

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



Effective Date: 1/14/2010

SUBJ: Implementation of Changes to the Revised 14 CFR Part 21

This order provides guidance to all Aircraft Certification Service personnel to assist in the implementation of the requirements pertaining to the quality system described in the revised Title 14, Code of Federal Regulations (14 CFR) part 21, Certification Procedures for Products, Articles, and Parts, published on 10/16/2009.

Frank P. Paskiewicz

Manager

Production and Airworthiness Division, AIR-200

Distribution: Electronic Only Initiated By: AIR-200

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Chapter 1. Introduction

- **1-1. Purpose of This Order.** This order assists aviation safety inspectors (ASI) with transitioning production approval holders' (PAH) quality systems into compliance with the revised 14 CFR part 21, Certification Procedures for Products, Articles, and Parts (part 21).
- **1-2. Audience.** All Aircraft Certification Service personnel in the Federal Aviation Administration (FAA) who provide oversight of the production approval process and are responsible for the certificate management of PAHs.
- **1-3. Where Can I Find This Order.** You can find this order on the FAA website at https://employees.faa.gov/tools_resources/orders_notices/
- **1-4. Effective Date.** This order is effective on January 14, 2010.

Chapter 2. Background and Compliance Dates

- **2-1. Background.** The FAA amended its certification procedures and identification requirements in 14 CFR part 21. The amendments updated and standardized requirements for PAHs, revised export airworthiness approval requirements, moved all part marking requirements from part 21 to part 45, and amended the identification requirements for products and articles. The rule also contains global changes. For example, "FAA" replaced the term "Administrator." Also, "quality system" replaced the term "quality control system" to capture the broader discipline of an all-encompassing quality system. The subparts in the rule have also been standardized in the layout and section heading when possible. For example, in subparts G, K, and O, §§ 21.137, 21.307, and 21.607 are all titled Quality System.
- **2-2.** Compliance Dates. This rule is effective on April 14th, 2010 (180 days after the rule is published). It contains both an April 14th, 2010 and an April 16th, 2011 (18 months) compliance date.
- **a.** The April 14th, 2010 compliance date applies to part 1; part 21, subparts H, I, L, and N; and part 45, subpart B, §§ 45.11 and 45.13. These changes do not affect, and are not affected by, other changes in the rule. Therefore, these changes were given a compliance date of 180 days after publication of the rule in the Federal Register.
- **b.** The April 16th, 2011 compliance date includes all other changes not included in the April 14th, 2010 compliance date, most of which are quality system changes in subparts G, K, and O. These changes promulgate new requirements or are tied to other requirements that have an extended compliance date and require more action on the part of the PAHs and the FAA to achieve compliance.

Chapter 3. Implementation

3-1. Assisting PAHs with Compliance to the Rule Change.

- **a. Implementation Plan**. To effectively implement the revised rule by the 18-month compliance date, it is essential that FAA personnel develop an implementation plan with its PAHs. At a minimum, the plan should cover the following items:
 - (1) Ongoing communication with the PAHs.
 - (2) Development of a timeline for the FAA to receive required documents from the PAH.
 - (3) Follow-up communication to ensure the timely submission of documents.
 - (4) Review of organization description document.
 - (5) Review and approval of the quality manual.
 - (6) Validation of compliance to the rule after approval.

b. Initial Communication.

- (1) Written Communication. ASIs should send each of its PAHs a notification letter. The notification letter should advise them of the publication of the rule and instruct them that it will be necessary to comply with the rule by the respective compliance dates. Refer to appendix A for a sample notification letter. The letter should
 - (a) Provide instructions for locating the complete rule and preamble on the internet.
- (b) Request the organization description document and quality manual required in subparts G, K, and O (the organization description may be included in the quality manual).
- (c) Provide the website where the PAH can find advisory circulars, orders, and questions and answers (Q&A's) to assist in implementing the new requirements of the rule.
 - (d) Advise the PAH to send its required documents early to prevent non-compliance.

Note: The organization description document and quality manual must be provided to the FAA by the 18-month compliance date for the PAH to remain in compliance.

(e) Request that the PAH work with the FAA to establish a plan to identify what changes are necessary, document the quality system, and provide the documents for approval.

Note: The sample letters found in the appendixes are only examples. The letters may be modified by the managing office as needed.

(2) **Oral Communication.** Within approximately 60 days of sending the notification letter, ASIs should verbally contact the PAH. This will help to assess the PAH's understanding of the rule and its implication to its production approval. ASIs should also –

- (a) Confirm that the PAH knows where to locate pertinent information.
- (b) Confirm that the PAH is reviewing its procedures for the changes to the rule that have a 180-day compliance date. If the PAH determines there are procedures affected by the 180-day compliance date, advise the PAH to work with the Manufacturing Inspection District Office (MIDO) to implement the necessary changes.
- (c) Establish a schedule of milestones for the PAH to meet before the 18-month compliance date.

c. Development of a Timeline with the PAH.

- (1) When contacting the PAH, work with them to set milestone dates for –
- (a) The PAH to review its quality system to note the differences between its existing systems and the new quality system requirements,
 - (b) The submittal of the organization description document, and
 - **(c)** The submittal of the quality manual.
- (2) Advise the PAH that in order to facilitate the timely review and approval of its quality manual, the FAA recommends that the PAH submits the quality manual and organization description document well in advance of the 18-month compliance date.
- (3) Determine which submittal method and media type will best accommodate the submission and review of its quality manual. Facsimile and email are permissible for the organization description document.
- **d. Follow-up Communication.** ASIs should follow up with their PAHs to ensure that they are reviewing its quality systems and preparing for compliance. A sample tracking sheet is available on the part 21 SharePoint site to assist the ASI in tracking the PAH's progress.

e. Review and Approval of Manuals.

(1) For the quality manual to be approved, it must address all 14 elements outlined in § 21.137. Keep in mind that these items are scaleable in scope and complexity depending on the size, complexity, and criticality of the product or article manufactured by the PAH. Some elements may be addressed in the manual as "N/A" if the PAH can provide evidence that an element does not apply. For example, a PAH producing software may not be required to have a calibration system. Examples of quality system scalability can be found by visiting the part 21 intranet website. 14 CFR §§ 21.138, 21.308, and 21.608 require the quality manual to be in English and to be retrievable in a form acceptable to the FAA. While not required to be included in the manual, ideally, quality manuals should also include the following:

- (a) A process to report failures, malfunctions, and defects as required by § 21.3.
- (b) A process to amend the organization description document as required by new subparts G, K, and O, §§ 21.146, 21.316, and 21.616.
- (c) A process to immediately notify the FAA, in writing, of changes to the quality system that may affect the inspection, conformity, or airworthiness of its product or article as required by new subparts G, K, and O, §§ 21.150, 21.320, and 21.620.
- (d) A process to obtain FAA approval before making any changes to the location of any of the PAHs' manufacturing facilities as required by the new subparts G, K, and O, §§ 21.139, 21.309, and 21.609.
- (2) Review the organization description document and quality manual to determine if they will meet the requirements of the new part 21 rule. If the documents will not meet the requirements of the new part 21 rule, advise the PAH they will need to make the necessary changes. If the documents will meet the requirements of the new part 21 rule, send an approval letter to the PAH stating that its quality manual meets the new requirements of the applicable subpart in 14 CFR part 21 and is therefore approved with an effective date of April 16, 2011 (18-month compliance date or later). Refer to appendix B for a sample approval letter.
 - (a) The approval letter should state that the PAH may not operate under the new quality manual (that has been created for the purpose of compliance with the new rule) until it reaches its effective date.
- (b) The approval letter will affirm that the FAA will validate compliance of the PAH's quality system at the next scheduled certificate management activity.
- **f. Verification**. Schedule certificate management activity to verify the new quality system for compliance to the rule in accordance with FAA Order 8120.2, Production Approval and Certificate Management Procedures.
- **3-2. Approved Production Inspection Systems (APIS).** All APISs will be required to obtain a production certificate (PC). The holder of an APIS will work with its MIDO to submit the necessary documents required by §§ 21.135 and 21.138. After the quality manual is approved and the quality system is validated, the MIDO will issue the PC. If the holder of an APIS chooses to convert to a PC within the 18-month compliance date, its quality system and quality manual must, at a minimum, meet the current requirements in 14 CFR part 21, § 21.143 for a PC. Ideally, the manual will include the 14 elements that will be required on the 18-month compliance date; this will help to facilitate a smooth transition to the new part 21 rule.
- **3-3. Applicants in Process.** If an applicant will receive production approval before the 18-month compliance date, they must meet the current requirements in the applicable subpart of 14 CFR part 21. However, the applicant may implement procedures that do not conflict with the existing rule for purposes of transitioning to the new requirements. For example, a fabrication inspection system (FIS) could be supplemented with elements of a quality system, such as internal

audits and corrective actions, before the 18-month compliance date. Applicants that will not receive production approval before the compliance date must meet the requirements of the new rule.

3-4. Implementation of Quality System Elements.

- **a.** PAHs are not required to implement the new quality procedures until the 18-month compliance date. It is, however, acceptable if a PAH is currently in compliance with the existing rule and coincidentally also meets requirements of the new rule. It is also acceptable for a PAH to implement procedures that comply with portions of the new rule and do not compromise its compliance to the existing rule before the 18-month compliance date.
- **b.** PAHs who wish to implement procedures that comply with the new rule before the compliance date should follow the current process with its MIDO for making changes to the quality system. In this case, the PAH should also simultaneously document these updates in its revised or newly-created quality manual which has been produced for the purpose of compliance with the new rule. A proactive approach will greatly facilitate a PAH's transition to the new rule.
- **3-5.** If a PAH Does Not Meet the Compliance Date. If a PAH does not meet the requirements of the new 14 CFR part 21 by the 18-month compliance date, send them a letter stating that their organization is no longer compliant with 14 CFR part 21 and is subject to enforcement action, up to and including the termination of its production approval.

01/14/2010 8120.17 Appendix A

Appendix A. Sample Notification Letter



October 20, 2009

ABC Aircraft Engine Company 1776 Bunker Hill Rd Revere, MA 00012

Dear Mr. Smith:

The FAA amended Title 14, Code of Federal Regulations (14 CFR), part 21, Certification Procedures for Products, and Parts. The final rule is now in the Federal Register and contains changes that will require you to take action to ensure that your company is in compliance with the new requirements.

The revised rule contains two groups of changes. The first group has a compliance date of 04/14/2010 and the second group has a compliance date of 04/16/2011. It is important to familiarize yourself with the changes by reading the rule and the preamble in their entirety. The complete rule can be found at www.faa.gov.

In an effort to standardize production approval requirements and incorporate industry best practices, the FAA revised the quality systems to ensure consistency among PC holders, PMA holders, and TSO authorizations. As a result, the rule now contains no references to Approved Production Inspection Systems (APIS) or Fabrication Inspection Systems (FIS). These changes will require you to —

- Establish a quality system that meets the requirements of § 21.137, § 21.307, or § 21.607, as applicable to your organization.
- Submit a document describing your organization as required by § 21.135, § 21.305, or § 21.605, as applicable to your organization.
- Provide a quality manual for FAA approval that meets the requirements of § 21.138, § 21.308, or § 21.608, as applicable to your organization.

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The rule also adds changes and provides some relief to the marking requirements of 14 CFR, part 45, Identification and Registration Marking. Part 45 now contains all part marking requirements. You may need to revise your quality manual or quality procedures to incorporate these changes.

The FAA published AC 21-42, Transition Document for 14 CFR parts 1, 21, 43, and 45, to help explain the changes and to aid in transitioning your company to the new requirements. The AC provides an explanation of each section's changes.

A website is also available to provide additional resources to aid you in incorporating these changes into your quality system. These resources include a video presentation, important links, fact sheets, and points of contact. Additionally, the website allows you to submit questions you may have; these questions and their answers may be posted on the website. You may access this website by visiting www.faa.gov and choosing the part 21 link.

To ensure that your company meets the new rule requirements and remains in compliance, it is important that you act as soon as possible to prepare for implementation of the required quality system and submit the necessary documents. If you do not meet the new requirements by the compliance date, your company may be subject to certificate management activity and enforcement action.

If you have any questions please feel free to contact this office. You can expect to hear from me or a member of our staff approximately 60 days after receiving this letter to discuss a schedule for delivery and approval of your organization description document and quality manual.

Sincerely,

Ben Smith Aviation Safety Inspector MIDO-42 01/14/2010 8120.17 Appendix B

Appendix B. Sample Approval Letter



October 20, 2010

ABC Aircraft Engine Company 1776 Bunker Hill Rd Revere, MA 00012

Dear Mr. Smith:

We have completed our review of your quality manual, and found that it meets the new requirements of [applicable CFR]. The FAA approves the submitted manual with an effective date of XX/XX/XXXX (18-month compliance date or later). The FAA reserves the right to require changes, additions, or clarifications that may become necessary as a result of subsequent inspections and/or evaluations.

The FAA will validate the submitted quality manual for compliance to the new requirements at your facility's next scheduled certificate management activity.

Please retain this notification on file as evidence of FAA's approval of your quality manual.

Document Name: Document Number: Revision Number: Date:

Sincerely,

Ben Smith Aviation Safety Inspector MIDO-42 01/14/2010 8120.17 Appendix C

Appendix C. Administrative Information

- 1. Distribution. This order is distributed to Washington Headquarters division levels of the Flight Standards Service, to the branch levels of the Aircraft Certification Service, to the branch levels in the regional Flight Standards Divisions and Aircraft Certification Directorates, to all Flight Standards District Offices, to all Aircraft Certification Offices, to all Aircraft Certification field offices, to all Manufacturing Inspection District and Satellite Offices, to the Aircraft Certification and Airworthiness Branches at the Federal Aviation Administration Academy, and to the Flight Standards Service Regulatory Support Division.
- **2. Delegation of Authority.** AIR-200 is responsible for issuing, revising, or canceling the material in this order.
- **3. 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 that 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.
- **4. Related Publications.** Orders and ACs 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.
- **5. Requests for Information.** All public requests for information regarding production approval or certificate management activities will be processed in accordance with the Freedom of Information Act. Refer to FAA Order 1270.1, Freedom of Information Act Program.
- **6. 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., PMA or TSO authorization) is not permitted.
- **7. Suggestions for Improvement.** Please forward all comments on deficiencies, clarifications, or improvements regarding this order to:

Aircraft Certification Service Administrative Services Branch, AIR-510 ATTN: Directives Management Officer 800 Independence Avenue, SW Washington, DC 20591

FAA Form 1320-19, Directive Feedback Information, is located as appendix D to this order for your convenience. If you require an immediate interpretation, please contact AIR-200 at (202) 385-6346; however, you should also complete Form 1320-19 as a follow-up to the conversation.

1/14/2010 8120.17 Appendix D

Appendix D. FAA Form 1320-19, Directive Feedback Information



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 8120.17	
To: Administrative Services Branch, AIR-510	
(Please check all appropriate line items)	
☐ An error (procedural or typographical) has been noted in p	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	ge 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 Form1320-19(10-98)	