CHANGE

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER 8120.2E
CHG 3

National Policy

Effective Date:
9/5/08

SUBJ: Production Approval and Certificate Management Procedures

1. Purpose. This change implements the use of AIR QMS Procedure AIR-002-085-W1 and its associated forms. The work instruction describes the required content of all applicant/PAH project folders maintained by the MIDO/CMO.

2. Who This Change Affects. 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.

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

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7 (and 8)	5/29/07	7 (and 8)	9/5/08

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

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CHANGE

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER 8120.2E
CHG 2

National Policy

Effective Date:
07/23/08

SUBJ: Production Approval and Certificate Management Procedures

1. Purpose. This change describes the process to be followed by the principal inspector when changing the type of noncompliance recorded on Form 8100-6, subsequent to the finalization of an audit or evaluation.

2. Who This Change Affects. 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.

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CHANGE

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER 8120.2E
CHG 1

National Policy

Effective Date:
5/29/08

SUBJ: Production Approval and Certificate Management Procedures

1. Purpose. This change modifies and clarifies critical characteristics and critical process attributes as listed in paragraph 149, Selection of Product Audit Characteristics.

2. Who This Change Affects. 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, to the International Policy Office, and to the Flight Standards Service Regulatory Support Division.

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

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

ORDER 8120.2E

Effective Date:
5/29/07

SUBJ: Production Approval and Certificate Management Procedures

FOREWORD

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 thereof 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/

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CHAPTER 1. INTRODUCTION

1. PURPOSE. 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.

2. 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, to the Suspected Unapproved Parts Program Office, to the Brussels Aircraft Certification Staff, and to the Flight Standards Service Regulatory Support Division.

3. CANCELLATION. Federal Aviation Administration (FAA) Order 8120.2D, Production Approval and Certificate Management Procedures, dated August 17, 2004, and its associated change(s), are canceled.

4. EXPLANATION OF MAJOR CHANGES. This revision—

a. Changes the term “resource targeting” to “risk management.”

b. Removes the “no time in service” requirement applicable to new unused products and parts thereof re-introduced back into the quality control or inspection system.

c. Eliminates the limitations on the circumstances under which a holder of a supplemental type certificate (STC) may apply for a production certificate (PC).

d. Incorporates several definitions developed in conjunction with manufacturing representatives from other civil aviation authorities.

e. Incorporates all Parts Manufacturer Approval (PMA) requirements, procedures, and information applicable to manufacturing inspection.

f. Changes the information required on the shipping document when detail parts, produced for installation in a PMA assembly or Technical Standard Order (TSO) article, are sold separately.

g. Consolidates all paragraphs applicable to supplier control into one part.

h. Clarifies information in figures 15 and 16, previously figures 9 and 10, respectively.

i. Clarifies several risk management procedures and requirements.

j. Defines the notification period for the hand-off of supplier control audits.

k. Clarifies personnel responsibilities for investigating and coordinating changes to the Category Parts List (CPL).

l. Adds language regarding the applicability of the holder/licensee of a 14 CFR § 21.27 type certificate (TC) to obtain a PC.

m. Incorporates the deviation, dated April 5, 2002, that authorizes an alternative to the supplier selection process.

n. Adds language regarding the reporting of a suspected unapproved part (SUP).

o. Clarifies the information required on identification plates for products manufactured under a licensing agreement program.

5. ACRONYMS. Acronyms used in this order are as follows:

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
DO	District Office
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
ODAR	Organizational Designated Airworthiness Representative
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
SDR	Service Difficulty Report
STC	Supplemental Type Certificate
SUP	Suspected Unapproved Part
TC	Type Certificate
TCDS	Type Certificate Data Sheet
TSO	Technical Standard Order

6. 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 thereof” 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 thereof.”

b. Associate Facility. This is a facility that has been approved as an extension to an original production approval holder (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) thereof, 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., Approved Production Inspection System (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) thereof, or processes with purchase order requirements, technical data, or specifications.

d. Category 1 Product or Part(s) Thereof. A product or part(s) thereof whose failure could prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.

e. Category 2 Product or Part(s) Thereof. A product or part(s) thereof whose failure would not prevent continued safe flight and landing; resulting consequences may reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.

f. Category 3 Product or Part(s) Thereof. A product or part(s) thereof whose failure would have no effect on continued safe flight and landing of the aircraft.

g. 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 thereof in accordance with an FAA-approved design.

h. 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 thereof.

i. Corrective Action. The measures taken to resolve unsatisfactory conditions and to prevent reoccurrence.

j. Days. A reference to calendar days, unless otherwise specified.

k. 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.

l. District Office. The Manufacturing Inspection District Office (MIDO), and where applicable, Certificate Management Office (CMO), having CM responsibility for a defined geographical area.

m. Evaluation. A systematic and independent examination of an established PAH or associated facility system based on the system elements defined in Order 8100.7.

n. Foreign Manufacturer. A person other than an FAA production approval holder who causes a product or part(s) thereof to be produced outside the United States.

o. Group I Facility. A PAH or associate facility identified by risk management assessment as having the greatest potential to produce nonconforming products or parts thereof.

p. Group II Facility. A PAH or associate facility identified by risk management assessment as having a moderate potential to produce nonconforming products or parts thereof.

q. Group III Facility. A PAH or associate facility identified by risk management assessment as having a low potential to produce nonconforming products or parts thereof.

r. Group IV Facility. A PAH or associate facility identified by risk management assessment as having little or no potential to produce nonconforming products or parts thereof.

s. Inspection System. The total network of administrative and technical data at an APIS or PMA holder required to control the product or part(s) thereof to 14 CFR.

t. Internal Procedure. A PAH's or associate facility's procedures that are not included as part of the FAA-approved data.

u. Manufacturer. A person as defined by 14 CFR part 1, Definitions and Abbreviations, who causes a product or part(s) thereof to be produced. A manufacturer may be a PAH or a supplier to a PAH.

v. 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.

w. Ongoing Certificate Management. The performance of CM requirements based on risk management that may be accomplished on a continuing basis.

x. Part(s) Thereof. Any part, material, appliance, system, subassembly, assembly, or software used in a product.

y. Production Approval. An authorization, approval, or certificate issued by the FAA that allows a manufacturer to produce products or parts thereof in accordance with FAA-approved design and an FAA-approved quality control or inspection system.

z. 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) thereof. [A person who has been issued a production approval by the FAA.]

aa. Principal Inspector. A manufacturing inspector who has been assigned CM responsibility of a particular PAH or associate facility.

bb. Produce. To manufacture, or cause to be manufactured, a product or part(s) thereof.

cc. Product. Aircraft, aircraft engine, or propeller.

dd. Production Certification Board. An FAA evaluation function consisting of a selected group of FAA specialists acting under the direction of the Production Certification Board (PCB) chairperson for the purpose of determining eligibility of the holder of a TC or an STC, or a licensee, for the issuance of a PC.

ee. 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.

ff. 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.

gg. Quality Control Data. Data that provides 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 thereof.

hh. 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.

ii. Random Certificate Management. The performance of CM tasks that may be accomplished on an as-needed basis.

jj. Random Sampling. A sampling procedure that ensures that each element in a population has an equal chance of being selected.

kk. Risk Management. A method of categorizing PAH's and associate facilities that provides for effective FAA CM resource deployment.

ll. Root Cause. The underlying cause of a systemic or recurring noncompliance, usually identified through structured analysis.

mm. 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.

nn. 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.

oo. Supplier. Any person or organization contracted to furnish aviation products, parts, appliances, components, materials, or services (at any tier).

7. 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 9, Forms Listing, provides a listing of the forms and their sources.

8. RELATION TO OTHER DIRECTIVES. 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.

9. 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. Any deficiencies found, clarifications needed, or improvements regarding the content of this order should be forwarded to the Planning and Financial Resources Management Branch, AIR-530, Attention: Directives Management Officer, for consideration. FAA Form 1320-19, Directive Feedback Information, is located on the last page 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.

10. 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.

11. 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.

12. 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.

13. RECORDS MANAGEMENT. Refer to Orders 0000.1, FAA Standard Subject Classification System, 1350.14, Records Management, and 1350.15, Records Organization, Transfer, and Distribution Standards, 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-W1 for guidance regarding the content, filing, and storage location of records related to the applicant/PAH. All records must be in accordance with documents referenced in this order by April 30, 2009. *

14.-19. RESERVED.

CHAPTER 2. PROCEDURES FOR ISSUING A PRODUCTION APPROVAL

SECTION 1. INTRODUCTION

20. GENERAL. 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

21. APPLICABILITY. Part 21, subpart F, is applicable to a manufacturer of a product or part(s) thereof without benefit of a PC.

22. PRIVILEGES. A manufacturer of a product or part(s) thereof in accordance with part 21, subpart F, is not granted any privileges. However, upon establishment of an 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 represent the Administrator as an Organizational Designated Airworthiness Representative (ODAR). FAA Order 8100.8, Designee Management Handbook, contains procedures for the administration of DMIRs and ODARs.

23. ADVISING THE APPLICANT. When production under the provisions of part 21, subpart F, is indicated, a 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) thereof 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 thereof 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 23k 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 district office (DO) audit at the new production facility. If a DO 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

24. 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) thereof 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) thereof inspected has a complete inspection record. Refer to figure 1 for a sample form.

25. 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.

26. 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 for a sample extension letter.

27. 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

28. 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 3 for a sample form.

FIGURE 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

FAA Form 8100-1 (5-92) Supersedes Previous Edition

(Instruction on page 2)

FIGURE 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. Ie., 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)

FIGURE 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 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:**	**P.C. No.**
	☒ New production certificate ☐ Additions to production Certificate *(Give 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

29. 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 1 of this order. Any inadequacies in the data submitted must be identified to the applicant for corrective action. After the data has 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 this data since there is no part 21 requirement for submittal of this data for approval.

30. 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.

31. PRELIMINARY DO AUDIT. When the MIDO has determined that the applicant has the capability to comply with § 21.125, the MIDO will conduct a DO audit as follows:

a. The DO audit evaluates the applicant's production facilities in accordance with 14 CFR, the FAA-approved design data, and the production inspection system data accepted in paragraph 29 of this order. The cognizant MIDO manager will select a team to conduct this audit. The team may consist of the cognizant principal inspector (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 7.

b. Notifying the Applicant. Upon completion of the DO 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 DO 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 8 for a sample Form 8120-14.

32. 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 thereof 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 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 49 of this order.

PART 4. ISSUANCE OF AN APIS

33. 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 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.

34. INITIAL RISK MANAGEMENT ASSESSMENT. Subsequent to the approval of the APIS, the MIDO/CMO will conduct a risk management 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 16 of this order.

35.-40. RESERVED.

FIGURE 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 thereof 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 4. SAMPLE LETTER FOR APPROVING A MANUFACTURER'S PRODUCTION INSPECTION SYSTEM (CONT'D)

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) thereof conforms with the type design data and is in a condition for safe operation.

FIGURE 4. SAMPLE LETTER FOR APPROVING A MANUFACTURER'S PRODUCTION INSPECTION SYSTEM (CONT'D)

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) thereof 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) thereof 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

41. APPLICABILITY.

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

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

(2) The 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 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 an 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.

42. 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 Organization Designation Authorization (ODA). Orders 8100.8 and 8100.15 contain procedures for the administration of DMIRs and ODAs, respectively.

43. 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 Aircraft Certification Office (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 DO audit at the new production facility or moved facility. If a DO 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 thereof 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 43d(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

44. APPLICATION. Application for a PC is made on Form 8110-12. Refer to figure 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 43d(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 DO audit to determine compliance with applicable regulations. A copy of the letter should be forwarded to the MIO. Refer to figure 5 for a sample letter.

45. PRELIMINARY DO AUDIT. The MIDO/CMO should make arrangements to conduct a DO 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 1 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 14 CFR, the FAA-approved design data, and the QC data approved in paragraph 45a 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 7.

c. Notifying the Applicant. Upon completion of the DO 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 DO 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 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

46. GENERAL. 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 51b(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.

47. 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.

48. 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, a meeting of FAA personnel will be held to review the results of the DO 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 45 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 7 and 8 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 8 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.

49. 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.

50. 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

51. 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 6 and 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 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.

(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 45, 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.

FIGURE 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

The United States of America
Department of Transportation
Federal Aviation Administration

Production Certificate

Number **6CE**

This certificate, issued to
ABC AIRCRAFT COMPANY
whose business address is
4954 AIRPORT DRIVE
KANSAS CITY, MISSOURI
and whose manufacturing facilities are located at
752 PRIMROSE LANE
St. LOUYS, MISSOURI
authorizes the production, at the facilities listed above, of reasonable duplicates
of **airplanes**
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 **5 May, 1999.**

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.***

By direction of the Administrator

Date issued:
August 10, 1999

J.J. Jones . *J. J. Jones*
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**

Sample

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 (12-69) SUPERSEDES FAA FORM 333

FIGURE 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

(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)

Sample

FIGURE 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.)

(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 is revised as necessary.

3 The engineering data submitted for the STC approval provides 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.

52. INITIAL RISK MANAGEMENT ASSESSMENT. Subsequent to the issuance of the PC, the MIDO/CMO will conduct a risk management 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 16 of this order.

53.-55. RESERVED.

SECTION 4. TECHNICAL STANDARD ORDER AUTHORIZATION (PART 21, SUBPART O)

PART 1. GENERAL

56. 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.

57. 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.

58. 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 thereof 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 DO audit at the new production facility or moved facility. If a DO 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 58f(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

59. APPLICATION.

a. An applicant (or an applicant's authorized agent) must submit an application for a TSO authorization by letter to the Manager, Aircraft Certification Office (ACO), in the region 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.

60. 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.

61. PRELIMINARY DO AUDIT. At the request of the ACO, the MIDO should make arrangements to conduct a DO 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 1 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 has 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 14 CFR, the FAA-approved design data, and the QC data approved in paragraph 61a 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 7 and 8 of this order.

c. Reporting. The MIDO will advise the ACO concerning the results of the DO 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

62. 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 DO audit.

63. 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.

64. INITIAL RISK MANAGEMENT ASSESSMENT. Subsequent to the issuance of the TSO authorization, the MIDO/CMO will conduct a risk management assessment of the TSO 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 16 of this order.

65.-67. RESERVED.

SECTION 5. PARTS MANUFACTURER APPROVAL (PART 21, SUBPART K)

PART 1. GENERAL

68. 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.**

69. 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.

70. 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 70b(3)(a) and 70b(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

71. 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 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).

(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. In addition, the document should attest that the licensed components have service histories with no known problems causing unsafe conditions. 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 "PMA assist letter" must include the following information, as appropriate:

1 Product model, name, and TC/STC number.

2 A statement that the PMA applicant is authorized to use the design data as identified by part name, drawing number, and revision level.

3 Information describing the authority of the PMA applicant to use the TC or STC holder's part number and other part marking information.

4 Information that establishes the life limits or airworthiness limitations of the part.

FIGURE 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

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

6 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 must describe how design change information will flow to the applicant, and consequently, to the FAA.

(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 supports 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 11 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 2 of this order.

72. 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.

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 12, condition 13, of this order.

FIGURE 10. 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: SE25206 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: SE25207 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. The type design being used by the PMA applicant is in compliance with any and all applicable airworthiness directives.

The above-named manufacturer is hereby authorized to use the approved (type design) data noted in the third column herein to manufacture replacement components (column 1). The PMA applicant will use General Air Corp. quality assurance processes to control design changes and disposition nonconforming parts. This certification may be used as part of the application for PMA (14 CFR § 21.303).

Approved:
General Air Corp.

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

PAGE 1 OF 1

c. Preliminary DO Audit. Prior to the original issuance of a PMA, the MIDO will conduct a DO 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 DO 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 10 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. The MIDO should ensure the "PMA assist letter" includes the information specified in paragraph 71a(4)(a) of this order.

g. Identicality Finding. Based on the review of the "PMA assist letter" that contains the information specified in paragraph 71a(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 11 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

73. 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.

FIGURE 11. 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: SE 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

74. 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 12 for a sample PMA letter.

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

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

75. INITIAL RISK MANAGEMENT ASSESSMENT. Subsequent to the issuance of the PMA, the MIDO/CMO will conduct a risk management 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 16 of this order.

PART 4. POST-PMA ACTIVITIES

76. 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.

77. TRANSFERABILITY. 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.

78. 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.

79. 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 21.

FIGURE 12. 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, meets 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.

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;

FIGURE 12. SAMPLE PMA LETTER (CONT'D)

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.

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.

FIGURE 12. SAMPLE PMA LETTER (CONT'D)

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 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 letter dated September 10, 2004, meets 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

80. 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.

81.-84. RESERVED.

SECTION 6. EXTENSION OF A PRODUCTION APPROVAL WITHIN THE UNITED STATES

PART 1. GENERAL

85. 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.

86. 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.

87. 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) thereof, 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 thereof and to the same extent as the original PAH.

b. When the associate facility produces the complete product or part(s) thereof 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 DO 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 DO.

PART 2. PROCESSING A REQUEST FOR EXTENSION OF A PRODUCTION APPROVAL

88. 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.

89. 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 thereof 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).

90. COORDINATION WITH THE GEOGRAPHIC DISTRICT OFFICE. Following the evaluation of the request from the original PAH, the MIDO/CMO will contact the DO 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 DO informing it of the request, a copy of the extension request, and the evaluation results. Refer to figure 14 for a sample memorandum.

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

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

(1) Reporting of DO 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

91. APPROVAL OF THE REQUEST. After satisfactory completion of the DO audit and any applicable corrective actions taken, the MIDO/CMO will approve the request. The MIDO/CMO will ensure the original PAH provides the DO 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 DO of the associate facility.

92. 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.

FIGURE 14. SAMPLE HAND-OFF MEMO FOR REQUESTING A DO AUDIT AND CM

Federal Aviation Administration

Memorandum

Date:	March 29, 2005
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 District Office Audit and Certificate Management at ABC Company

This office has received a letter from Airplane Aircraft Company, dated March 6, 2005 (attached), requesting an extension of its production approval to the ABC Company.

In accordance with FAA Order 8120.2E, paragraph 89, 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 DO 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 14. SAMPLE HAND-OFF MEMO FOR REQUESTING A DO AUDIT AND CM (CONT'D)

2

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. DO 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 DO 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 14. SAMPLE HAND-OFF MEMO FOR REQUESTING A DO AUDIT AND CM (CONT'D)

3

Document Certificate Management Activity in CMIS

After your satisfactory completion of the DO 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 8120.2E. 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

SECTION 7. NON-U.S. MANUFACTURING FACILITIES—DETERMINATION OF UNDUE BURDEN AND NO UNDUE BURDEN

93. 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.

94.-95. RESERVED.

CHAPTER 3. CERTIFICATE MANAGEMENT PROCEDURES

SECTION 1. INTRODUCTION

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

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

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

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

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

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

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

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

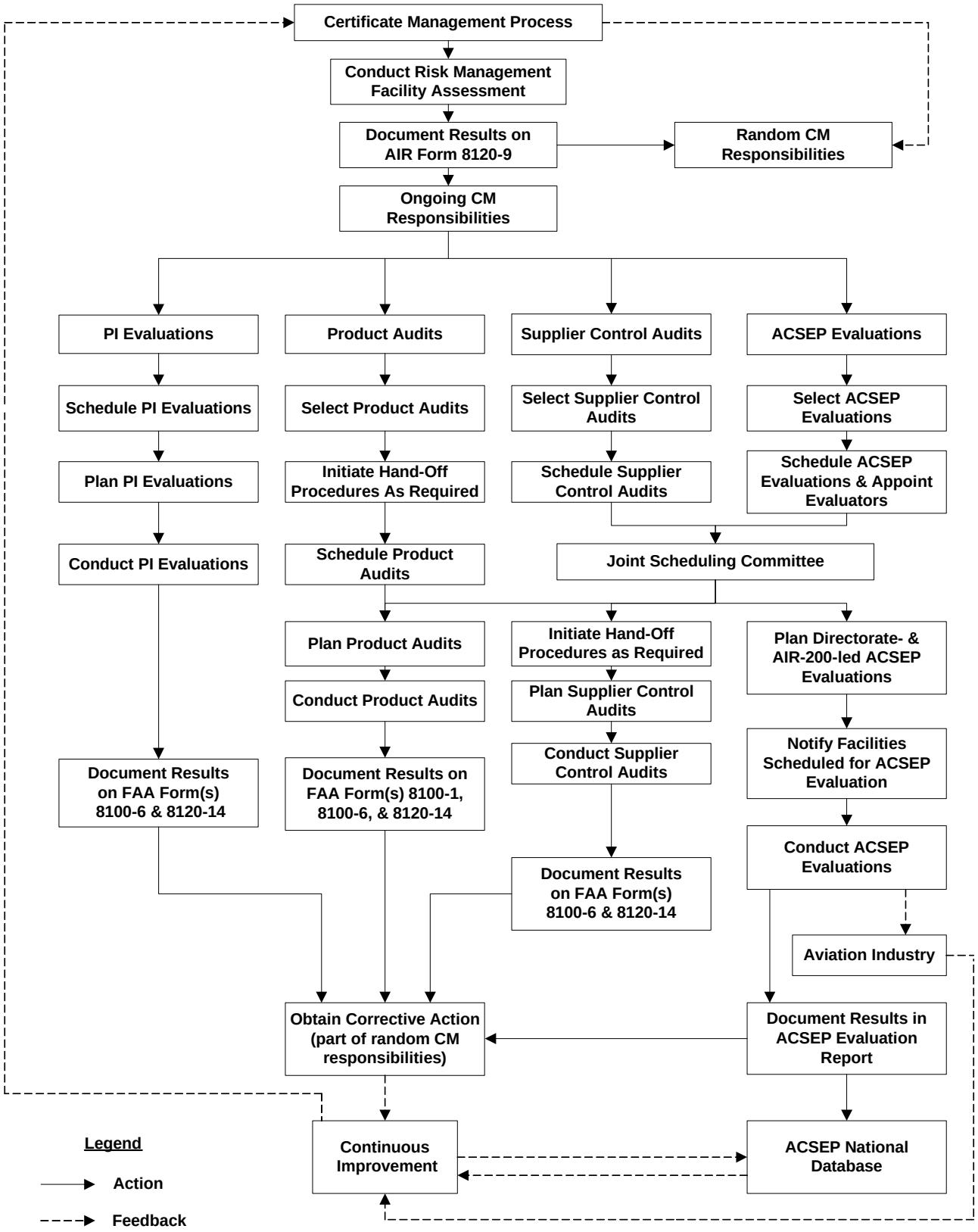
(2) Investigate service difficulties that involve quality control or inspection problems.

(3) Investigate regulatory violations.

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

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

FIGURE 15. CERTIFICATE MANAGEMENT LIFE CYCLE PROCESS



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

97. ASSIGNMENT OF CM COORDINATOR. Many of the tasks identified in this chapter for MIO, MIDO, or CMO managers are primarily administrative. A high degree of operational efficiency may be achieved by assigning many of these tasks to a designated CM coordinator. Directorate managers should consider whether such an assignment would be beneficial for their organizations. The types of tasks that a CM coordinator could coordinate are as follows:

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

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

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

d. Dissemination of general CM-related information.

98. STATUS OF A PAH. For purposes of CM, the status of a PAH and its applicable project(s) can be identified as one of the following:

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

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

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

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

99.-102. RESERVED.

SECTION 2. ONGOING CM RESPONSIBILITIES

PART 1. INTRODUCTION

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

FIGURE 16. CERTIFICATE MANAGEMENT RESPONSIBILITIES (ONGOING)
Minimum Requirements

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

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

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

104. CERTIFICATE MANAGEMENT PLAN. A CM plan assists the PI in planning and tracking the performance of ongoing CM responsibilities. Each MIDO/CMO may prepare a CM plan annually for each PAH and associate facility after risk management assessments have been completed, within a timeframe established by the MIO. The MIDO/CMO may subsequently amend the CM plan as necessary to include additional or reduced requirements and schedule changes. As a minimum, the CM plan should include the following:

a. Name of PAH or associate facility.

b. Current risk management group and category.

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

d. List of hand-offs or CAA requests sent, including, as a minimum, the name of the geographic MIDO/CMO that has accepted the hand-off or the CAA that has accepted the request, the type of audit requested, the name of the facility receiving the audit, and the name of the responsible PAH or associate facility.

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

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

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

(1) Identity of the facility to be audited.

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

(3) Date(s) of the audit.

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

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

b. Provide the managing office with details of any finding or observation (noncompliance) encountered during the audit. For example, if there is a trend showing recurring test failures or nonconforming articles, it may be evidence of a system breakdown or a compliance problem at that facility. The managing office will determine if there are any system issues or major problems that should be forwarded to the applicable CAA for its consideration.

106. RECORDING NONCOMPLIANCES. The PI will record all noncompliances, including those reported by a CAA while performing CM activities for the FAA, on Form 8100-6, in accordance with paragraph 1b and the guidelines listed in appendix 7 of this order. The FAA will notify a PAH of noncompliances found at its supplier. For all other circumstances, the FAA will not reveal noncompliances to a manufacturer other than the particular manufacturer involved unless a formal request has been processed in accordance with the Freedom of Information Act. Reference Order 1270.1.

107. RESERVED.

PART 2. RISK MANAGEMENT

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

e. The PI will complete AIR Form 8120-9 in accordance with the instructions provided in CMIS.

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

FIGURE 17. SAMPLE AIR FORM 8120-9

U.S. Department of Transportation
Federal Aviation Administration

Risk Management Facility Assessment Sheet

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

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

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

Criticality: Category 1 Product, Part or Appliance

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

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

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

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

Facility Name: XYZ Aircraft Company

Response Date: 3/11/05

Project #: PA9999CE

MIDO/CMO: Orlando

Principal Inspector: Smith

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

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

Assigned risk management group:	II

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

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

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

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

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

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

c. Significant change in key management.

d. Significant turnover of critical staff.

e. Significant increase or reduction in workforce.

f. Deliberate non-responsiveness to corrective action requests.

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

h. Addition of a complex manufacturing process.

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

j. Significant quality or inspection system changes.

k. Significant increase in the use of foreign suppliers.

l. Movement or shift of production location or volume.

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

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

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

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

117.-122. RESERVED.

PART 3. SUPPLIER CONTROL

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

123. GENERAL. A PAH or associate facility may utilize suppliers when it has established an FAA-approved QC or inspection system that provides assurance that all parts or services furnished by its suppliers are in compliance with its particular production approval and 14 CFR. The PAH or associate facility should:

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

(1) Where the supplier may be located.

(2) Whether the parts received by the PAH or associate facility are also FAA-approved (PMA or TSO).

(3) Whether materials are accompanied by airworthiness approval tags, or their equivalent, issued by the CAA of a bilateral country.

(4) Whether materials or equipment are supplied by the end product purchaser (customer-furnished equipment, buyer-furnished equipment, or government-furnished equipment).

(5) Whether the FAA performs an audit at the supplier.

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

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

(8) Whether the quality data received from the supplier are in English.

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

(1) Authorizes to the supplier, in writing, the authority to ship directly to a user/operator. An individual written authorization is not required for each direct shipment. The authorization may include limitations such as specific part number(s), time periods, or particular user/operators. This authorization will be maintained by the PAH or associate facility for review by the cognizant MIDO/CMO.

(2) Includes, in its FAA-approved quality control or inspection system, controls to compensate for the absence of inspection normally conducted at the PAH's or associate facility's location, e.g., receiving inspection and test. Compensating factors should include on-site evaluations of the supplier and the inspection of the part at the supplier by:

(a) The PAH or associate facility, or

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

(3) Ensures that each part so shipped is accompanied by a shipping ticket, invoice, or other document containing a declaration that the individual part was produced under the terms of the production approval, and that inspection/acceptance has been accomplished by either the PAH/associate facility or by delegated inspection authority. The shipping document for parts manufactured under PMA, PC, APIS, and TC Only also should identify the product on which the part is eligible for installation. The shipping document for subcomponents manufactured for TSO articles should contain the TSO number. When FAA Form 8130-3, Airworthiness Approval Tag, is used for this purpose, the direct-ship authorization will be annotated in accordance with FAA Order 8130.21, Procedures for Completion and Use of FAA Form 8130-3, Authorized Release Certificate, Airworthiness Approval Tag.

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

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

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

d. Make available to the FAA a current list of its suppliers.

e. Notify its suppliers that its facilities are subject to FAA CM.

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

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

b. Supplier Control Audit. Refer to part 3 of this section. Specifically, the PI will determine that the supplier complies with purchase order and/or quality requirements. In some instances, this activity may be handed off to another MIDO/CMO, or may require CAA assistance.

125. DETERMINATION OF SUPPLIER CONTROL. The PI may determine whether a PAH or associate facility is controlling its suppliers by reviewing the results of the PI evaluation at the PAH or associate facility, when applicable, and the results of the supplier control audits at the selected PAH/associate facility suppliers, including the results of all applicable CAA audits. This review should be accomplished annually, immediately following the last scheduled supplier control audit, PI evaluation, or CAA audit, whichever occurs last. During the review, the PI should look for evidence that may indicate a system breakdown in supplier control by the PAH or associate facility. When a systemic noncompliance is identified, the PI should prepare Form 8100-6 and retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. The PI should request corrective action for a system breakdown in accordance with section 3, part 5, of this chapter.

126.-128. RESERVED.

SUBPART B. SUPPLIER CONTROL AUDIT

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

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

a. Group I Facility.

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

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

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

b. Group II Facility.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Hand-Offs. MIO managers should accept and support hand-offs of supplier control audits that are scheduled within the minimum requirements of paragraph 129 of this order. MIO managers should ensure that supplier control audits that are handed off to their directorates are added to their directorate supplier control audit lists and scheduled. Updated directorate supplier control audit lists should be provided to the other MIO managers before the ACSEP Joint Scheduling Committee meeting. There should be no hand-offs of supplier control audits that are scheduled beyond the minimum number required, unless an agreement is made with the MIO of the directorate where the supplier is located. Contentious hand-offs, such as those that have significant resource implications, should not be scheduled at this time. Participants should discuss contentious hand-offs and agree on an appropriate solution.

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

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

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

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

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

(3) A copy of the PAH's, or supplier's, QC or FIS procedures that are required to be implemented at the particular supplier's facility, unless these documents are available to the FAA at the supplier's facility.

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

(5) Any authority permitting direct shipment.

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

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

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

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

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

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

c. Corrective Action Validation. Occasionally, it may be necessary to validate corrective actions at a supplier facility located outside of the geographical boundary of the responsible CM office. When a hand-off to the geographic MIDO/CMO is appropriate for this purpose, the following hand-off procedures will be used:

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

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

(b) The name, title, and telephone number of the person to contact at the supplier and PAH facilities that can furnish purchase order(s), QC or FIS data, technical data, or other pertinent information.

(c) A copy of the PAH's or supplier's QC or FIS procedures that are required to be implemented at the particular supplier's facility, unless these documents are available to the FAA at the supplier's facility.

(d) A copy of the noncompliance.

(e) A copy of the PAH's corrective action response.

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

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

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

(b) Submit a memorandum to the requesting MIDO/CMO upon completion of the corrective action validation. This memorandum should summarize the results of the validation, and include all applicable Form(s) 8100-6 or 8100-1, or printed copies of electronic equivalents. The requesting MIDO/CMO will consider its hand-off request complete upon receipt of this memorandum.

134. NOTIFYING A PAH OR ASSOCIATE FACILITY. Prior to conducting a supplier control audit, the MIDO/CMO that will be conducting the audit will notify the responsible PAH or associate facility. The PI should prepare a notification letter and send it to the PAH no later than 30 days prior to the audit. The PAH is responsible for notifying the supplier of the scheduled supplier control audit. If changes occur after the notification letter has been sent, notify the PAH by letter or other appropriate means. If a supplier control audit has been handed off as described in paragraph 133b of this order, the office receiving the request will send the notification letter to the PAH or associate facility and provide a copy to the requesting office. Figure 18 contains a sample notification letter.

135. CONDUCTING AND RECORDING A SUPPLIER CONTROL AUDIT. Every effort should be made to conduct a supplier control audit when the supplier has an active purchase order from the PAH or associate facility. The supplier control audit will be conducted using the PAH's quality flow-down requirements noted on the applicable purchase order. Quality flow-down requirements may include, but are not limited to, the control of raw and nonconforming materials, records, sample plans, inspection systems, calibration systems, certificates of conformance, software, age-controlled products, special processes, first article inspections, subtier suppliers, and design data.

a. If circumstances arise and an active purchase order is not available, a supplier control audit still may be accomplished utilizing historical records that are traceable to the PAH's quality flow-down requirements noted on an applicable purchase order.

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

FIGURE 18. SAMPLE SUPPLIER CONTROL AUDIT NOTIFICATION LETTER

U.S. Department
of Transportation

Federal Aviation Administration

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

July 13, 2001

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

Dear Ms. Brown:

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

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

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

Sincerely,

Julia Gotta

Julia Gotta
Seattle Manufacturing Inspection
District Office

cc: Fort Worth MIDO

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

136.-138. RESERVED.

PART 4. PRINCIPAL INSPECTOR EVALUATION

139. GENERAL. A PI evaluation is an evaluation conducted by a PI at a PAH or associate facility, normally by the PI assigned CM responsibility. If specific expertise is required during a PI evaluation, the PI should advise the MIDO/CMO manager. A PI evaluation will be scheduled using the risk management group and category assignment determined under part 2 of this section. Refer also to figure 16 of this order. ACSEP system element criteria from Order 8100.7 will be used to conduct PI evaluations. The PI evaluation will be scheduled and conducted as follows:

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

a. Group I Facility.

(1) Category 1 or 2 Facility.

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

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

(2) Category 3 Facility.

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

(b) Evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data, WILL BE completed at least once in the 12-month period.

b. Group II Facility.

(1) Category 1 or 2 Facility.

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

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

(2) Category 3 Facility.

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

(b) Evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data, WILL BE completed at least once in the 12-month period.

c. Group III Facility.

(1) Category 1 or 2 Facility.

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

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

(2) Category 3 Facility.

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

(b) Evaluation of the top four noncompliant system elements/subelements applicable at the facility, as identified annually by each directorate through an analysis of CMIS data, WILL BE completed at least once in the 24-month period.

d. Group IV Category 3 Facility.

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

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

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

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

141.-143. RESERVED.

PART 5. AIRCRAFT CERTIFICATION SYSTEMS EVALUATION PROGRAM EVALUATION

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

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

a. Group I Facility.

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

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

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

b. Group II Facility.

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

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

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

c. Group III Facility.

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

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

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

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

145.-147. RESERVED.

PART 6. PRODUCT AUDIT

148. GENERAL. A product audit evaluates the effectiveness of the PAH's or associate facility's quality control or inspection system and the airworthiness of products utilizing critical and certain non-critical characteristics and/or processing attributes generated during the manufacturing process. The product audit may be initiated at any point in the manufacturing process after inspections have been completed. The product audit is conducted at a production approval holder or associate facility, but may also be conducted at a supplier facility where a product or part(s) thereof is manufactured. If specific expertise is required during this audit, the PI should advise the MIDO/CMO manager. If a product audit is required in another geographic MIDO/CMO, the PI will comply with the hand-off procedures in paragraph 133 of this order. Product audits will be conducted in conjunction with every scheduled ACSEP evaluation. In addition, product audits are conducted in conjunction with scheduled PI evaluations as follows:

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

a. Group I Facility.

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

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

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

b. Group II Facility.

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

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

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

149. SELECTION OF PRODUCT AUDIT CHARACTERISTICS. The product audit will be conducted utilizing critical characteristics and/or critical processing attributes generated during the manufacturing process, as well as certain non-critical characteristics and/or non-critical processing attributes. These characteristics and attributes are defined as follows:

a. Critical characteristics are those where failure to maintain conformity could cause loss of function and create an unsafe condition. Critical process attributes are those where lack of conformity directly affects the product or part(s) thereof and could cause failure or create an unsafe condition. The selection of the critical characteristics and/or critical process attributes 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 website located at http://av-info.faa.gov/isdr/.

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

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

a. Final Product.

b. Subassembly.

c. Detail Parts.

d. Raw Material.

151. PRODUCT AUDIT CRITERIA. The audit criteria used in the performance of a product audit to establish conformity to approved type design are listed below. This audit criteria is a minimum and not all-inclusive. Figure 19 indicates which criteria are applicable to each product audit area, as a minimum.

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

a. Operational/functional. Verify that the subassembly or final product conforms to the functional/operational test criteria (e.g., revalidating test results, test setup, software revision, software checksum, rig approval, certified equipment, use of approved procedures, certified test parameters, use of required rig, and calibration).

b. Dimensional. Compare actual recorded measurement(s) of the selected characteristic with the approved design data. Verify characteristics are inspected using the correct calibrated tooling, gauging, fixtures, etc., surface finish dimensions and radius meet drawing tolerances, inspections are performed in proper sequence (following work instructions); e.g., review or revalidate inspection records.

c. Visual. Inspect part for obvious external defects; e.g., corrosion, burrs, handling damage, scratches.

d. Identification. Compare actual identification plates, tags, markings etc. with approved design data or purchase order requirements and verify that identification is maintained throughout the product line; e.g., part numbers, serial numbers, lot numbers for raw material, inspection stamps. For software revision verification, verify software part number can be displayed on screen or software load verified by documentation review.

e. Documentation. Verify the latest revision level or changes, proper work instructions, completed operations, proper authorizations; proper use of statistical sampling; e.g., certificate of conformance, work travelers, blueprints, specifications, first article inspection records.

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

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

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

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

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

153. RECORDING COMPLETION OF A PRODUCT AUDIT. The completion of a product audit will be recorded on Form 8120-14 by the person conducting the audit. However, Form 8120-14 is not required for an ACSEP evaluation. When a product audit is conducted in conjunction with a PI evaluation or a supplier control audit, it may be recorded on the same form prepared for those activities. When a product audit is conducted as a stand-alone activity, one form will be completed for each product audit completed. Prepare this form in accordance with appendix 8 of this order. The PI will retain all applicable objective evidence in accordance with Manual FAA-IR-04-01. Any corrective action required should be accomplished in accordance with chapter 3, section 3, part 5 of this order.

154.-156. RESERVED.

SECTION 3. RANDOM CM RESPONSIBILITIES

PART 1. INTRODUCTION

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

158.-159. RESERVED.

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

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

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

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

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

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

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

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

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

a. Identify any inadequacies found in the changed quality control or inspection system and request corrective action from the PAH.

b. After any required corrective actions have been taken, process the changes as follows:

(1) For changes to a quality system at a PC or TSO authorization holder, forward a letter to the PAH approving the quality system changes, including applicable changes submitted to the FAA-approved inspection and test procedures. Refer to the sample letter in figure 20.

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

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

164.-167. RESERVED.

PART 3. INVESTIGATION OF SERVICE DIFFICULTIES

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

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

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

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

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

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

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

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

U.S. Department
of Transportation
Federal Aviation Administration

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

August 10, 2000

ABC Aircraft Company
4954 Airport Drive
Renton, Washington 12345

Notification of Quality Control System Change Status

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

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

Document Name: Quality Management Manual.

Document Number: 101248

Revision Number: C

Date: June 30, 2000

Dewey Revu

Dewey Revu
[Principal Inspector or Manager]

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

U.S. Department
of Transportation
Federal Aviation Administration

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

July 26, 2000

ABC Aircraft Parts Company
4954 Airport Drive
Newington, Connecticut 12345

Notification of Inspection System Change Status

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

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

Document Name: Inspection System Manual

Document Number: 11204

Revision Number: F

Date: March 15, 2000

Duke E. Season

Duke E. Season
[Principal Inspector or Manager]

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

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

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

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

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

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

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

171. REPORTING A SERVICE DIFFICULTY INVESTIGATION.

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

(1) Name and address of manufacturer.

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

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

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

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

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

(7) Effect on products in service.

(8) Recommendations and/or further actions required.

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

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

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

172. FOREIGN MANUFACTURERS. Foreign manufacturers are exempted from the reporting requirements of § 21.3. When foreign manufactured products or articles approved under § 21.29, § 21.502, or § 21.617 are involved in service difficulties, the MIO in the directorate where the service difficulty occurred will initiate an investigation. A complete report will be provided to the MIO and Standards Staff of the Directorate having geographical responsibility over the particular country where the product or article manufacturer is located. Upon receipt and evaluation of the report, the MIO having geographical responsibility will bring the matter to the attention of the CAA for further investigation and corrective action as necessary. If critical parts, processes, or methods are involved, airworthiness directives or alert bulletin action should be considered. If the condition is serious and affects safety and if adequate corrective action is not immediately forthcoming from the foreign manufacturer or CAA, action under § 13.19 would also be necessary. Coordinate such enforcement action through the Assistant Chief Counsel, Enforcement Division, AGC-300, AIR-40, and the State Department.

173.-175. RESERVED.

PART 4. INVESTIGATION OF REGULATORY VIOLATIONS

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

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

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

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

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

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

182.-184. RESERVED.

PART 5. CORRECTIVE ACTION

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

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

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

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

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

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

* **c.** When a determination is made in accordance with appendix 7 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) The PI will 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 22 for applicable flowchart): *

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

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

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

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

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

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

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

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

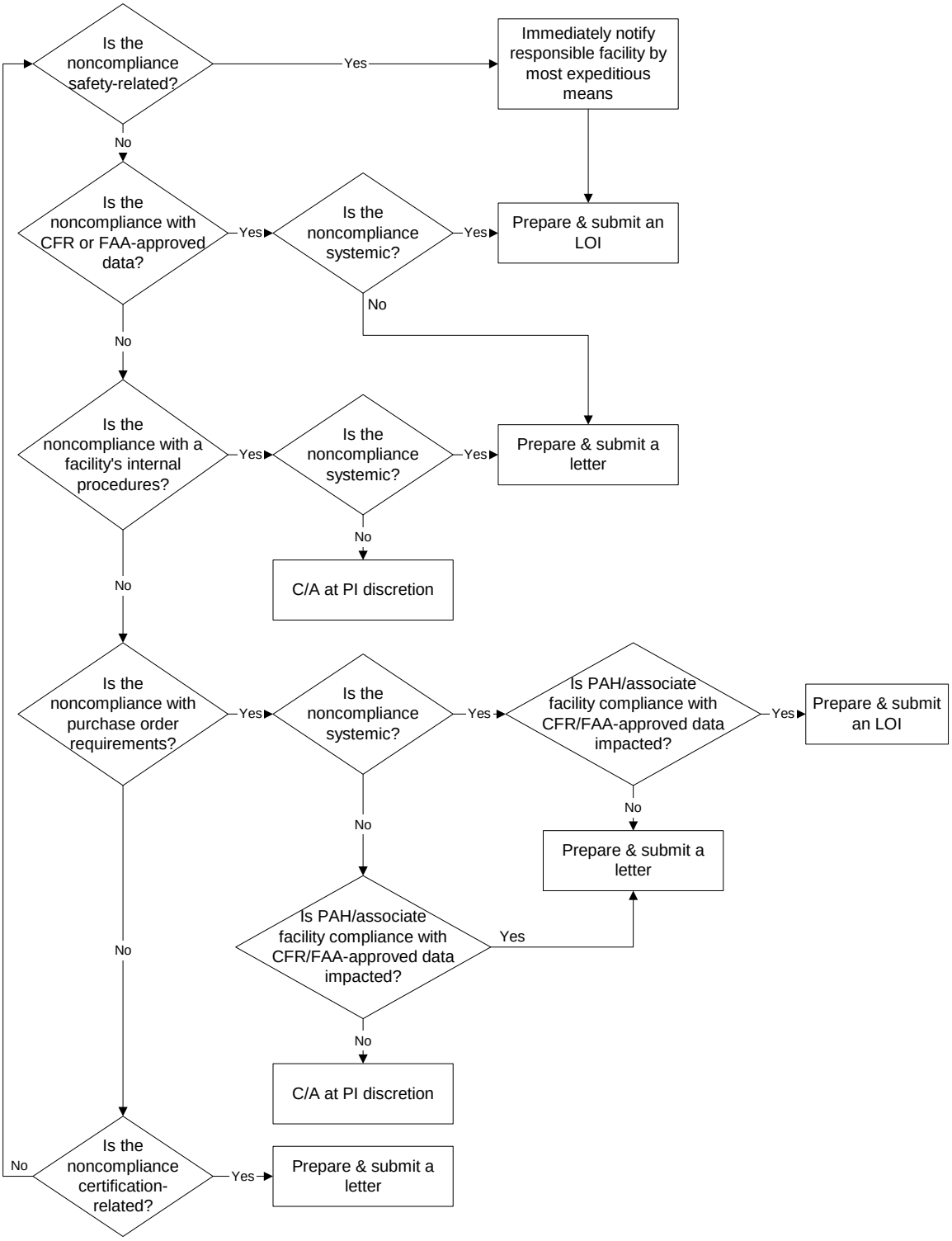
(7) Isolated Noncompliance with Purchase Order Requirements (by a Supplier to a PAH or Associate Facility).

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

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

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

FIGURE 22. CORRECTIVE ACTION FLOWCHART



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

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

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

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

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

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

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

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

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

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

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

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

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

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

189.-191. RESERVED.

PART 6. UNSCHEDULED AUDITS, EVALUATIONS, OR INVESTIGATIONS

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

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

a. Accidents and incidents.

b. Deliberate violations.

c. Repetitive SDRs.

d. SUP investigations.

e. Excessive owner/operator complaints.

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

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

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

i. Relocation of production facility.

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

(1) A CAA request should include clear, concise, and specific instructions to the FAA that includes the following: company name, address, phone number, and point of contact; details concerning the extent of surveillance to be conducted on behalf of the CAA; and, documentation to be submitted to the CAA. The responsible geographic MIO will ensure that the request is complete before assigning it to a MIDO/CMO.

(2) The responsible geographic MIDO/CMO will review all completed documentation being submitted to the CAA to ensure the requirements of the CAA request have been met. On completion of the review, and incorporation of any applicable corrections, the responsible geographic MIDO/CMO will prepare a cover letter to accompany the documentation and forward it to AIR-40 for review and comment. After incorporating any applicable corrections to the cover letter, the completed documentation and cover letter will be forwarded to the MIO manager for signature. The MIO manager will forward all documentation to the requesting CAA.

(3) When the CAA conducts its own surveillance activities at a U.S. manufacturer, the FAA may be invited to observe or participate. The responsible geographic MIDO/CMO should consider accepting the CAA invitation only when there is no impact on scheduled ongoing CM activities or other random CM activities with higher priority.

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

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

195.-197. RESERVED.

PART 7. PROVIDING GUIDANCE TO A PAH OR ASSOCIATE FACILITY

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

a. Quality control or inspection system changes.

b. Facility changes.

c. Technical assistance.

d. Updating supplier lists.

e. Service difficulty and corrective action review.

f. Support of ACSEP evaluations.

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

h. Understanding of applicable regulations.

APPENDIX 1. 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. This 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 has 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 thereof 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 is 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 is 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) thereof 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 thereof that have left a PAH's quality system. The process must ensure the following criteria are met:

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

(2) The products or parts thereof 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 thereof meet their type design. When a determination cannot be made by a visual inspection, the products or parts thereof must be re-introduced to the quality control or inspection system at a point where functional testing is possible.

APPENDIX 1. EVALUATION OF A PAH'S QUALITY OR INSPECTION SYSTEM (CONT'D)

h. New products and parts thereof 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 thereof 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 thereof 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 thereof. 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 thereof.

(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 time frame, production sequence, tooling configuration, operator(s), batch, etc. In order 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 thereof conform to the approved design data.

APPENDIX 1. EVALUATION OF A PAH'S QUALITY OR INSPECTION SYSTEM (CONT'D)

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 has 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. This 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 has 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 this data since there is no part 21 requirement for submittal of this data for approval. This 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 2. 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.

APPENDIX 2. FABRICATION INSPECTION SYSTEM (CONT'D)

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.

APPENDIX 2. FABRICATION INSPECTION SYSTEM (CONT'D)

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.

APPENDIX 2. FABRICATION INSPECTION SYSTEM (CONT'D)

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.

APPENDIX 2. FABRICATION INSPECTION SYSTEM (CONT'D)

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 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA

1. PURPOSE. This appendix provides additional guidance to assist the PI in completing the assessment section of the Risk Management Facility Assessment Sheet.

2. SPECIFIC GUIDANCE. There are 21 risk management indicators in the automated Risk Management Facility Assessment Sheet. These indicators are listed in figure 1 of this appendix. The PI must assess each of these indicators. The criteria listed below provide guidance to assist the PI in completing this assessment. The criteria are 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 in parentheses to each criteria corresponds directly with the indicator number on the automated Risk Management Facility Assessment Sheet.

FIGURE 1. RISK MANAGEMENT INDICATORS

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

a. Change in Key Management (1). Management changes can have a significant impact, positive or negative, on a company and its production/quality profile. In rating this indicator, consider the following:

(1) Management changes generally have a greater impact on small companies than on large companies, all other things being equal.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

(2) Key managers may include people such as the director of quality/quality manager, facility manager, chief engineer, section or line managers, DOA/DAS coordinator, or company president/CEO.

(3) The background of new management personnel is key. In general, internal selections are 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 14 CFR and experience with the FAA are important.

(4) 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 amount of production/quality oversight within the company. New programs or product lines may alter existing lines of authority and supervision. Ownership changes may result in wholesale replacement of managers.

(5) 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 14 CFR and on quality. Cost-cutting and greater "bottom line" pressure can undermine or dilute a company's quality orientation.

b. Turnover of Critical Staff (2). Loss of staff members who play a critical role in ensuring quality can dramatically impact the production of conforming products or parts thereof. Consultation with the appropriate ACO 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:

(1) Critical staff turnover generally has a greater impact on small companies than on large companies, all other things being equal.

(2) Critical staff may include people such as quality inspectors, foremen, engineers, test technicians, audit staff, designees; any one-of-a-kind specialty (e.g., level III nondestructive testing [NDT]); or any key FAA contact.

(3) If losses are replaced or backfilled, consider the background of new staff. As with key managers, internal selections are preferable to external hires, although a solid aviation or product background may compensate. Similarly, civil experience is generally better than military, due to 14 CFR/FAA familiarity. Technical expertise, however, is paramount for individuals in these key positions.

(4) 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 quality. If, on the other hand, the changes result from the end of a major project or program, there may be no cause for alarm.

(5) In any event, consider the strength of the company's quality system. If it's well established, with fully documented procedures, then it may be able to absorb the loss of key people without affecting quality. Consider whether the quality program remains intact, and is not being scaled back as these individuals leave.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

c. Reduction in Workforce/Layoffs (3). Workforce reductions and layoffs may or may not have an impact on quality; it depends on how and why they occur, and who's involved. Consider the following in assessing this indicator:

(1) Workforce reductions can generally be managed/absorbed more easily by large companies than by small companies, all other things being equal.

(2) The pace or rate of any reduction is important. If it's gradual, steady, and implemented over time, then there may be no cause for concern. On the other hand, if it's abrupt, haphazard, or uncoordinated, and/or occurs over a short timeframe, that's probably a sign of potential trouble.

(3) Obviously who is being downsized or laid off is critical. Assemblers and line staff may be of concern, while administrative and support staff probably won't be. Reductions in quality, engineering, or other areas key to FAA's interests should always raise a red flag.

(4) Another key consideration is the reason(s) for the reduction. If it's due to the end of a major program, or part of a normal industry cycle, it may not be problematic. Downsizing, streamlining, and reorganizations, by contrast, may be of concern depending on how they're handled. Any deemphasis on aviation work should be viewed with caution. In some cases, reductions may primarily involve the military versus the civil side of the house, and pose no great concern to the FAA.

(5) Whether or not the remaining staff are being retrained or crosstrained to perform new functions is also a factor here. The basic qualifications of staff performing key functions or roles, as well as the adequacy and effectiveness of any training provided to people assuming new or expanded duties, should be factored into your determination.

d. Expansion or Growth (4). A company's expansion or growth can also raise potential quality concerns. Again, the how and why of these events is what you should look at when evaluating this indicator:

(1) The speed and breadth of growth are critical. If it's controlled and steady, as opposed to rapid, "overnight" expansion, there's generally less potential for problems. If the growth involves opening a new facility or facilities, or results in new or additional geographical dispersion of the workforce, there could be quality issues.

(2) The nature of any growth also needs to be considered. More of what they've already been doing is generally not a problem. But if they're expanding into new business areas, product lines, technology, or production methods, watch out. Likewise, if they're acquiring new/additional approvals, heightened concern may be warranted.

(3) Don't overlook proxy growth, or internal growth, i.e., things that may not be immediately obvious. Greater use of outsourcing, subcontracting, or suppliers can expand a company's business without changing its staff or facility size. Similarly, an internal shift from military to civil work can significantly affect the quality picture. Generating more output with the same or fewer resources, through process streamlining or productivity enhancements, can also create de-facto growth.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

(4) The extent to which staff size and capability have kept pace with any growth is also important. If they've added people, particularly designees, and/or provided appropriate training to staff in any new areas, that's a sign of well-managed growth. The absence of such actions should probably raise a red flag.

e. Merger or Takeover (5). Mergers and takeovers have become increasingly common in the aviation industry. Who's buying and what they are doing to or with the acquired company and its system should drive your rating here:

(1) A key question is whether or not the buyer (company or individual) has an aviation background; if not, you may be in for problems, at least initially. If they do, prior FAA experience and knowledge of 14 CFR is an additional plus, since they'll know the ropes better and also have a compliance track record you can check.

(2) A second key consideration is the impact on quality system(s). If the companies' products are substantially different, integrating their quality systems may be challenging and problematic. If a current PAH is taken over, keeping the core system approved by the FAA intact is of prime concern. Retaining key people, or replacing them with qualified staff, is also important here.

(3) Some merger or takeover transactions have no real impact in terms of quality. The outcome may simply be a name change, and/or it may occur at a very high level, e.g., mega-mergers among major DOD contractors. In these cases there's often no impact on the civil side of the company, or the changes don't trickle down to affect the production approval holder level.

f. ACSEP or PI/CM Noncompliances (6). Noncompliances resulting from prior FAA evaluations of an approval holder are a key part of any company's quality track record. In evaluating this indicator, consider the following variables:

(1) Critical system elements generally include, but are not limited to, supplier control, manufacturing processes, special manufacturing processes, and design data control.

(2) Multiple noncompliances from any single ACSEP evaluation, or over the course of a year as a result of PI evaluations, product audits, and supplier control audits may be a signal of systemic problems. One or more safety-related noncompliances, or evidence that any system element is not under control, are also usually grounds for heightened concern.

(3) Any repeat noncompliances, either in ACSEP evaluations, PI evaluations, product audits, or supplier control audits, should raise a red flag. It's important, though, to consider how many full ACSEP evaluations the company has been through, and what the general trend in evaluation results has been. Companies that have been through multiple evaluations should, in general, perform better than first-timers. If they're not improving or holding steady, beware.

(4) Any sudden and/or significant negative change in a company's performance (e.g., from a single, minor noncompliance to multiple noncompliances, and/or the occurrence of safety issues) should be viewed with apprehension.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

g. Civil Penalties (7). Assessment of a civil penalty against a production approval holder is a significant sanction by the FAA. In evaluating this indicator for a given company, however, consider the following circumstances:

(1) The number, frequency, and nature of civil penalty actions is important. A single, isolated incident which resulted in a civil penalty may not be cause for alarm. Two or more civil penalties within one year, however, or any civil penalty based on safety-related items, generally should be considered problematic.

(2) The company's civil penalty history is also important in assessing this indicator. In particular, any repeat civil penalty items, or any civil penalty issued due to failure to comply with an earlier administrative action, should raise a red flag.

(3) The overall magnitude or impact of the violation(s) may also be relevant to your assessment. For example, if an infraction involved a large number of products or units in service, and/or a high dollar value of materials, its quality impact may be more significant. Likewise, civil penalties that resulted from a SUP investigation may also signal more serious problems.

h. Corrective Response History (8). An approval holder's corrective response history is an indication of how seriously the company takes its quality responsibilities. Key variables associated with this indicator include the following:

(1) PAH responsiveness to problems is an important consideration. Some hallmarks of responsiveness 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.

(2) In some cases non-responsiveness may be unintentional, or due to mitigating circumstances. Relatively new companies, for example, and/or companies with inexperienced staffs may not meet the standards defined above, at least initially. Non-responsiveness from companies that have held their approvals for more than a couple of years, however, should be considered a quality issue.

(3) The level of trust and quality of communication between the company and the FAA are also relevant to this indicator. Fast, professional, and thorough responses to inquiries or information requests should be the norm. Frequent contact and interaction with the PI, initiated by the company, should also be viewed positively. Negativity toward the FAA, on the other hand, particularly on the part of management, can impede communication and cooperation.

i. Cost of Quality (9). Cost of quality information can be difficult to interpret and evaluate in terms of quality impact. Factors to bear in mind in assessing this indicator include the following:

(1) At present, cost of quality information is not generally available to the FAA. Most small companies don't track it in detail, and many others who do may be reluctant or unwilling to share it for proprietary reasons.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

(2) One evaluation method is to look at the percentage distribution of quality costs among the three major cost categories of prevention, appraisal, and failure/rework. While there is no ideal distribution, in general the commitment of resources to upfront, preventive measures may indicate a more deliberate and proactive approach to quality control.

(3) Trends in a company's cost of quality over time may also be relevant. Sharp movement, either up or down, is often a warning sign. Changes in a particular area, as opposed to overall, may point to specific problems. What's behind the cost changes may also be important. New technology, new production systems or methods, or outsourcing/offshore operations can all drive cost of quality up or down.

(4) In addition to formal cost of quality data, there are also several "proxy" indicators of quality costs. High scrap or rework rates during routine production runs, for example, may be a signal of problems in the system. A high volume of warranty returns may also indicate problems, as can a high level of MRB activity.

j. Service Difficulties (10). In-service difficulties caused by manufacturing defects or poor quality control can be an indication of serious system problems. Consideration of the following points can assist you in evaluating this indicator. Discussion of specific points with the ACO may also be beneficial.

(1) Overall, very few service difficulties are traced back or attributed to manufacturing or quality problems; the vast majority are due to maintenance or operational factors.

(2) 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.

(3) For service difficulties which are attributable to manufacturing, the overall magnitude or impact of the problem may be relevant to your assessment. For example, if a service difficulty involved a particularly severe or dangerous problem, or a large number of products or units in service, its quality impact may be more significant. A single isolated incident, on the other hand, may not always be cause for alarm.

(4) Significant service difficulties will generally trigger an immediate response, which can include unscheduled PI or ACSEP evaluations, as appropriate.

k. Complex Manufacturing Process (11). Evaluating the complexity of an approval holder's manufacturing process requires consideration of a number of variables. Major criteria to apply in this regard include the following:

(1) 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.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

(2) 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.

(3) 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.

(4) The qualifications and skill level of both company and FAA staff relative to the process(es) are also important. Even a simple, well-established process can be complex to those who aren't experienced in or knowledgeable of the technology involved. In most cases, the longer a company has been working with a technology, the less need for concern. Evidence that skill levels are being maintained or upgraded is also important.

(5) Outsourcing of manufacturing processes, both production and testing, is also an element to consider. If, for example, key complex elements of the process are subcontracted to highly expert firms, the potential risk may be lessened.

l. Complex Product, Part, or Appliance (12). Evaluating the complexity of an approval holder's product, part, or appliance likewise involves a number of variables. Consideration of the following points can assist you in evaluating this indicator. Discussion of specific points with the ACO may also be beneficial.

(1) 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 probable complexity.

(2) 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, integrated, or fuzzy relationships. If any other systems are dependent on the end item, that typically increases overall complexity.

(3) The materials used in the end item are also relevant to complexity. If it includes any nontraditional, exotic, or revolutionary materials, and/or material(s) that haven't been used in this way before, then its complexity is probably heightened. As with process complexity, the company's experience and skill with the material or product is also a factor. Limited knowledge or expertise can make simple things complicated.

(4) Another good indicator of complexity is the item's certification basis. If defining the rule(s) and/or finding compliance with 14 CFR was difficult, or if multiple exemptions or special conditions were required, that may also reflect the item's complexity.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

m. New Manufacturing Process (13). Introduction of a new manufacturing process, whether truly original or just new to the company, can create potential quality issues. Consider the following for this indicator:

(1) Approval of the quality manual change or update incorporating any new process is a major milestone; however, it is generally not the end of PI concern and interest.

(2) How well the new process is understood by the company, the FAA, and industry in general is an important consideration. If company staff 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.

(3) The extent to which the company has demonstrated control of any new process is also key. An acceptable or normal rejection rate and limited MRB activity are generally positive signs of control. Documented repeatability and reliability should also be expected. In-service experience with no quality problems in evidence is likewise a sign of full process integration and control.

n. New/Emerging Technology (14). Often what's considered new or emerging technology is in reality an extension or iteration of existing knowledge and methods. Evaluate the following criteria with respect to this indicator for companies employing new technology. Discussion of specific points with the ACO may also be beneficial.

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

(2) 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 FAA interest may be appropriate.

(3) 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 14 CFR, or if any new or revised rules resulted from its certification, it should probably be considered new technology.

(4) The technology's service history should also be considered. If it has a substantial number of service hours or cycles, such that failures are explainable, understood, and predictable to some extent, then in general it would not be considered new or emerging technology.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

o. Production Volume (15). Changes or fluctuations in a company's production volume may or may not be cause for concern. Circumstances or influences to think about for this indicator include the following:

(1) The magnitude and rate of any volume changes are important. A fractional increase or decrease is generally not an issue, but a multiple change probably should be cause for concern. Gradual and steady adjustments can usually be managed well, while rapid and/or haphazard movement, either up or down, often indicates underlying problems.

(2) The reason for the change is likewise critical. New orders or product lines can drive up production quickly, as can short or special product runs. On the other hand, downsizing, mergers, or takeovers can move the numbers rapidly in the opposite direction. Normal industry cycles may produce predictable volume changes.

(3) When and how often changes occur is also important. If the company is pushing to meet end of month/quarter/year production targets, or to meet contract due dates and possibly avoid penalties for late deliveries, watch out. If these kinds of fluctuations are repetitive, however, the company may have enough experience with them to manage effectively.

(4) The bottom line consideration should be the company's capacity to handle the changes. If they acquire or maintain an adequate number and type of staff, including a sufficient number of designees, then concern may not be warranted. Likewise, if their quality system is revised to handle any changes, up or down, volume fluctuation may not be problematic.

p. Product Continuity (16). Product continuity is generally regarded as positive, but there can be a down side. Consider the following when evaluating this indicator:

(1) Determine if the continuity has had any negative consequences. Risks include complacency, lax adherence to procedures, and corner cutting. Companies may go on "automatic pilot" after a period of time. If the product has been totally static, without even minor improvements or enhancements, that may be grounds for concern.

(2) The context of the product's continuity is also important. If suppliers and material sources have been stable as well, that's generally positive. However, if they've been constantly in flux, the continuity may be illusory. Similarly, if the company's key staff/internal knowledge base been depleted, there may be potential for problems.

(3) The reasons for any continuity or discontinuity should be examined. Resistance to change or limited resources/capabilities is often behind static continuity. Purchase of certificates, addition of product lines, and downsizing, mergers, or takeovers, by contrast, frequently create discontinuity. In either event, heightened FAA interest may be appropriate.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

q. Quality System Changes (17). Quality system changes are a regular, recurring, and expected part of the production approval holder program. Circumstances or factors, however, which might provide grounds for concern in this area include the following:

(1) In general, large companies make more frequent, proactive changes to their quality systems, while smaller companies tend to make fewer, more reactive (i.e., FAA driven) changes.

(2) The reasons behind any system changes are critical. Process improvements or enhancements are often positive, provided they're not motivated primarily by cost cutting and 14 CFR compliance is maintained. Changes based on FAA recommendations or reported noncompliances are likewise to be encouraged. Changes initiated in pursuit of ISO-9000/9001 certification may warrant concern in light of 14 CFR compatibility issues. Wholesale changes instituted by a new quality manager may trigger subsequent problems.

(3) The overall nature and magnitude of changes to the system should be considered. Minor, administrative changes are probably not an issue, but major, substantive changes, e.g., transitioning to TQM, SPC, etc., may give rise to potential quality system issues. If the FAA has not fully reviewed these changes, additional concern is probably warranted.

(4) If transitioning to team approach (TQM), look for characteristics of a good program: implementation plan, not rushing into it; thorough training program for affected staff; interim review and oversight of process during transition period; final inspection retained, with a unique stamp; and no diminution of "quality focus/mindset" once new methods are in place.

r. Engineering/Design Changes (18). Engineering or design changes are likewise not uncommon or necessarily problematic; why they're initiated and how they're handled is the key. Look at the following criteria with respect to this indicator. Discussion of specific points with the ACO may also be beneficial.

(1) The strength and adequacy of the design data control system is paramount. All design changes should be well described and fully documented, in a timely and consistent manner. If they're not, be concerned. Look for positive characteristics such as simplicity and ease of administration. Automated systems, e.g., CAD, require qualified staff to manage them.

(2) The predominant nature of the changes is also important. Product enhancements, improvements, or customizing generally are not cause for concern. Changes made to correct problems, by contrast, may be. Customer-driven changes may reflect potential problems more frequently than self-generated ones. Major changes generally should cause greater concern than minor ones.

(3) Also consider the company/product context. Large companies building type-certificated products against newer designs will often have many design changes. Likewise, supplemental type certificates may also generate many changes. Newer, less experienced companies with many changes may raise a red flag.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

s. Increased Inspection Delegation to Suppliers (19). Increased delegation of inspection authority to suppliers can raise potentially serious quality concerns. Key considerations in evaluating this indicator include the following:

(1) The strength and adequacy of the PAH's supplier control system is critical. The system should be well documented and stable, not subject to constant changes. How often the PAH gets out to the suppliers is also key. If the buyer doesn't visit or audit on a regular basis, that should be a red flag. If the PAH qualifies or trains its suppliers, that's often a definite plus.

(2) Look at methods/systems used by the PAH. If a dock-to-stock or just-in-time delivery program has been implemented, the potential for problems may be greater. Damage and content inspection alone, as opposed to receiving inspections or source sampling, can also be cause for concern. Delegation of testing is also a potential red flag.

(3) The suppliers themselves should have a quality system in place, either the buyer's or their own, with written procedures. There should also be documentation that procedures are followed. Absent these conditions, heightened concern is warranted.

t. Increased Use of Foreign Suppliers (20). Substantial growth in the number of foreign suppliers has raised a variety of issues and concerns. In assessing this indicator, the following considerations should be paramount:

(1) The extent of control and oversight exercised by the approval holder is critical. Use of dock-to-stock or just-in-time delivery methods with foreign suppliers may be cause for concern. Infrequent visits to foreign suppliers by the PAH should also raise a red flag.

(2) What the suppliers are doing or making is also important in assessing potential impact. If it's assembly only, there may be less cause for concern. If, on the other hand, they're producing major components or subsystems, or entire end products, the potential for quality issues is much greater. The priority or criticality of what they're producing is also of obvious importance.

(3) Look at the approval holder's rationale for using foreign suppliers. If it's primarily cost cutting, or the result of an offset contract stipulation, there may be a basis for concern. On the other hand, joint ventures or agreements to gain access to specialized expertise or technology may be less problematic.

(4) The impact of any bilateral agreement should also be considered. If an agreement is in place, the civil aviation authority of the supplier's country conducts appropriate surveillance, and the information is shared with FAA, this may offset other concerns. If no agreement is in place, lack of 100 percent incoming inspection by the PAH should be cause for concern.

APPENDIX 3. RISK MANAGEMENT INDICATOR ASSESSMENT CRITERIA (CONT'D)

u. New Design in Production (21). The introduction of a new design into the production system usually proceeds without major difficulty. Consider the following in assessing this indicator. Discussion of specific points with the ACO may also be beneficial.

(1) In most cases, new designs represent an evolution or iteration of what companies have already been building. Seldom is the change revolutionary or a major technological leap forward.

(2) The company's experience with related product lines is important. If the new design is a major departure from what they've done before, and the end item is really "new" to the company, then heightened concern is prudent. If, on the other hand, it's simply the latest version of something they've been building, there's likely to be little impact.

(3) The degree of change or adaptation required in the existing production system is perhaps most critical. Some new designs require no or minimal changes, while others involve major alterations or essentially new process(es). Either of these is potentially less problematic than one that requires many small, specialized, intricate, or easily missed changes.

(4) The origin of the new design may be a factor as well. Buying the design/approval, as opposed to developing an original in-house, in some cases may create transition or integration issues. Acquiring a new design through a merger or takeover likewise may create potential safety concerns.

APPENDIX 4. CATEGORY PARTS LIST

1. PURPOSE. This appendix describes the Category Parts List (CPL) used to determine the unit criticality for risk management.

2. CATEGORY PARTS LIST. The CPL contains a list of assemblies and part(s) thereof that have been assigned a category rating of 1 or 2. To receive a category rating of 1, an assembly or part thereof 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 thereof 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.

a. If an assembly or part thereof is listed on the CPL, the PI will use its designated category rating to determine the unit criticality on AIR Form 8120-9.

b. If an assembly or part thereof is not listed on the CPL, it will be considered as Category 3. The PI will use this category rating to determine the unit criticality on AIR Form 8120-9.

3. STRUCTURE OF THE CPL. Refer to figure 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.

4. CPL REVISION PROCESS. A request to add a Category 1 or 2 assembly or part thereof to the CPL, to change the category of an existing assembly or part thereof on the CPL, or to remove an existing assembly or part thereof 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 2):

NOTE: A request to change the category of an existing CPL assembly or part thereof 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 3, 4, and 5):

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

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

APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

FIGURE 1. SAMPLE CATEGORY PARTS LIST

Revision New dated 12/3/00

AIRCRAFT CERTIFICATION SERVICE CATEGORY PARTS LIST

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 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) **Crew Oxygen System** (27-2), (29-2) **Indicating System** Warning, Caution, and Advisory Lights (27-2), (29-2), Main Rotor Indicating System (27-2), (29-2) Engine Power (27-2), (29-2) Engine Temperature (27-2), (29-2)	23, 25, 27, 29

(3) Describe the reason for adding the assembly or part thereof, for changing the category of an existing assembly or part thereof, or for removing an existing assembly or part thereof.

(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 thereof 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 thereof, or requesting removal of an existing assembly or part thereof, 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.

APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

c. The MIO manager logs 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 thereof or to change an existing category, assigns the appropriate category to the assembly or part thereof.

(3) If the action is to accept a request to remove an assembly or part thereof 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.

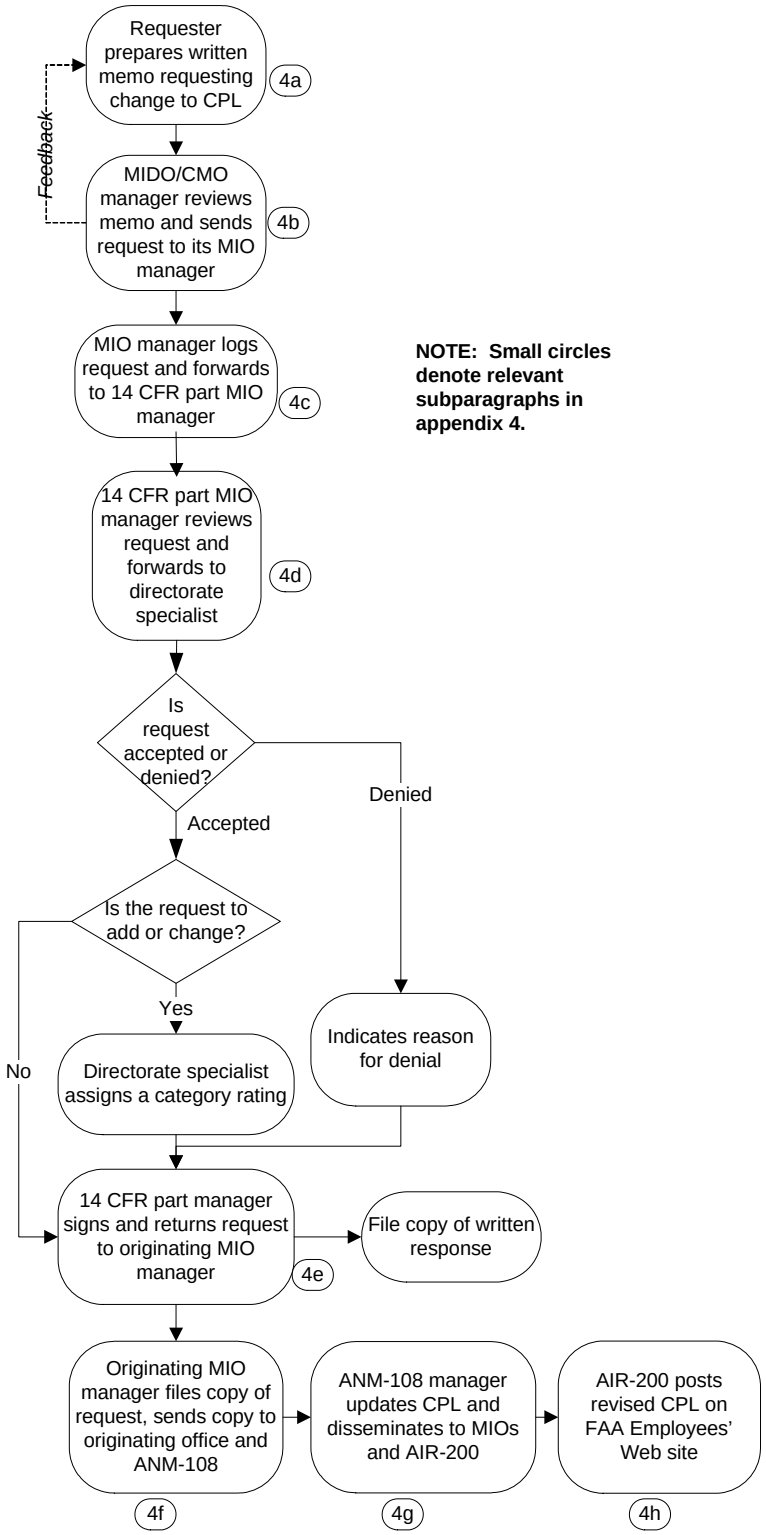
f. The originating MIO manager will file a copy of the memo, notify the originating MIDO/CMO, and send a copy to the manager, ANM-108.

g. The ANM-108 MIO manager updates the CPL and disseminates the revised CPL to the other MIO managers and AIR-200 at the end of each quarter.

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

APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

FIGURE 2. CPL REVISION PROCESS FLOWCHART



APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

FIGURE 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

APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

FIGURE 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

APPENDIX 4. CATEGORY PARTS LIST (CONT'D)

FIGURE 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 5. RISK MANAGEMENT REPORTS

1. PURPOSE. This appendix explains the content of the Directorate Report and the Office Report.

2. TYPES OF REPORTS. Risk management reports may be accessed through CMIS. The Directorate Report will list all facilities assessed within the selected directorate. The Office Report will list all facilities assessed within the selected MIDO/CMO. Each type of report is formatted as follows:

a. Office identifier.

b. Risk Management Group assigned.

c. Quality System name.

d. Unit Criticality Category assigned.

e. Facility name.

f. Principal Inspector assigned.

g. Date scored.

h. Meta Factors.

(1) System Strength: A rating of "Optimal," "Adequate," or "Marginal" will be indicated. System strength encompasses factors over which a facility generally has more direct control or influence (i.e., the stability of the organization, its performance history, and the various elements and influences that drive its production dynamics). A rating of "Optimal" indicates that the strength of the system in place has been assessed as having little potential impact on the integrity of FAA-approved design and product quality. A rating of "Adequate" indicates that the strength of the system in place has been assessed as having an average potential impact on the integrity of FAA-approved design and product quality. A rating of "Marginal" indicates that the strength of the system in place has been assessed as having a substantial potential impact on the integrity of FAA-approved design and product quality.

(2) Inherent Risk: A rating of "Substantial," "Moderate," or "Minimal" will be indicated. Inherent risk encompasses factors that are generally associated with the type of business the facility has chosen to be in, and remain constant unless the facility changes its business. These factors are the level of technology with which the facility is working, and the criticality of the end unit or units of production. A rating of "Substantial" indicates that a facility's level of technology has been assessed as having a substantial potential impact on the integrity of FAA-approved design and product quality, and the unit criticality is high. A rating of "Moderate" indicates that a facility's level of technology has been assessed as having a moderate potential impact on the integrity of FAA-approved design and product quality, and the unit criticality is moderate. A rating of "Minimal" indicates that a facility's level of technology has been assessed as having little potential impact on the integrity of FAA-approved design and product quality, and the unit criticality is low.

APPENDIX 6. RISK MANAGEMENT MODEL VALIDATION PLAN

1. PURPOSE. This appendix explains the structure and application of the risk management model validation plan. The objective of the plan is to ensure that the model consistently and accurately identifies those PAH's and associate facilities having the greatest potential to produce nonconforming products or parts thereof. It also defines a basis for continually refining and modifying the model as required to achieve this objective. The plan utilizes several validations to accomplish these objectives.

2. RISK MANAGEMENT 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 Risk Management Indicators and Unit Criticality. 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 model and its basic application processes. As such, this validation provides a real-time validity check on the ratings for the risk management indicators and unit criticality, and on the initial risk management group assignments generated by the model. This validation not only provides managerial oversight for the process but also allows for a different perspective in determining the final ratings for risk management indicators and unit criticality.

(1) Data Source(s): AIR Form(s) 8120-9.

(2) Parties Responsible for Validation: Facility PI and MIDO/CMO manager.

(3) Description: Chapter 3, section 2 of this order requires the MIDO/CMO manager to review each completed AIR Form 8120-9 for agreement with the PI's assessment ratings of the risk management indicators and unit criticality. In so doing, the MIDO/CMO manager is provided an opportunity to help ensure consistency between and among PIs in the application of the model, 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 assessments entered on AIR Form 8120-9.

b. Validation of the Continued Relevance of the Risk Management Model's Impact 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 risk management model elements, detailed planning for analysis and reporting will be required.

(1) Data Source(s): The risk management module within CMIS is the data source for this validation.

(2) Parties Responsible for Validation: Directorates.

APPENDIX 6. RISK MANAGEMENT MODEL VALIDATION PLAN (CONT'D)

(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 model's risk management indicators that do not significantly contribute to the identification of the risk management group assignment. The data will be analyzed to identify risk management indicators that are predominantly rated as "c" (not applicable), and to determine whether or not such indicators should continue to be used in the model.

c. Validation of the Risk Management Model's Ability to Reflect PI Experience and Judgment. This validation is conducted every three years. The individual impact indicators and the relative weights assigned to each were based on interviews conducted with PIs and engineers and reflect their combined knowledge, experience, and judgment. It is necessary to periodically revalidate this basis in order to ensure that the model continues to reflect this experience and judgment. Since this validation is data-driven, and aimed at the adequacy of the risk management model elements, detailed planning for analysis and reporting will be required.

(1) Data Source(s): The risk management Office Reports are the primary data sources for this validation. In addition, each directorate will use a risk management questionnaire to assess the validity of the risk management groups 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 model's impact indicators reflects the experience and judgment of the PIs. Once every three years, following assignment of the risk management groups, 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 risk management Office Reports, identify any risk management group assignment they disagree with, and provide written justification for their opinion. The differences identified with the risk management groups assigned and the written justifications will be analyzed to detect any patterns or trends in the data attributable to inadequacies in the model. A small number of justifiable changes to the risk management groups is a strong nominal indicator of model validity; i.e., if a large majority of the model's risk management group assignments are accepted, then the knowledge and experience of the directorate staff is adequately reflected in the model.

APPENDIX 7. 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 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) thereof. 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.**

APPENDIX 7. PREPARATION INSTRUCTIONS FOR FAA FORM 8100-6, NONCOMPLIANCE RECORD (CONT'D)

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. For ACSEP evaluations only, insert the applicable 14 CFR part or section that establishes the responsibility of any delegated facility evaluated (i.e., § 21.245, § 21.445, or SFAR NO. 36, § 6(a)(2)). 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.

APPENDIX 7. PREPARATION INSTRUCTIONS FOR FAA FORM 8100-6, NONCOMPLIANCE RECORD (CONT'D)

(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.

APPENDIX 7. PREPARATION INSTRUCTIONS FOR FAA FORM 8100-6, NONCOMPLIANCE RECORD (CONT'D)

FIGURE 1. SAMPLE FAA FORM 8100-6

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

U.S. Department of Transportation
Federal Aviation Administration

Noncompliance Record

ACSEP No./Report No. *(1)* N/A

Project No. *(2)* PT900NE

Type of Activity: ☐ DO Audit ☐ PI Evaluation ☐ ACSEP ☐ Supplier Control Audit ☒ Product Audit ☐ Other *(3)*

System Element Evaluated: *(4)*	Controlling Document: *(5)*	Applicable CFR Section: *(6)*
Manufacturing Processes Evaluation Criteria Number: 413	RC Purchase Order #94 of 11/23/1997 FAA-approved data? ☐ Yes ☒ No	21.607

Type Of Noncompliance: Safety-Related ☐ Systemic ☒ Isolated ☐ Certification-Related ☐ No. 1 *(7)*

Required Condition: *(8)*

RC Purchase Order (PO) #94 for rotor support couplings states: "J&J Machining Co. shall comply with RC Quality Manual, Section 4, and purchase raw materials exclusively from YOYO International Material Broker. Terms of purchase will include a request for a metallurgical lab report with each shipment. These reports will be retained by J&J Machining Co. for a minimum of 5 years."

J&J Machining Co. Quality Manual, paragraph 12.4(c), states: "All raw material purchase orders shall include a statement requiring suppliers to furnish a metallurgical lab report with each shipment. The reports will be retained by J&J Machining Co. metallurgical lab in accordance with paragraph 23.6."

Encountered Condition: *(9)* ☒ *Discussed with Facility* ***(10)***

Ten J&J Machining Co. purchase orders for raw materials to be used for the manufacture of rotor support couplings under RC PO #94 were reviewed (J3-122; J3-114; J3-221; J3-98; J3-301; J3-110; J3-245; J3-15; J3-278; J3-184). All ten POs were issued to YOYO International Material Broker as required by RC PO #94, and all included the statement for furnishing a metallurgical lab report with each shipment. All raw material shipments were completed between January 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

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 (2-02) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

APPENDIX 8. 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 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. If the system element/subelement is not applicable at a facility, enter "N/A." If the system element/subelement was not evaluated, enter "N/E."

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) thereof audited.

l. Block 12. An "X" in the column next to the product or part(s) thereof 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) thereof audited, when the result of the activity is unsatisfactory.

APPENDIX 8. PREPARATION INSTRUCTIONS FOR FAA FORM 8120-14, PRODUCTION APPROVAL/CERTIFICATE MANAGEMENT ACTIVITY REPORT (CONT'D)

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 DO 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.

APPENDIX 8. PREPARATION INSTRUCTIONS FOR FAA FORM 8120-14, PRODUCTION APPROVAL/CERTIFICATE MANAGEMENT ACTIVITY REPORT (CONT'D)

FIGURE 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)*

DO 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 DO 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 (8-04) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

APPENDIX 8. PREPARATION INSTRUCTIONS FOR FAA FORM 8120-14, PRODUCTION APPROVAL/CERTIFICATE MANAGEMENT ACTIVITY REPORT (CONT'D)

FIGURE 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)*

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 (8-04) FOR OFFICIAL USE ONLY (when filled in)
Public availability to be determined under 5 U.S.C. 552

APPENDIX 9. FORMS LISTING

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

FIGURE 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 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
AIR Form 8120-9	Risk Management Facility Assessment Sheet
FAA Form 8120-14	Production Approval/Certificate Management Activity Report

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 8120.2E

To: Directive Management Officer, AIR-530

(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 (8-89)