

provisions of that agreement for that article for import into the United States.

Subpart O—Technical Standard Order Approvals

SOURCE: Docket No. FAA-2006-25877, Amdt. 21-92, 74 FR 53392, Oct. 16, 2009, unless otherwise noted.

§ 21.601 Applicability and definitions.

- (a) This subpart prescribes—
- (1) Procedural requirements for issuing TSO authorizations;
 - (2) Rules governing the holders of TSO authorizations; and
 - (3) Procedural requirements for issuing letters of TSO design approval.
- (b) For the purposes of this subpart—
- (1) A TSO issued by the FAA is a minimum performance standard for specified articles used on civil aircraft;
 - (2) A TSO authorization is an FAA design and production approval issued to the manufacturer of an article that has been found to meet a specific TSO;
 - (3) A letter of TSO design approval is an FAA design approval for an article that has been found to meet a specific TSO in accordance with the procedures of § 21.621;
 - (4) An article manufactured under a TSO authorization, an FAA letter of acceptance as described in § 21.613(b), or an article manufactured under a letter of TSO design approval described in § 21.621 is an approved article for the purpose of meeting the regulations of this chapter that require the article to be approved; and
 - (5) An article manufacturer is the person who controls the design and quality of the article produced (or to be produced, in the case of an application), including any related parts, processes, or services procured from an outside source.

§ 21.603 Application.

- (a) An applicant for a TSO authorization must apply to the appropriate aircraft certification office in the form and manner prescribed by the FAA. The applicant must include the following documents in the application:
- (1) A statement of conformance certifying that the applicant has met the requirements of this subpart and that

the article concerned meets the applicable TSO that is effective on the date of application for that article.

(2) One copy of the technical data required in the applicable TSO.

(b) If the applicant anticipates a series of minor changes in accordance with § 21.619, the applicant may set forth in its application the basic model number of the article and the part number of the components with open brackets after it to denote that suffix change letters or numbers (or combinations of them) will be added from time to time.

(c) If the application is deficient, the applicant must, when requested by the FAA, provide any additional information necessary to show compliance with this part. If the applicant fails to provide the additional information within 30 days after the FAA's request, the FAA denies the application and notifies the applicant.

§ 21.605 Organization.

Each applicant for or holder of a TSO authorization must provide the FAA with a document describing how the applicant's organization will ensure compliance with the provisions of this subpart. At a minimum, the document must describe assigned responsibilities and delegated authority, and the functional relationship of those responsible for quality to management and other organizational components.

§ 21.607 Quality system.

Each applicant for or holder of a TSO authorization must establish a quality system that meets the requirements of § 21.137.

§ 21.608 Quality manual.

Each applicant for or holder of a TSO authorization must provide a manual describing its quality system to the FAA for approval. The manual must be in the English language and retrievable in a form acceptable to the FAA.

§ 21.609 Location of or change to manufacturing facilities.

(a) An applicant may obtain a TSO authorization for manufacturing facilities located outside of the United

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States if the FAA finds no undue burden in administering the applicable requirements of Title 49 U.S.C. and this subchapter.

(b) The TSO authorization holder must obtain FAA approval before making any changes to the location of any of its manufacturing facilities.

(c) The TSO authorization holder must immediately notify the FAA, in writing, of any change to the manufacturing facilities that may affect the inspection, conformity, or airworthiness of its product or article.

§21.610 Inspections and tests.

Each applicant for or holder of a TSO authorization must allow the FAA to inspect its quality system, facilities, technical data, and any manufactured articles and witness any tests, including any inspections or tests at a supplier facility, necessary to determine compliance with this subchapter.

§21.611 Issuance.

If the FAA finds that the applicant complies with the requirements of this subchapter, the FAA issues a TSO authorization to the applicant (including all TSO deviations granted to the applicant).

§21.613 Duration.

(a) A TSO authorization or letter of TSO design approval is effective until surrendered, withdrawn, or otherwise terminated by the FAA.

(b) If a TSO is revised or canceled, the holder of an affected FAA letter of acceptance of a statement of conformance, TSO authorization, or letter of TSO design approval may continue to manufacture articles that meet the original TSO without obtaining a new acceptance, authorization, or approval but must comply with the requirements of this chapter.

§21.614 Transferability.

The holder of a TSO authorization or letter of TSO design approval may not transfer the TSO authorization or letter of TSO design approval.

§21.616 Responsibility of holder.

Each holder of a TSO authorization must—

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(a) Amend the document required by §21.605 as necessary to reflect changes in the organization and provide these amendments to the FAA.

(b) Maintain a quality system in compliance with the data and procedures approved for the TSO authorization;

(c) Ensure that each manufactured article conforms to its approved design, is in a condition for safe operation, and meets the applicable TSO;

(d) Mark the TSO article for which an approval has been issued. Marking must be in accordance with part 45 of this chapter, including any critical parts;

(e) Identify any portion of the TSO article (e.g., sub-assemblies, component parts, or replacement articles) that leave the manufacturer's facility as FAA approved with the manufacturer's part number and name, trademark, symbol, or other FAA approved manufacturer's identification;

(f) Have access to design data necessary to determine conformity and airworthiness for each article produced under the TSO authorization. The manufacturer must retain this data until it no longer manufactures the article. At that time, copies of the data must be sent to the FAA;

(g) Retain its TSO authorization and make it available to the FAA upon request; and

(h) Make available to the FAA information regarding all delegation of authority to suppliers.

§21.618 Approval for deviation.

(a) Each manufacturer who requests approval to deviate from any performance standard of a TSO must show that factors or design features providing an equivalent level of safety compensate for the standards from which a deviation is requested.

(b) The manufacturer must send requests for approval to deviate, together with all pertinent data, to the appropriate aircraft certification office. If the article is manufactured under the authority of a foreign country or jurisdiction, the manufacturer must send requests for approval to deviate, together with all pertinent data, through the civil aviation authority of that country or jurisdiction to the FAA.

§ 21.619 Design changes.

(a) *Minor changes by the manufacturer holding a TSO authorization.* The manufacturer of an article under an authorization issued under this part may make minor design changes (any change other than a major change) without further approval by the FAA. In this case, the changed article keeps the original model number (part numbers may be used to identify minor changes) and the manufacturer must forward to the appropriate aircraft certification office, any revised data that are necessary for compliance with § 21.603(b).

(b) *Major changes by the manufacturer holding a TSO authorization.* Any design change by the manufacturer extensive enough to require a substantially complete investigation to determine compliance with a TSO is a major change. Before making a major change, the manufacturer must assign a new type or model designation to the article and apply for an authorization under § 21.603.

(c) *Changes by persons other than the manufacturer.* No design change by any person (other than the manufacturer who provided the statement of conformance for the article) is eligible for approval under this part unless the person seeking the approval is a manufacturer and applies under § 21.603(a) for a separate TSO authorization. Persons other than a manufacturer may obtain approval for design changes under part 43 or under the applicable airworthiness regulations of this chapter.

§ 21.620 Changes in quality system.

After the issuance of a TSO authorization—

(a) Each change to the quality system is subject to review by the FAA; and

(b) The holder of the TSO authorization must immediately notify the FAA, in writing, of any change that may affect the inspection, conformity, or airworthiness of its article.

§ 21.621 Issue of letters of TSO design approval: Import articles.

(a) The FAA may issue a letter of TSO design approval for an article—

(1) Designed and manufactured in a foreign country or jurisdiction subject

to the export provisions of an agreement with the United States for the acceptance of these articles for import; and

(2) For import into the United States if—

(i) The State of Design certifies that the article has been examined, tested, and found to meet the applicable TSO or the applicable performance standards of the State of Design and any other performance standards the FAA may prescribe to provide a level of safety equivalent to that provided by the TSO; and

(ii) The manufacturer has provided to the FAA one copy of the technical data required in the applicable performance standard through its State of Design.

(b) The FAA issues the letter of TSO design approval that lists any deviation granted under § 21.618.

[Doc. No. FAA-2006-25877, Amdt. 21-92, 74 FR 53392, Oct. 16, 2009; Amdt. 21-92A, 75 FR 9095, Mar. 1, 2010]

Subpart P—Special Federal Aviation Regulations

SOURCE: Docket No. FAA-2011-0186, 76 FR 12555, Mar. 8, 2011, unless otherwise noted.

§ 21.700 SFAR No. 111—Lavatory Oxygen Systems.

The requirements of § 121.1500 of this chapter also apply to this part.

PART 23—AIRWORTHINESS STANDARDS: NORMAL, UTILITY, ACROBATIC, AND COMMUTER CATEGORY AIRPLANES

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