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 have 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:

(i) The maximum torque load, considered as ultimate, imposed by 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.

(b) The maximum torque load, considered as ultimate, imposed by sudden engine stoppage due to a structural failure, including fan blade failure.

(c) 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.

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.


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.
On August 6, 1998, a comment was submitted to the docket requesting that the agency extend the comment period on the proposed rule 60 days. The comment noted that certain information relevant to the rulemaking was not included in the public docket. Because the docket was scheduled to close on August 12, 1998, there was insufficient time to prepare and submit a letter of extension to the docket. However, the agency agrees that an additional period will provide time for interested parties to review the proposed rule and information now placed in the public docket and submit written comments. Therefore, the agency is reopening the comment period for an additional 60 days, until February 8, 1999.

Interested persons may, on or before February 8, 1999 submit to the Dockets Management Branch (address above) written comments on the proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The proposed rule and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 1, 1998.

William K. Hubbard, Associate Commissioner for Policy Coordination.

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