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.

[FR Doc. 98–32821 Filed 12–9–98; 8:45 am]

BILLING CODE 4910–13–M

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.

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.

[FR Doc. 98–32744 Filed 12–9–98; 8:45 am]

BILLING CODE 4160–01–F

OVERSEAS PRIVATE INVESTMENT CORPORATION

22 CFR Parts 706 and 713

RIN 3420–AA02

Production of Nonpublic Records and Testimony of OPIC Employees in Legal Proceedings

AGENCY: Overseas Private Investment Corporation.

ACTION: Notice of proposed rulemaking.

SUMMARY: OPIC proposes to establish rules regarding subpoenas seeking nonpublic records or the testimony of OPIC employees in legal proceedings. The proposed rule facilitates access to records in OPIC's custody by centralizing agency decision-making with respect to demands for records or testimony in such legal proceedings. The proposed rule provides procedures, requirements and information on how OPIC will handle these matters and expressly prohibits any disclosure or testimony except as provided by the proposed rule. The effect of the rule will be, among other benefits, to ensure an efficient use of OPIC resources, promote uniformity in decisions, protect confidential information, maintain agency control over the release of official information, protect the interests of the United States, and provide guidance to parties. The proposed rule will also amend the current rule regarding release of OPIC records which are exempt from disclosure under the Freedom of Information Act, to conform with the procedures provided in this proposed rule.

DATES: Submit comments on or before February 8, 1999.

ADDRESSES: Direct comments to Mitchel Neurock, Counsel for Administrative Affairs. Mail or hand-deliver comments to: Overseas Private Investment Corporation, 1100 New York Avenue, NW, Washington, DC 20527. Fax comments to (202) 408–0297. E-mail comments to mneur@opic.gov. Please send comments via one method only.

FOR FURTHER INFORMATION CONTACT: Mitchel Neurock, Counsel for Administrative Affairs, at (202) 336–8400.

SUPPLEMENTARY INFORMATION:

Background

OPIC receives subpoenas and requests for OPIC employees to provide evidence in legal proceedings. Typically, subpoenas are for OPIC records which are not available to the public under the Freedom of Information Act (FOIA). Also, OPIC receives subpoenas and requests for OPIC employees to appear as witnesses in legal proceedings in conjunction with requests for nonpublic records or to provide testimony.

In recent years, the number of requests has averaged 3 to 4 per year. Often, these subpoenas and requests relate to litigation involving projects financed and/or insured in whole or in part by OPIC, where one or more parties want to use nonpublic records, such as OPIC financing documents, in the case. In addition, parties to litigation frequently wish to have an OPIC employee, often a finance or insurance officer, testify to establish the authenticity of the records or to explain the information contained in those records. If OPIC provides these records and an OPIC employee appears as a witness, this will cause a significant disruption in the employee's work schedule. In many cases, parties want to use the OPIC employee as an expert witness on matters such as the fundamentals of project finance or other issues involving opinion evidence. OPIC's experience has been that, in practically all cases, the parties can address these issues by eliciting the testimony of other witnesses, including the testimony of their own independent expert witnesses. They may also use their own records.

OPIC's current regulations fail to inform parties about any matter concerning submission of subpoenas. There is no guidance for parties seeking to submit subpoenas addressing when parties should submit a request for nonpublic documents or testimony, the time period for OPIC's review of such a request, potential fees, or, if a request is granted, any restrictions which OPIC might place upon the disclosure of records or the appearance of an OPIC employee as a witness. There is also no guidance for parties about the factors OPIC will consider in making its determination in response to such requests.

The proposed rule fills in these gaps in OPIC's current regulations. OPIC has tried to write the proposed rule in an easy-to-read, question-and-answer format, to promote straightforward English. The proposed rule, in brief: prohibits disclosure of nonpublic records or testimony by OPIC employees absent compliance with the rule; lets the public know what information to submit and what factors OPIC will consider; and sets out filing fees, deadlines and potential restrictions on disclosure of nonpublic documents and testimony of OPIC employees. The proposed charges for witnesses are the same as those provided by the federal courts, and the fees relating to the production of records are the same as those charged under FOIA.

A few simple definitions clarify that the proposed rule applies to a broad range of cases (not just matters before courts). The proposed rule applies to former as well as to current OPIC employees. Former OPIC employees remain prohibited from testifying about specific matters for which they had responsibility during their OPIC employment, unless permitted to testify as provided in the proposed rule. They would not, however, be barred from appearing on general matters or otherwise employing their expertise (as expert witnesses, for example).

The proposed rule solves some problems which have arisen in the past. It should eliminate or reduce eleventh hour requests for nonpublic documents or testimony of OPIC employees. The procedures and criteria will ensure a more efficient use of OPIC resources, will minimize the possibility of involving OPIC in issues unrelated to its responsibilities, will promote