Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM151; Notice No. 25-98-04-SC]

Special Conditions: Boeing Model 757–300 Sudden Engine Stoppage

AGENCY: Federal Aviation Administration (FAA), DOT. ACTION: Notice of proposed special conditions.

SUMMARY: This notice proposes special conditions for the Boeing Model 757-300 airplane. This airplane will have a novel or unusual design feature associated with sudden engine stoppage. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These proposed special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. DATES: Comments must be received on or before January 11, 1999.

ADDRESSES: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Regional Counsel, Attn: Rules Docket (ANM-7), Docket No. NM151, 1601 Lind Avenue SW., Renton, Washington, 98055–4056, or delivered in duplicate to the Regional Counsel at the above address. Comments must be marked: NM151. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: Joe Jacobsen, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98055–4056; telephone (425) 227–2011; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of these proposed special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments will be considered by the Administrator. The proposals described in this notice may be changed in light of the comments received. All comments received will be available in the Rules Docket for examination by interested persons, both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerning this rulemaking will be filed in the docket. Persons wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to NM151." The postcard will be date stamped and returned to the commenter.

Background

On February 21, 1996, Boeing applied for an amendment to Type Certificate No. A2NM to include the new Model 757-300 airplane, a derivative of the Model 757–200 currently approved under Type Certificate No. A2NM. The Model 757-300 airplane is a swept wing, conventional tail, twin engine, turbofan powered transport. Each engine will be capable of delivering 43,100 pounds of thrust. The airframe has been strengthened to accommodate the increased design loads and weights. The airplane has a seating capacity of up to 295, and a maximum takeoff weight of 270,000 pounds (122,470 Kg).

Type Certification Basis

Under the provisions of 14 CFR 21.101, Boeing must show that the Model 757–300 airplane meets the applicable provisions of the regulations incorporated by reference in Type Certificate No. A2NM, or the applicable regulations in effect on the date of application for the change to the Model 757–300. The regulations incorporated by reference in the type certificate are commonly referred to as the "original"

type certification basis." The regulations incorporated by reference in Type Certificate No. A2NM include part 25, as amended by Amendments 25-1 through 25-45, and certain other later amended sections of part 25 that are not relevant to these proposed special conditions. In addition, Boeing has chosen to comply with the applicable regulations in effect on February 21, 1996; specifically part 25 as amended by Amendments 25-1 through 25-85 and certain other earlier amended sections of part 25 that are not relevant to these proposed special conditions. Three exemptions have been granted. The special conditions that may be developed as a result of this notice will form an additional part of the type certification basis.

If the Administrator finds that the applicable airworthiness regulations (i.e., part 25, as amended) do not contain adequate or appropriate safety standards for the Boeing Model 757–300 airplane because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model 757–300 airplane must comply with the fuel vent and exhaust emission requirements of part 34, effective September 10, 1990, plus any amendments in effect at the time of certification; and the noise certification requirements of part 36, effective December 1, 1969, as amended by Amendment 36–1 through the amendment in effect at the time of certification.

Special conditions, as appropriate, are issued in accordance with 14 CFR 11.49 after public notice, as required by §§ 11.28 and 11.29(b), and become part of the type certification basis in accordance with § 21.101(b)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model under the provisions of § 21.101(a)(1).

Novel or Unusual Design Features

The engine proposed for the Boeing Model 757–300 airplane is a high-bypass ratio fan jet engine that will not seize and produce transient torque loads in the same manner that is envisioned by current § 25.361(b)(1) related to "sudden engine stoppage."

Discussion

For the engine proposed for the Model 757-300 airplanes, the limit engine torque load imposed by sudden engine stoppage due to malfunction or structural failure (such as compressor jamming) has been a specific requirement for transport category airplanes since 1957. The size, configuration, and failure modes of jet engines has changed considerably from those envisioned in 14 CFR 25.361(b) when the engine seizure requirement was first adopted. Engines have grown much larger and are now designed with large bypass fans capable of producing much higher torque loads if they become jammed.

Relative to the engine configuration that existed when the rule was developed in 1957, the present generation of engines are sufficiently different and novel to justify issuance of a special condition to establish appropriate design standards. The latest generation of jet engines are capable of producing engine seizure torque loads that are significantly higher than previous generations of engines.

The FAA is developing a new regulation and a new advisory circular that will provide more comprehensive criteria for treating engine torque loads resulting from sudden engine stoppage. In the meantime, a special condition is needed to establish appropriate criteria for the Boeing Model 757–300 airplane.

Limit Engine Torque Loads for Sudden Engine Stoppage

In order to maintain the level of safety envisioned by § 25.361(b), more comprehensive criteria are needed for the new generation of high bypass engines. These proposed special conditions would distinguish between the more common seizure events and those rare seizure events resulting from structural failures in the engine. For these more rare but severe seizure events, the proposed criteria would allow some deformation in the engine supporting structure (ultimate load design) in order to absorb the higher energy associated with the high bypass engines, while at the same time protecting the adjacent primary structure in the wing and fuselage by applying a higher factor of safety to the

maximum torque load imposed by sudden engine stoppage due to a structural failure.

Applicability

As discussed above, these special conditions are applicable to the Boeing Model 757–300. Should Boeing apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well under the provisions of § 21.101(a)(1).

Conclusion

This action affects only certain novel or unusual design features on one model series of airplanes. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 25

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Proposed Special Conditions

Accordingly, the Federal Aviation Administration (FAA) proposes the following special conditions as part of the type certification basis for Boeing Model 757–300 airplanes.

- 1. *Engine Torque Loads*. In lieu of compliance with § 25.361(b), compliance with the following special condition is proposed:
- (a) For turbine engine installations, the mounts and local supporting structure must be designed to withstand each of the following:
- (1) The maximum torque load, considered as limit, imposed by:
- (i) sudden deceleration of the engine due to a malfunction that could result in a temporary loss of power or thrust capability, and that could cause a shutdown due to vibrations; and
- (ii) the maximum acceleration of the engine.
- (2)The maximum torque load, considered as ultimate, imposed by sudden engine stoppage due to a structural failure, including fan blade failure.
- (3) The load condition defined in paragraph (a)(2) of this section is also assumed to act on adjacent airframe structure, such as the wing and fuselage. This load condition is multiplied by a factor of 1.25 to obtain ultimate loads when the load is applied to the adjacent wing and fuselage supporting structure.

Issued in Renton, Washington, on December 3, 1998.

John W. McGraw,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service, ANM-100.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 207, 807, and 1271

[Docket No. 97N-484R]

RIN 0910-AB05

Establishment Registration and Listing for Manufacturers of Human Cellular and Tissue–Based Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the proposed rule concerning establishment registration and listing for manufacturers of human cellular and tissue-based products that was published in the **Federal Register** of May 14, 1998 (63 FR 26744). FDA is taking this action in response to a request for an extension and to allow interested parties additional time for review and to submit comments.

DATES: Submit written comments on the proposed rule by February 8, 1999. ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the Federal Register of May 14, 1998 (63 FR 26744), FDA published a proposed rule to require manufacturers of certain human cellular and tissue-based products to register with the agency and list their products. In addition, the agency proposed to amend the registration and listing regulations that currently apply to human cellular and tissue-based products regulated as drugs, devices, and/or biological products. Interested persons were given until August 12, 1998, to submit written comments on the proposed rule.