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.

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

PAGE CHANGE CONTROL CHART

Remove Pages	Dated	Insert Pages	Dated
ix and x	5/29/07	ix and x	07/23/08
95 thru 101 (and 102)	5/29/07	95 thru 101 (and 102)	07/23/08

/s/

Frank P. Paskiewicz
Manager, Production and
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Initiated By: AIR-200

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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.

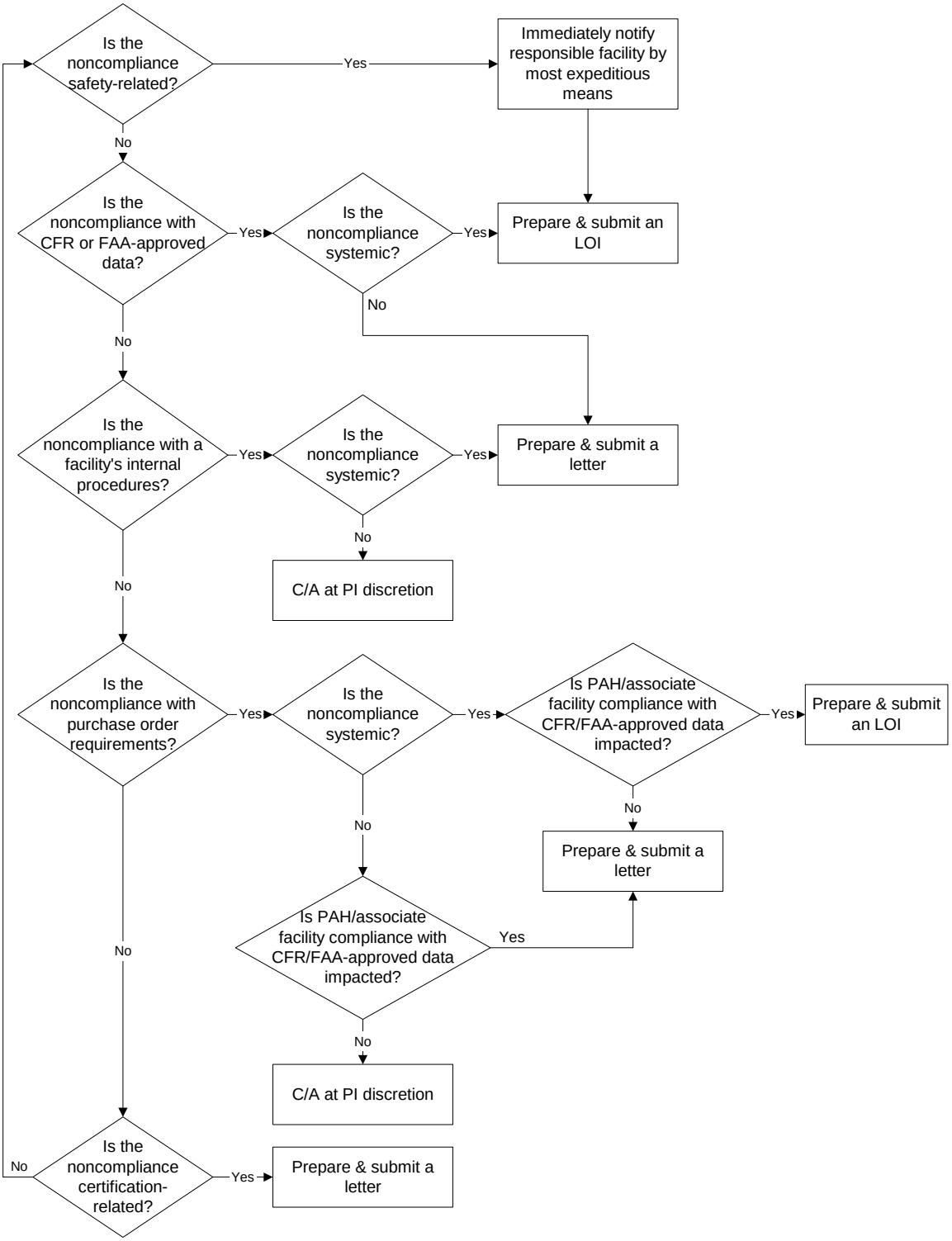
(7) Isolated Noncompliance with Purchase Order Requirements (by a Supplier to a PAH or Associate Facility).

(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.