 14 CFR part or section, whenever possible. List all documents that demonstrate the link back to the controlling document or 14 CFR.

i. Block 9. A detailed explanation of the encountered condition.

(1) Explain why the encountered condition differs from the required condition.

(2) Identify where the encountered condition was found.

(3) Identify the total number of items checked and the total number of items found to be in noncompliance.

(4) List the items found to be in noncompliance, using identification numbers or other specific identifiers whenever possible.

(5) Record any evidence the facility provided during the evaluation to show that corrective action was taken or initiated.

(6) When the encountered condition finds FAA-approved data to be in noncompliance with an applicable 14 CFR part or section, include a note that further investigation by the ACO, MIO, MIDO, or CMO may be required.

(7) List all objective evidence obtained that describes the encountered condition.

j. Block 10. A check in the box to indicate that the encountered condition has been discussed with the facility escort, as a minimum.

k. Block 11. The typed or printed name and signature of the person recording the noncompliance.

> **Note: Evaluators-in-training and support service personnel participating in ACSEP evaluations may sign this block. However, the block must be countersigned by an appointed ACSEP evaluator.**

l. Block 12. The routing office symbol of the recorder.

m. Block 13. The date the form is completed.

Figure F-1. Sample FAA Form 8100-6

This form is a representation of the original form and not to be construed as the original form.

Noncompliance Record

U.S. Department of Transportation
Federal Aviation Administration

ACSEP No./Report No. *(1)*: N/A

Project No. *(2)*: PT900NE

Type of Activity: ☐ MIDO Audit ☐ PI Evaluation ☐ ACSEP ☐ Supplier Control Audit ☒ Product Audit ☐ Other *(3)*

System Element Evaluated: *(4)*	Controlling Document: *(5)*	Applicable CFR Section: *(6)*
Manufacturing Processes	RC Purchase Order #94 of 11/23/1997	21.607
Evaluation Criteria Number:		
413	FAA-approved data? ☐ Yes ☒ No	

Type Of Noncompliance: Safety-Related ☐ Systemic ☒ Isolated ☐ Certification-Related ☐ No. 1 *(7)*

Required Condition: *(8)*

RC Purchase Order (PO) #94 for rotor support couplings states: "J&J Machining Co. shall comply with RC Quality Manual, Section 4, and purchase raw materials exclusively from YOYO International Material Broker. Terms of purchase will include a request for a metallurgical lab report with each shipment. These reports will be retained by J&J Machining Co. for a minimum of 5 years."

J&J Machining Co. Quality Manual, paragraph 12.4(c), states: "All raw material purchase orders shall include a statement requiring suppliers to furnish a metallurgical lab report with each shipment. The reports will be retained by J&J Machining Co. metallurgical lab in accordance with paragraph 23.6."

Encountered Condition: *(9)* ☒ *Discussed with Facility* **(10)**

Ten J&J Machining Co. purchase orders for raw materials to be used for the manufacture of rotor support couplings under RC PO #94 were reviewed (J3-122; J3-114; J3-221; J3-98; J3-301; J3-110; J3-245; J3-15; J3-278; J3-184). All ten POs were issued to YOYO International Material Broker was required by RC PO #94, and all included the statement for furnishing a metallurgical lab report with each shipment. All raw material shipments were completed between January 1997 and March 1998. The J&J Machining Co. metallurgical lab files were reviewed to determine whether metallurgical lab reports had been furnished with each shipment required by the ten POs. Only one metallurgical lab report was found to be on file (shipment under PO #J3-122).

Attachments:

RC Purchase Order #94

RC Quality Manual, Section 4

J&J Machining Co. Quality Manual, paragraphs 12.4(c) and 23.6

J&J Machining Co. PO # J3-122; J3-114; J3-221; J3-98; J3-301; J3-110; J3-245; J3-15; J3-278; J3-184

Sample

Typed Name and Signature of Recorder: *(11)*	Office Symbol *(12)*	Date *(13)*
Julia R. Gotta *Julia Gotta*	ANE MIDO 42	5/1/01

FAA Form 8100-6 (12-08)

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

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

1. Purpose. This appendix provides instructions for completing Form 8120-14. This form is used to document all activity, except ACSEP evaluations, at PAHs, associate facilities, and their suppliers. When combined with the respective Form(s) 8100-6 and, if applicable, Form 8100-1, a complete report of the activity conducted is available for subsequent planning.

2. Specific Guidance. Figure G-1 shows Form 8120-14 with numbered blocks. Prepare the form by inserting in:

a. Block 1. The name and address of the PAH or associate facility as recorded on the production approval.

b. Block 2. The project number(s) applicable to the production approval(s).

c. Block 3. The name and address of the supplier as recorded on the PAH's documentation.

d. Block 4. A check mark in the appropriate box(es) to indicate the type of production approval.

e. Block 5. A check mark in the appropriate box(es) to indicate the type of activity that was conducted.

f. Block 6. The starting date and the ending date of the activity that was conducted.

g. Block 7. The title, revision number, and date of any quality manual submitted to the FAA by the PAH or associate facility. The applicable 14 CFR part or section may also be entered. If no quality data is submitted, enter the applicable 14 CFR part or section. For a supplier, enter the applicable purchase order or quality requirements from the PAH or associate facility.

h. Block 8. The date that applicable quality data submitted by a PAH or associate facility is approved by the FAA. If quality data is not subject to FAA approval, enter "N/A."

i. Block 9. An "X" in the column next to the system element/subelement evaluated when the result of the activity is satisfactory.

j. Block 10. The respective Form 8100-6 noncompliance numbers for the system element evaluated, when the result of the activity is unsatisfactory.

k. Block 11. The nomenclature and part number(s) of the product or part(s) audited.

l. Block 12. An "X" in the column next to the product or part(s) audited when the result of the activity is satisfactory.

m. Block 13. The respective Form 8100-6 noncompliance numbers for the product or part(s) audited, when the result of the activity is unsatisfactory.

n. Block 14. The specific purchase order or quality requirement audited.

o. Block 15. An "X" in the column next to the specific purchase order or quality requirement audited when the result of the activity is satisfactory.

p. Block 16. The respective Form 8100-6 noncompliance numbers for the specific purchase order or quality requirements audited, when the result of the activity is unsatisfactory.

q. Block 17. Enter the names, titles, and office symbols of all FAA personnel who participated in the activity.

r. Block 18. The typed or printed name and signature of the person conducting the audit or PI evaluation. In most cases, this will be the PI responsible for the PAH or associate facility.

> **Note: When Form 8120-14 is used to document a PI evaluation or MIDO audit with multiple team members, the signature in block 18 is that of the team leader. This form, with the above signature, can then be used to support the continued appointment as an ACSEP team leader in accordance with Order 8100.7, chapter 2, paragraph 21b(1).**

s. Block 19. The office symbol of the person completing this form.

t. Block 20. The date that this form is completed.

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

This form is a representation of the original form and not to be construed as the original form.

U.S. Department of Transportation
Federal Aviation Administration

Production Approval/ Certificate Management Activity Report

Manufacturer/Address: RC Couplings, 10001 Admiral Square, Haverhill MA 01830 *(1)*

Project No.: PQ 1234NE *(2)*

Supplier/Address: N/A *(3)*

Production Basis: *(4)*

PC ☐ APIS ☐ TSO authorization ☐ PMA ☒

Production Approval/Certificate Management Activity: *(5)*

MIDO Audit ☐ PI Evaluation ☒ Product Audit ☒ Supplier Control Audit ☐ Other ☐

Activity Dates: From 4/1/2003 To 4/2/2003 *(6)*

Quality Data –Title, Revision, Date, and/or CFR Section Involved: *(7)*

RC Quality Manual, Rev. C, 1/27/1997

Date of FAA Approval of Quality Data: N/A *(8)*

PI EVALUATION OR MIDO AUDIT RESULTS

SYSTEM ELEMENT	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No. (s)*
1. Organizational Management	*(9)*	*(10)*
2. Design Control		
3. Software Quality Assurance		
4. Manufacturing Processes		
4a. Manufacturing and Special Manufacturing Processes		#1 and #2
4b. Material Receiving, Handling & Storage		
4c. Airworthiness Determination		
5. Manufacturing Controls		
5a. Statistical Quality Control (SQC)		
5b. Tool and Gauge		#3
5c. Testing		
5d. Nondestructive Inspection		
5e. Nonconforming Material		
6. Supplier Control		

PRODUCT AUDIT RESULTS

PRODUCT AUDITED (Nomenclature/Part Number)	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No.(s)*
Rotor support coupling, P/N RC25 - 1000 *(11)*	*(12)*	#4 thru #6 *(13)*

FAA Form 8120-14 (12-08) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

Sample

Figure G-1. Sample FAA Form 8120-14 (Back)

This form is a representation of the original form and not to be construed as the original form.

SUPPLIER CONTROL AUDIT RESULTS

PURCHASE ORDER/QUALITY REQUIREMENTS	SATISFACTORY *"X" if applicable*	UNSATISFACTORY *List FAA Form 8100-6 Noncompliance No.(s)*
(14)	*(15)*	*(16)*

Sample

PARTICIPATING EVALUATORS *(17)*

NAME	TITLE	OFFICE SYMBOL

Typed/Printed Name and Signature of PI: *(18)*		Office Symbol *(19)*	Date *(20)*
Julia R. Gotta	*Julia Gotta*	ANE MIDO 42	4/3/2003

FAA Form 8120-14 (12-08) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

Appendix H. Forms Listing

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

Figure H-1. Forms Available from FAA Logistics Center

Form Number	Title	NSN	Unit of Issue
FAA Form 8100-1	Conformity Inspection Record	0052-00-039-3001	Package
FAA Form 8110-12	Application for Type Certificate, Production Certificate, or Supplemental Type Certificate	0052-00-025-0001	Sheet
FAA Form 8120-3	Production Limitation Record	0052-00-025-7001	Sheet
FAA Form 8120-4	Production Certificate	0052-00-025-6001	Package
FAA Form 8130-3	Airworthiness Approval Tag	0052-00-012-9005	Pad
FAA Form 8130-9	Statement of Conformity	0052-00-847-2000	Sheet

Figure H-2. Forms Available Within CMIS

Form Number	Title
FAA Form 8100-1	Conformity Inspection Record
FAA Form 8100-6	Noncompliance Record
FAA Form 8120-3	Production Limitation Record
FAA Form 8120-4	Production Certificate
FAA Form 8120-14	Production Approval/Certificate Management Activity Report

Appendix I. Acronyms

14 CFR	Title 14, Code of Federal Regulations
AC	Advisory Circular
ACO	Aircraft Certification Office
ACSEP	Aircraft Certification Systems Evaluation Program
APIS	Approved Production Inspection System
ASI	Aviation Safety Inspector
CAA	Civil Aviation Authority
CM	Certificate Management
CMIS	Certificate Management Information System
CMO	Certificate Management Office
CPL	Category Parts List
DMIR	Designated Manufacturing Inspection Representative
DOA	Delegation Option Authorization
EEP	Enhanced Enforcement Program
FAA	Federal Aviation Administration
FIS	Fabrication Inspection System
ICSSP	International Cooperative Supplier Surveillance Program
MIDO	Manufacturing Inspection District Office
MIO	Manufacturing Inspection Office
MRB	Material Review Board
NTE	Not To Exceed
OAC	Original Airworthiness Certificate
ODA	Organization Designation Authorization
PAH	Production Approval Holder

PC	Production Certificate
PCB	Production Certification Board
PI	Principal Inspector
PLR	Production Limitation Record
PMA	Parts Manufacturer Approval
QC	Quality Control
RBRT	Risk-Based Resource Targeting
SDR	Service Difficulty Report
STC	Supplemental Type Certificate
SUP	Suspected Unapproved Part
TC	Type Certificate
TCDS	Type Certificate Data Sheet
TSO	Technical Standard Order

Appendix J. Definitions

For the purpose of this order, the following definitions apply:

a. Article. Materials, parts, and/or appliances produced under the provision of a TSO authorization. All references in this order to "parts" include TSO articles, as applicable. An article as specified in § 21.143(a) (which includes any material, part, subassembly, assembly, system, or appliance that is used in the type-certificated product) is referred to herein as a "part."

b. Associate Facility. This is a facility that has been approved as an extension to an original PAH. This facility is owned and operated by the same corporate management as the original PAH that controls the design and quality of the product or part(s), except for companies participating in joint-production and/or co-production business agreements. The associate facility must be listed as a manufacturing facility on the PC or the letter of authorization for other production approvals, e.g., APIS, PMA, or TSO authorization (reference chapter 2, section 6 of this order).

c. Audit. A systematic and independent examination to determine compliance of an established supplier system, inspected product or part(s), or processes with purchase order requirements, technical data, or specifications.

d. Certificate. A document (i.e., a certificate or approval) issued by the FAA that recognizes an applicant's or PAH's established quality control or inspection system and allows for the production of products or parts in accordance with an FAA-approved design.

e. Certificate Management. The method by which the FAA ensures that a PAH remains in compliance with those pertinent regulations that govern the manufacturing of its particular products or parts.

f. Corrective Action. The measures taken to resolve unsatisfactory conditions and to prevent reoccurrence.

g. Days. A reference to calendar days, unless otherwise specified.

h. Distributor. A supplier that engages specifically in the buying and selling of aviation products, parts, appliances, components, or materials, and that conducts no manufacturing activities.

i. Evaluation. A systematic and independent examination of an established PAH or associated facility system based on the system elements defined in Order 8100.7.

j. Foreign Manufacturer. A person other than an FAA production approval holder who causes a product or part(s) to be produced outside the United States.

k. Inspection System. The total network of administrative and technical data at an APIS or PMA holder required to control the product or part(s) to 14 CFR.

l. Internal Procedure. A PAH's or associate facility's procedures that are not included as part of the FAA-approved data.

m. Manufacturer. A person as defined by 14 CFR part 1, Definitions and Abbreviations, who causes a product or part(s) to be produced. A manufacturer may be a PAH or a supplier to a PAH.

n. Noncompliance. A PAH's or associate facility's operating practice that is found to be inconsistent with 14 CFR, FAA-approved data, or internal procedures. A supplier's operating practice found to be inconsistent with a PAH's or associate facility's purchase order requirements is considered to be a noncompliance by the PAH or associate facility.

o. Ongoing Certificate Management. The performance of CM requirements based on an RBRT assessment that may be accomplished on a continuing basis.

p. Part(s). Any part, material, appliance, system, subassembly, assembly, or software used in a product.

q. Production Approval. An authorization, approval, or certificate issued by the FAA that allows a manufacturer to produce products or parts in accordance with FAA-approved design and an FAA-approved quality control or inspection system.

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

s. Principal Inspector. A manufacturing inspector who has been assigned CM responsibility of a particular PAH or associate facility.

t. Produce. To manufacture, or cause to be manufactured, a product or part(s).

u. Product. Aircraft, aircraft engine, or propeller.

v. Production Certification Board. An FAA evaluation function consisting of a selected group of FAA specialists acting under the direction of the PCB chairperson for the purpose of determining eligibility of the holder of a TC or a STC, or a licensee, for the issuance of a PC.

w. Quality Assurance. A management system for programming and coordinating the quality maintenance and improvement efforts of the various groups in a design and/or manufacturing organization, so as to permit design and/or production in compliance with regulatory and customer requirements.

x. Quality Control. Conduct and direct supervision of the quality tasks (inspection of the product) to ensure that the quality requirements of the product are achieved.

y. Quality Control Data. Data that provide a description of the quality control system required by part 21 for a PC or TSO authorization holder. These data would encompass the methods, procedures, processes, inspections, tests, specifications, charts, lists, forms, etc., which the PAH employs to produce products or parts.

z. Quality System. An organizational structure with responsibilities, procedures, processes, and resources that implements a management function to determine and enforce quality principles. A quality system encompasses quality assurance and quality control.

aa. Random Certificate Management. The performance of CM tasks that may be accomplished on an as-needed basis.

bb. Random Sampling. A sampling procedure that ensures that each element in a population has an equal chance of being selected.

cc. Risk-Based Resource Targeting. A structured process designed to support AIR management in determining risk, assigning resources based on that risk, and prioritizing multiple projects.

dd. Root Cause. The underlying cause of a systemic or recurring noncompliance, usually identified through structured analysis.

ee. Specialist. As related to the facility audit function of PC or APIS Boards, FAA manufacturing inspectors/supervisors or flight test, structures, systems, and/or equipment engineering personnel.

ff. Standard Part. A part that is manufactured in complete compliance with an established government or industry-accepted specification, which contains design, manufacturing, and uniform identification requirements. The specification must include all information necessary to produce and conform the part, and must be published so that any person/organization may manufacture the part.

gg. Supplier. Any person or organization contracted to furnish aviation products, parts, appliances, components, materials, or services (at any tier).

Appendix K. Administrative Information

1. Distribution. This order is distributed to Washington Headquarters division levels of the Flight Standards Service, to the branch levels of the Aircraft Certification Service, to the branch levels in the regional Flight Standards Divisions and Aircraft Certification Directorates, to all Flight Standards District Offices, to all Aircraft Certification Offices, to all Aircraft Certification field offices, to all Manufacturing Inspection District and Satellite Offices, to the Aircraft Certification and Airworthiness Branches at the Federal Aviation Administration Academy, and to the Flight Standards Service Regulatory Support Division.

2. Authority to Change This Order. The issuance, revision, or cancellation of the material in this order is the responsibility of the Aircraft Certification Service, Production and Airworthiness Division, AIR-200. This division will accomplish all changes, as required, to carry out the agency's responsibility to provide for production approval and CM.

3. Forms. This order identifies several forms used for the evaluation, approval, and CM of production activities. Some of the forms are provided by AIR-200 in electronic format. Appendix H, Forms Listing, provides a listing of the forms and their sources.

4. Deviations. Adherence to the procedures in this order is necessary for uniform administration of this directive material. Any deviations from this guidance material must be coordinated and approved by AIR-200. If a deviation becomes necessary, the FAA employee involved should ensure the deviations are substantiated, documented, and concurred with by the appropriate supervisor. The deviation must be submitted to AIR-200 for review and approval. The limits of federal protection for FAA employees are defined by Title 28 U.S.C. § 2679.

5. Related Publications. Orders referenced in this directive list only the basic order number. It is the responsibility of the user to establish that the latest revision/amendments are being utilized.

6. Requests for Information. All public requests for information regarding production approval or CM activities will be processed in accordance with the Freedom of Information Act. Refer to FAA Order 1270.1, Freedom of Information Act Program.

7. Electronic Signature. The use of an electronic signature for the issuance of a production certificate and a production limitation record, or a production approval letter (i.e., APIS, PMA, or TSO authorization) is not permitted.

8. Suggestions for Improvement. Any deficiencies found, clarifications needed, or improvements regarding the content of this order should be forwarded to the Planning and Program Management Division, AIR-500, Attention: Directives Management Officer, for consideration. FAA Form 1320-19, Directive Feedback Information, is located in appendix L of this order for your convenience or you may obtain it electronically from the FAA Web site. A copy may be forwarded to the Production and Airworthiness Division, AIR-200, Attention: Comments to Order 8120.2. If an interpretation is urgently needed, you may contact AIR-200 for guidance, but you should also use the Form 1320-19 as a follow up to each verbal conversation.

9. Records Management. Refer to Orders 0000.1, FAA Standard Subject Classification System, 1350.14, Records Management, and 1350.15, Records Organization, Transfer, and Destruction Standards, FAA-IR-04-01, Aircraft Certification Service Records Management Requirements Manual, or your office Records Management Officer (RMO)/Directives Management Officer (DMO) for guidance regarding retention or disposition of records. Refer to AIR Quality Management System Procedure AIR-002-085-WI for guidance regarding the content, filing, and storage locations of records related to the applicant/PAH. All records must be in accordance with documents referenced in this order by April 30, 2009.

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

U.S. Department of Transportation
Federal Aviation Administration

Directive Feedback Information

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

Subject: FAA Order 8120.2F

To: The Planning and Program Management Division, AIR-500

(Please check all appropriate line items)

☐ An error (procedural or typographical) has been noted in paragraph _____ on page _____.

☐ Recommend paragraph _____ on page _____ be changed as follows:
(attach separate sheet if necessary)

☐ In a future change to this directive, please include coverage on the following subject *(briefly describe what you want added):*

☐ Other comments:

☐ I would like to discuss the above. Please contact me.

Submitted by: _____ Date: _____

FTS Telephone Number: _____ Routing Symbol: _____

FAA Form 1320-19 (10-98)