

2009 Part 21 Rule Change

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Revised 2/1/18

Part 1 – Definitions and Abbreviations

§ 1.1 – General definitions.

1. **Will 14 CFR part 1 be updated to include definitions from part 21 as well as from other subchapters, such as parts 43 and 45?** No. These revised definitions are specific to parts 21, 43, and 45.

Subpart A – General

§ 21.1 - Applicability and definitions.

1. **Under the definition of "Article," what is the meaning of "Process"?** The FAA has defined "article" to include processes, particularly in reference to TSO parts. There are instances when a stand-alone process is considered an article. One example is software.
2. **Is there a design approval given for a "Process"?** Under the old 14 CFR §21.305(d) and the new § 21.8(d), a design approval can be granted for a process.
3. **What does "Jurisdiction" mean in the text of the definitions?** "Jurisdiction" is a term used in conjunction with a bilateral agreement in reference to an entity that is not a country (i.e., the European Union).

§ 21.3 - Reporting of failures, malfunctions, and defects.

1. **How does the term "approval" affect self-certification on § 21.621?** We do not understand the use of the term "self-certification" in the question. The FAA issues the § 21.621 Technical Standard Order (TSO) import article design approval based on our bilateral partner's certification and receipt of required technical data. Since the bilateral partner is responsible for the continuing operational safety and reporting aspects of the TSO manufacturer, § 21.3(d)(2) excludes them from having to report directly to the FAA. For articles approved in this manner, FAA expects reporting to come from our bilateral partner.

Subpart B – Type Certificates

§ 21.20 - Compliance with applicable requirements.

1. **The certifying statement in § 21.20 is intended for the Aircraft Certification Office (ACO) prior to Type Certificate (TC) or Amended TC. Will the rule be clear on the certifying statement going to the ACO, and that the ACO should not commence any activity until that statement is received?** No. It is not intended for this statement to be a precondition to commencement of work. It is intended to be a precondition to issuance of the TC, per § 21.21, or STC, per § 21.117. The applicant receives this statement after they have had the opportunity to show compliance with all applicable requirements that the FAA has identified in the certification

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basis. Therefore, it is expected that the ACO or delegated organization would have commenced work before receiving this statement.

2. **Will the certifying statement be required with each submittal?** Yes. The applicant must submit a statement certifying that they have shown compliance with all of the standards identified in the certification basis. This must be done prior to the issuance of the certificate. The ACO (or delegated organization) and applicant have flexibility on a method for submitting data on an ongoing basis but the FAA will not make a finding until the applicant provides a statement that they have shown compliance. The FAA's finding is made when the certificate is issued.

§ 21.21 - Issue of type certificate: normal, utility, acrobatic, commuter, and transport category aircraft; manned free balloons; special classes of aircraft; aircraft engines; propellers.

1. **Is this rule enforceable? Isn't the same requirement in §21.21 for all applicants to show compliance? What would the statement required per the new § 21.20 do for us?** The requirement to have the applicant submit a Statement of Compliance is enforceable, as § 21.20 states they must submit a Statement of Compliance for TC or STC issuance. Section 21.21 states the applicant must submit all technical information necessary to show compliance. Applicants have come to depend on the ACO or delegated organization to ensure that showings were made for the entire certification basis. Once the FAA has determined the certification basis, it is the applicant's responsibility to show compliance with all of the relevant airworthiness standards. The applicant's Statement of Compliance is intended to emphasize their role and shared responsibility in the certification process.

§ 21.29 - Issue of type certificate: import products.

1. **Are we going to remove §§ 21.29 and 21.25 from the Type Certificate Data Sheet (TCDS) since it is a procedure and not an airworthiness standard?** No. Section 21.25 contains the airworthiness standards for restricted category TCs under §§ 21.25(a)(1) and 21.25(a)(2). The § 21.29 Import TC indicates an import product approved based on the airworthiness standards of § 21.29.
2. **Are we going to include State of Design on the TCDS?** It is already in the § 21.29 Import TC.

§ 21.31 - Type design.

1. **Why did we not add “commercial part” to this section? How is the Commercial Parts List (CPL) incorporated?** The commercial parts list becomes part of the Instructions for Continued Airworthiness (ICA) as stated in § 21.50, and is incorporated through § 21.31(c), or as otherwise required by the FAA.

§ 21.50 - Instructions for continued airworthiness and manufacturer's maintenance manuals having airworthiness limitations sections.

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1. **Can CPLs be amended or changed? Who can do it? Can an STC holder create, amend, and change a CPL? Can a Major Repair, Major Alterations and Airworthiness (MRA) Organization Designation Authorization (ODA) do it?** Only Design Approval Holders (DAH) can create and amend a CPL. In this case, the DAHs include TC, STC, Parts Manufacturer Approval (PMA) (and Technical Standard Order Authorization (TSOA)) holders.
2. **Will ODAs be able to approve the CPL?** Yes.
3. **Does a commercial part qualify for an Authorized Release Certificate (FAA Form 8130-3 Airworthiness Approval Tag)?** If the part is on a CPL, then the part could qualify for an 8130-3 tag. The airworthiness approval must be issued in accordance with FAA Order 8130.21. A CPL is developed by the design approval holder in accordance with § 21.50 and approved by the FAA. This list is part of the Instruction for Continued Airworthiness (ICA) and contains parts designated by the design approval holder as "commercial parts."
4. **If I have commercial off the shelf (COTS) parts that are part of my type design, am I required to create a commercial parts list and add those parts to my ICAs?** No. Developing a commercial parts list is voluntary.
5. **If the manufacturer of commercial parts makes an upgrade or changes to the design, how will we know?** This answer has two scenarios:
 - a. If the holder of the TC desires to continue using a specific part as a commercial part, it is the responsibility of the TC holder to update the commercial parts list in accordance with § 21.50 as models change.
 - b. If an installer is installing a commercial part on a TC product, it is the responsibility of the installer to ensure that only approved models from the commercial parts list are installed.

Subpart D – Changes to Type Certificates

§ 21.95 - Approval of minor changes in type design.

1. **Will any agreements between the company and FAA Aircraft Certification Office (ACO) be included in the procedure for design data control? Does the company have to describe how they will submit updates for major and minor changes? Are updates submitted only once the data is approved, or should they submit proposed changes?** Changes to design data under §§ 21.95, 21.97, 21.319, and 21.619 should not be confused with changes to design data control under § 21.137(a). The ability to include procedures or agreements between the company and ACO regarding design data remains the same.

Subpart F – Production Under Type Certificate

§ 21.122 - Location of or change to manufacturing facilities.

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1. **Will PCs outside the U.S. be allowed to have designees?** Yes. However, the undue burden process must be followed to determine the use of designees.
2. **How will we do designee oversight?** The FAA will conduct designee oversight as it is currently done, in accordance with FAA Order 8100.8.
3. **Will the designee have to be a U.S. citizen?** The designee does not have to be a U.S. citizen.
4. **Section 21.122(a) allows an applicant a PC outside the United States.**
 - a. **Will there be any relief on the Decision Paper process?** No. The current Decision Paper process will not change.
 - b. **Will we still be required to accomplish a Decision Paper?** Yes. You will still be required to accomplish a decision paper since there is still an undue burden determination required in part 21.

[§ 21.123](#) - Production under type certificate.

1. **Will record retention for engineering documents (software and complex hardware) be included in the 5-year record retention?** No. Engineering documents are part of the type design and must be kept for the lifetime of the product TC.
2. **How did the FAA come up with the 5/10 year requirement for record retention?** This was an Aviation Rule Advisory Committee (ARAC) recommendation.

Subpart G – Production Certificates

[§ 21.135](#) - Organization.

1. **Does the new rule § 21.135 apply to TSO authorization grantees?** No. Section 21.135 applies to applicants for and holders of a production certificate. However, the same requirement for TSOA Holders exist in § 21.605.
2. **The new regulation requires a description of the organization. How do I describe it?** The rule requires a document describing how the organization will ensure compliance with the provisions of this subpart. This can be done as a narrative and may include flow-charts. The FAA recognizes the varying business models and organizational structures of different businesses. The intent of this requirement is to obtain a commitment from top management to establish a quality system that complies with this part and ensures that each product and article conforms to its approved design and is in a condition for safe operation and to continually improve that quality system.

[§ 21.137](#) - Quality system.

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1. **Can a Production Approval Holder (PAH) address any of the 14 elements of the quality system as non-applicable (N/A) in their quality manual?** The PAH can list the element within their quality manual as "not applicable." The FAA will then determine whether or not this element is truly not applicable to the PAH and approve or disapprove the submittal. A possible example of a quality system element being not applicable could be a PAH for software not requiring a calibration system.
2. **The preamble states the quality system is scalable. What does this mean?** Each applicant for or holder of a production approval must establish and describe, in writing, a quality system that ensures that each product and article conforms to its approved design and is in a condition for safe operation. The quality system must address the 14 elements listed in § 21.137. [Examples of Scalability of Quality System under 21.137](#), by system element to large and small companies.

[§ 21.138](#) - Quality manual.

1. **If I submit a quality manual within the required time and the MIDO does not approve the manual by the compliance date, can I continue to produce parts?** Yes. To be in compliance with the rule, the PAH must have submitted their manual describing their quality system to the FAA for approval in accordance with §§ 21.138, 21.308, and 21.608 by the compliance date. Although the FAA has not approved the manual by the compliance date, PAHs must operate to their new/revised quality manual and comply with the new part 21 rule.
2. **If a PAH previously submitted data describing their quality control system or fabrication inspection system (via a quality manual or other document), will a new/revised manual need to be submitted to the FAA?** Yes. To be compliant with the new part 21 rule, all PAHs must submit a manual that describes the quality systems required by §§ 21.137, 21.307, and 21.607. Some PAHs may already have manuals that describes the requirements in §§ 21.137, 21.307, and 21.607 and will simply need to be submit those manuals to the FAA for approval.

[§ 21.139](#) - Location of or change to manufacturing facilities.

1. **Request that there be a definition, standardization and clarification of "Immediate Notification."** Request is noted. Requests for changes to directives should be submitted via a Directive Feedback Information, FAA Form 1320-19.

[§ 21.145](#) - Privileges.

1. **May a 145 Repair Station utilize its existing quality system for the PMA quality system and if so may they reference the existing Repair Station Quality Manual when developing the approved PMA quality manual?** No. The quality system requirements for your Repair Station are not the same as those required by part 21 for a PMA. However, you may use your Repair Station quality system and manual as a basis for your PMA quality system and quality manual. The hybrid system would need to account for all the requirements necessary to meet both sets of

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regulations. As a consequence of having both quality systems in one manual and the manual becoming approved data by the FAA, your PI for the PMA would evaluate, perform certificate management, and possibly take enforcement action on all aspects of your quality system as documented in your approved quality manual. While it is indeed possible for you to document both sets of quality system requirements within a single quality manual, it is not recommended.

Subpart K – Parts Manufacturer Approvals

§ 21.305 - Organization.

1. **14 CFR 21.305 states to provide a document describing how we will comply with the FAA provisions, so this a separate document from our Quality Manual and procedures?** It will be up to the production approval holder as to whether the document required by §§ 21.135, 21.305, or 21.605 is separate or included in the quality manual.
2. **Our Quality Manual and our PMA Quality Procedure have this explanatory information for these two documents. Will they suffice? Or, is there a specific format or requirement (other than what is listed in § 21.305) if this is a separate document?** If they meet the intent of § 21.305, they will suffice. There is no specific format for this document.

§ 21.316 - Responsibility of holder.

1. **How do you identify or mark parts that are listed on the Master Drawing List (MDL) on the supplement?** (Reference § 21.316 (d)(e)) Parts listed on the MDL will be marked in accordance with 14 CFR part 45.
2. **Does § 21.316(e) mean that a sub-assembly that leaves the manufacturer's facility has to be FAA approved and therefore properly marked; or does it mean that, if it is FAA approved, it has to be properly marked? If the second case is correct, what determines whether or not the sub-assembly should be FAA-approved?** Section 21.316(e) requires identification, not marking. Marking, as required by § 21.316(d), is for the PMA article itself, not the component parts/sub-assemblies from which it is made. Component parts/sub-assemblies for the PMA articles, must be manufactured under an FAA approved quality system and must be identified in accordance with design data requirements.

Subpart L – Export Airworthiness Approvals

§ 21.325 - Export airworthiness approvals.

1. **Has the requirement to issue an export airworthiness approval for unassembled aircraft been deleted or has it been relocated?** The previous language in § 21.325(b) specific to unassembled aircraft has been deleted. The rule regarding export airworthiness approvals applies whether the aircraft is assembled or unassembled.

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§ 21.327 - Application.

1. **Can a non-PAH apply for an export 8130-3 tag for a demonstrably airworthy article?** Yes. A non-PAH may apply for an 8130-3 tag. In accordance with § 21.327, any person may apply for an export airworthiness approval.
2. **Has the requirement for a weight and balance within 12 month been removed from requirement for issuance of export?** Yes. We removed this requirement from the rule. However, it may still be a requirement of an importing country or jurisdiction.

§ 21.331 - Issue of airworthiness approval tags for Class II products.

1. **Because the class designations (I, II, and III) have been removed from the rule and guidance material, in what form (oral or written) should applications be submitted when applying for an export certificate of airworthiness (Form 8130-4) or an export airworthiness approval (Form 8130-3)?** Under the new rule, applications to export aircraft will continue to be made in writing using FAA Form 8130-1, Application for Export Certificate of Airworthiness. Similarly, under the new rule, applications to export aircraft engines, propellers, and articles will now be made orally.

§ 21.335 - Responsibilities of exporters.

1. **What is the appropriate form or manner for the disclosure required from an exporter concerning the duration of effectiveness of preservation and packaging of articles subject to export airworthiness approvals?** This information will be stated orally or on FAA Form 8130-1, Application for Export Airworthiness Approval, during the application process, as applicable.
2. **It is common that most commercially available packaging does not include data stating the duration of effectiveness of the packaging. Most commercially available packaging also does not include data that would enable an exporter to accurately calculate the duration of effectiveness of the packaging. In cases where neither the packaging manufacturer nor the parts OEM publishes information about the duration of effectiveness of preservation and packaging, what statement should the exporter use in meeting the requirements of 14 CFR 21.335(b)?** The intent of §21.335(b) is not to create an additional requirement. The wording used in this section of the rule is similar to the wording used in the previous rule in §21.327(f)(7), and is currently requested in boxes 9 and 19 of FAA Form 8130-1, Application for Export Airworthiness Approval. The statement the exporter should use is the same statement that would have been used when previously filling out box 9 or 19 of FAA Form 8130.1.

Part 21 Questions Not Related to a Specific Subpart or Section

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1. **How is software manufacturing handled in the new part 21?** Software manufacturing is handled the same as before the rule change.
2. **How does the new part 21 apply to the reproduction and installation of software?** There is no change. The new part 21 does not specifically address software and will have no effect on the reproduction and installation of software.

Part 43 – Maintenance, Preventive Maintenance, Rebuilding, and Alteration

1. **New § 21.9(a)(4) addresses the new classification of commercial parts and their method for being installed on a type certificated article. There is no mention of how these parts can be repaired once installed. Would the manufacturer of the commercial part be able to repair these parts or would they have to be repaired under part 43? If they are to be repaired under Part 43, would the manufacturer have to be considered an uncertificated maintenance provider (provided they were indeed uncertificated)? Would the part require approval for return to service before installation (after repair)?** The new § 21.9(a)(4) provides for a replacement commercial part that does not need further FAA approval regarding the installation of the replacement part. There have been no changes concerning the maintenance of commercial parts installed on an aircraft. Commercial parts may be maintained in accordance with part 43 if instructions for continued airworthiness (ICA) were accepted detailing the maintenance procedures for maintaining the commercial part as part of the approval of the alteration installing the part on the aircraft (§ 43.13(a)). This maintenance is to be performed by someone authorized per § 43.7 and approved for return to services as prescribed in § 43.9. The requirement of § 43.13(a) cannot be met if ICA detailing the maintenance of a commercial part have not been accepted. Therefore, if a commercial part fails or malfunction without having these ICA the only options to repair the aircraft are to remove the commercial part from the aircraft or replace it with a part as prescribed in § 21.9(a)(4).
It should also be noted that a manufacturer is not authorized to perform repairs in accordance with § 43.3.

Part 45 – Identification and Registration Marking

§ 45.15 - Marking requirements for PMA articles, TSO articles, and critical parts.

1. **What is the difference between "Identification" and "Marking"?** Portions of products and articles produced by a production approval holder (PAH) or under a type certificate (TC) that leave the manufacturer's facility must include specific identification information (part number and name, trademark, symbol, or other FAA-approved identification). These portions of products and articles include sub-assemblies, component parts, or replacement articles. Identification can be accomplished by marking, tagging, placing in a container, providing a document with the required information, or other FAA-approved methods. Marking refers to the physical,

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permanent, and legible application of information such as attaching a data plate, etching, or stamping of a product or article. Required marking information can be found in part 45, subpart B, Marking of Products and Articles. Marking is only required to be applied to the product or article for which the approval is granted and to critical parts, as defined in § 45.15(c).

2. **Is "critical parts" defined?** No. Critical parts are referenced in § 45.15, however, there is no definition.
3. **Does guidance allow for installers or suppliers to part mark the parts (i.e. TSO holder for hoses)?** If a PAH has authorized a supplier to mark articles, then yes, a supplier may apply the markings required by 14 CFR part 45. With regard to "installers," there is guidance concerning the marking of parts after it has left the manufacturing facility. FAA Notice 8900.74, Parts marking provides guidance for the re-marking of part when performing maintenance. Advisory Circular AC 43-18, Fabrication of Aircraft Parts by Maintenance Personnel provides guidance for owner produced parts.
4. **The eligibility marking in the part is going away requiring only "FAA-PMA." Does the PMA holder still need to provide a document with the eligibility (packing list, tag, etc.) of the part to the customer when shipping the part?** No. Although not required, you may send the eligibility in shipping documents if you choose.
5. **Are PMA marking requirements applicable to commercial parts?** No.
6. **Did AIR-200 address the format for marking an article when it has both a TSO and a PMA?** No. When an article is being delivered from the PAH, PAH must specify under which design and production approval the article was manufactured. This is done by identifying the article with either PMA markings or TSO markings.