provided under the contracts, and to otherwise enforce the contracts in accordance with their terms. In no case will the Administrator settle a debt or claim for less than the value (after considering the government's collection costs) of the borrower's system and other collateral securing the debt or claim.

(2) RUS may use such methods, analyses, and assessments as the Administrator deems appropriate to determine the value of the borrower's system.

(g) *Rates.* The Administrator will consider the rates charged for electric service by the borrower and, in the case of a power supply borrower, by its members, taking into account, among other factors, the practices of the Federal Energy Regulatory Commission (FERC), as adapted to the cooperative structure of borrowers, and, where applicable, FERC treatment of any investments by co-owners in projects jointly owned by the borrower.

(h) *Collection action.* The Administrator will consider whether a settlement is favorable to the government in comparison with the amount that can be recovered by enforced collection procedures.

(i) *Regulatory approvals.* Before the Administrator will approve a settlement, the borrower must provide satisfactory evidence that it has obtained all approvals required of regulatory bodies that the Administrator determines are needed to implement rates or other provisions of the settlement, or that are needed in any other way for the borrower to fulfill its obligations under the settlement.

(j) *Conditions regarding management and operations.* As a condition of debt settlement, the borrower, and in the case of a power supply borrower, its members, will be required to implement those changes in structure, management, operations, and performance deemed necessary by the Administrator. Those changes may include, but are not limited to, the following:

(1) The borrower may be required to undertake a corporate restructuring and/or sell a portion of its plant, facilities, or other assets

(2) The borrower may be required to replace senior management and/or hire outside experts acceptable to the Administrator. Such changes may include a commitment by the borrower's board of directors to restructure and/or obtain new membership to improve board oversight and leadership;

(3) The borrower may be required to agree to:

(i) Controls by RUS on the general funds of the borrower, as well as on any investments, loans or guarantees by the borrower, notwithstanding any limitations on RUS' control rights in the borrower's loan documents or RUS regulations; and

(ii) Requirements deemed necessary by RUS to perfect and protect its lien on cash deposits, securities, equipment, vehicles, and other items of real or non-real property; and

(4) In the case of a power supply borrower, the borrower may be required to obtain credit support from its member systems, as well as pledges and action plans by the members to change their operations, management, and organizational structure (e.g., shared services, mergers, or consolidations) in order to reduce operating costs, improve efficiency, and/or expand markets and revenues.

(k) *Conveyance of assets.* As a condition of a settlement, a borrower may be required to convey some or all its assets to the government.

(l) *Additional conditions.* The borrower will be required to warrant and agree that no bonuses or similar extraordinary compensation has been or will be provided, for reasons related to the settlement of government debt, to any officer or employee of the borrower or to other persons or entities identified by RUS. The Administrator may impose such other terms and conditions of debt settlement as the Administrator determines to be in the government's interests.

(m) *Certification of accuracy.* Before the Administrator will approve a debt settlement, the manager or other appropriate official of the borrower must certify that all information provided to the government by the borrower or by any agent of the borrower, in connection with the debt settlement, is true, correct, and complete in all material respects.

§ 1717.1205 Waiver of existing conditions on borrowers.

Pursuant to section 331(b) of the Con Act, the Administrator, at his or her sole discretion, may waive or otherwise reduce conditions and requirements imposed on a borrower by its loan documents if the Administrator determines that such action will contribute to enhancement of the government's recovery of debt. Such waivers or reductions in conditions and requirements under this section shall not include the exercise of any of the debt settlement measures set forth in § 1717.1204(c), which are subject to all of the requirements of said § 1717.1204.

§ 1717.1206 Loans subsequent to settlement.

In considering any future loan requests from a borrower whose debt has been settled in whole or in part (including the surviving entity of merged or consolidated borrowers, where at least one of said borrowers had its debts settled), it will be presumed that credit support for the full amount of the requested loan will be required. Such support may be in a number of forms, provided that they are acceptable to the Administrator on a case by case basis. They may include, but need not be limited to, equity infusions and guarantees of debt repayment, either from the applicant's members (in the case of a power supply borrower), or from a third party.

§ 1717.1207 RUS obligations under loan guarantees.

Nothing in this subpart affects the obligations of RUS under loan guarantee commitments it has made to the Federal Financing Bank or other lenders.

§ 1717.1208 Government's rights under loan documents.

Nothing in this subpart limits, modifies, or otherwise affects the rights of the government under loan documents executed with borrowers, or under law or equity.

Dated: September 19, 1997.

Jill Long Thompson,

Under Secretary, Rural Development.

[FR Doc. 97–25315 Filed 9–25–97; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–141; Special Conditions No. 25–ANM–132]

Special Conditions: Boeing Model 737–600/–700/–800; High Intensity Radiated Fields (HIRF)/Engine Stoppage

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for Boeing Model 737–600/–700/–800 airplanes. These airplanes will have novel and unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level

of safety equivalent to that provided by the existing airworthiness standards.

EFFECTIVE DATE: September 17, 1997.

FOR FURTHER INFORMATION CONTACT:

Gregory Dunn, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (425) 227–2799; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Background

On February 4, 1993, Boeing submitted an application for an amendment to Type Certificate A16WE to include the next generation 737 family of airplanes. Two of these airplanes will have the same length as the present 737–300 and 737–500. The third version will be the existing 737–400, stretched to add two additional passenger rows. In addition, all models will have increased wing size, higher thrust engines, and body structure modifications due to increased design weights and higher wing and tail loads. The maximum operating altitude is to be increased from 37,000 ft. to 41,000 ft. The long range cruise speed is increased to 0.78 Mach or better. The range is increased to be transcontinental of approximately 2,950 nmi. There is only one engine type being offered, which is a derivative of the existing CFM56 referred to as the CFM56–7.

Type Certification Basis

Under the provisions of 14 CFR § 21.101, Boeing must show that the Model 737–600/–700/–800 airplanes meet the applicable provisions of the regulations incorporated by reference in Type Certificate A16WE, or the applicable regulations in effect on the date of application for the change to the Model 737. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The certification basis for the Model 737–600/–700/–800 airplanes includes 14 CFR part 25, as amended by Amendments 25–1 through 25–77, except as indicated below:

Section No.	Title	At amdt. 25–
25.365	Pressurized Compartment Loads.	0
25.561	Emergency Landing Conditions—General.	0
25.562	Emergency Landing Dynamic Conditions.	*64
25.571	Damage-tolerance and Fatigue Evaluation of Structure.	**0,77
25.607	Fasteners	**0,77
25.631	Bird Strike Damage.	**0,77
25.699	Lift and Drag Device Indicator.	**0,77
25.783(f)	Doors	**15,77
25.807(c)(3)	Emergency Exits	15
25.813	Emergency Exit Access.	45
25.832	Cabin Ozone Concentration.	***0,77
25.1309	Equipment, Systems and Installations.	**0,77
25.1419(c)	Ice Protection	**23,77

Boeing has also elected to comply with Amendments 25–78 and 25–80 and portions of Amendments 25–79, 25–84, and 25–86.

*Flight attendants seats will be qualified to Technical Standard Order C127. Passenger and flight deck seats will comply with 14 CFR 25.562 (a),(b),((c)(1),(2),(3),(4),(7), and (8)).

**Applicable to new and significantly modified structure and systems and portions of the airplane affected by these changes. Where two amendment levels are shown for the same paragraph, the number without the asterisks (*) applies to structures, systems, and portions of the airplane which are not new or significantly modified. The structure, systems, and components which comply with the later amendment will be identified in Boeing document D010A001, approved by the FAA and JAA, and referenced on the type certificate data sheet.

***Boeing provides FAA approved data (Document number D6–49779) to 737 operators to enable the operators to show ozone compliance per 14 CFR 121.578 for their specific route structures.

Amendment level ''0'' is the original published version of Part 25 (February 1, 1965).

In addition, the certification basis will be upgraded to include the Part 25 complement to any Part 121 amendments adopted prior to the certification date and having impact on transport category airplane type designs, and these special conditions.

In addition to the applicable airworthiness regulations and special conditions, the Model 737–600/–700/–800 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34, and the noise certification requirements of 14 CFR part 36.

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 737–600/–700/–800 airplanes because of novel or unusual design features, special conditions are prescribed under the provisions of 14 CFR 21.16 to establish a level of safety equivalent to that established in the regulations.

Special conditions, as appropriate, are issued in accordance with 14 CFR 11.49 after public notice, as required by 14 CFR 11.28 and 11.29, and become part of the type certification basis in accordance with 14 CFR 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 14 CFR 21.101(a)(1).

Novel or Unusual Design Features

The Boeing Model 737–600/–700/–800 airplanes will incorporate new avionic/electronic systems, such as the Air Data Inertial Reference System (ADIRS) and Common Display System (CDS), that perform critical functions. These systems may be vulnerable to HIRF external to the airplane. In addition, the CFM56–7B engine proposed for the Boeing 737–700 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

There is no specific regulation that addresses protection requirements for electrical and electronic systems from HIRF. Increased power levels from ground-based radio transmitters and the growing use of sensitive electrical and electronic systems to command and control airplanes have made it necessary to provide adequate protection.

To ensure that a level of safety is achieved equivalent to that intended by the regulations incorporated by reference, a special condition is needed for the Boeing Model 737–600/–700/–800, which requires that new electrical and electronic systems that perform critical functions be designed and installed to preclude component damage and interruption of function due to both the direct and indirect effects of HIRF.

For the CFM56–7B engine, 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 change considerably from those envisioned in 14 CFR 25.361(b) when the engine seizure requirement was first adopted.

Relative to the engine configurations 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 FAA is developing a new regulation and new advisory circular that will provide more comprehensive criteria for treating engine loads resulting from structural failures. In the meantime, a special condition is needed to establish appropriate criteria for the Boeing 737–600/–700/–800 airplanes.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, coupled with electronic command and control of the airplane, the immunity of critical digital avionics systems to HIRF must be established.

It is not possible to precisely define the HIRF to which the airplane will be exposed in service. There is also uncertainty concerning the effectiveness of airframe shielding for HIRF. Furthermore, coupling of electromagnetic energy to cockpit-installed equipment through the cockpit window apertures is undefined. Based on surveys and analysis of existing HIRF emitters, an adequate level of protection exists when compliance with the HIRF protection special condition is shown with either paragraphs 1, or 2 below:

1. A minimum threat of 100 volts per meter peak electric field strength from 10 KHz to 18 GHz.

a. The threat must be applied to the system elements and their associated wiring harnesses without the benefit of airframe shielding.

b. Demonstration of this level of protection is established through system tests and analysis.

2. A threat external to the airframe of the following field strengths for the frequency ranges indicated.

Frequency	Peak (V/M)	Average (V/M)
10 KHz–100 KHz	50	50
100 KHz–500 KHz	60	60
500 KHz–2 MHz	70	70
2 MHz–30 MHz	200	200
30 MHz–100 MHz	30	30
100 MHz–200 MHz	150	33
200 MHz–400 MHz	70	70
400 MHz–700 MHz	4,020	935
700 MHz–1 GHz	1,700	170
1 GHz–2 GHz	5,000	990
2 GHz–4 GHz	6,680	840
4 GHz–6 GHz	6,850	310
6 GHz–8 GHz	3,600	670
8 GHz–12 GHz	3,500	1,270
12 GHz–18 GHz	3,500	360
18 GHz–40 GHz	2,100	750

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. This special condition distinguishes between the more common events and those rare events resulting from structural failures in the engine. For these more rare but severe events, these criteria allow deformation in the engine supporting structure 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 an additional factor on these loads.

Discussion of Comments

Notice of proposed special conditions No. SC–97–3–NM for the Boeing 737–600/–700/–800 airplanes was published in the **Federal Register** on May 14, 1997 (62 FR 26453).

Comments were received from an engine manufacturer who, while supporting the need for the engine torque loads requirements, offers the following comments for consideration.

The commenter recommends that the words ''* * * and that could cause a shutdown due to vibrations'' be removed from paragraph 2(b)(1)(i) of the special conditions. The commenter states that its position is based on a comparison of the proposed special condition with similar work currently underway within the Aviation Rulemaking Advisory Committee (ARAC). The commenter notes differences between these two proposals. For example, the special condition adds a provision that the engine malfunction for limit load calculation be such that it ''could cause a shutdown due to engine vibrations,'' while this provision was removed from the ARAC proposal, whose intent is to address engine events beyond maximum acceleration and other than structural failures, seizures, jamming, and unbalance, such as engine surge. The commenter further notes that the special condition does not explicitly state that the limit torque acts simultaneously with 1g flight loads, although this may be intended.

The FAA recognizes that the ARAC working group is studying this issue and that its final proposal may be different from what has already been applied as a special condition on several airplanes. However, until more definitive criteria have been accepted by industry and by the FAA, the special condition will remain unchanged. The special condition is based on the assumption that the airplane will be subjected to 1g flight loads throughout the engine torque event.

Applicability

As discussed above, these special conditions are applicable to the Model 737–600/–700/–800 airplanes. Should Boeing Commercial Airplane Group 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 14 CFR 21.101(a)(1).

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for the Model 737–600/–700/–800 airplanes is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

Conclusion

This action affects only certain design features on the Boeing Model 737–600/–700/–800 airplanes. It is not a rule of general applicability and 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

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

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

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Boeing Model 737–600/–700/–800 airplanes.

1. *Protection from Unwanted Effects of High-Intensity Radiated Fields (HIRF).* Each electrical and electronic system that performs critical functions must be designed and installed to ensure that the operation and operational capability of these systems

to perform critical functions are not adversely affected when the airplane is exposed to high intensity radiated fields.

For the purpose of this special condition, the following definition applies:

Critical Functions. Functions whose failure would contribute to or cause a failure condition that would prevent the continued safe flight and landing of the airplane.

2. *Engine Torque Loads*. In lieu of compliance with § 25.361(b), compliance with the following must be shown:

(b) 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 (b)(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 September 17, 1997.

Vi L. Lipski,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–25509 Filed 9–25–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 801

[Docket No. 95N–0374]

RIN 0910–AA32

Latex Condoms; User Labeling; Expiration Dating

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule that requires the labeling of latex condoms to contain an expiration date based upon physical and mechanical testing performed after exposing the product to varying conditions that age latex. Studies show that latex condoms degrade over time. Such degradation has a significant effect on the product's ability to provide a barrier to sexually transmitted diseases (STD's), including human immunodeficiency virus (HIV). This requirement is established in order to provide consumers with essential information regarding the safe use of these products.

EFFECTIVE DATE: March 25, 1998.

FOR FURTHER INFORMATION CONTACT: Donald E. Marlowe, Center for Devices and Radiological Health (HFZ–100), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–2444.

SUPPLEMENTARY INFORMATION:

I. Background

It is estimated that over 1 million persons in the United States are infected with HIV (Ref. 1). Although nonsexual transmission can occur, HIV is transmitted primarily through sexual contact. With the prevalence of HIV infection and the risk of transmission of other STD's, the importance of the quality of an effective barrier to the transmission of infection is crucial. Because latex membranes, such as condoms and medical gloves, are effective barriers against the spread of various diseases, including hepatitis, HIV, and other STD's (Refs. 2, 4, and 5), the Centers for Disease Control and Prevention and the Surgeon General of the Public Health Service have recommended that latex condoms be used according to instructions with every act of intercourse for maximum protection against STD's (Ref. 3).

The effectiveness of latex condoms as a barrier, however, is dependent upon the integrity of the latex material. Degradation of latex film products (e.g., the embrittlement of the latex film, an increase in the porosity of the membrane, or other loss of physical properties) occurs when latex is exposed to various types of environmental conditions (such as elevated temperature, fluorescent lights, or ozone) normally experienced in product use, shipment, or storage conditions. Exposure to these environmental conditions degrade the film progressively over time and may result in bursts, rips, tears, or seepages that allow the transmission of disease.

To understand the effects of aging and other storage conditions on latex properties, the State of Washington's Board of Pharmacy initiated an FDA-sponsored study of the material integrity of latex condoms (the FDA/Washington study) in July of 1989 (Ref. 6). At the laboratories of the FDA/Washington study, packaged and unpackaged latex condoms were exposed to 20 and 30 °C (representing room temperature) for up to 5 years. In order to represent exposure to the upper extreme of environmental temperatures, condoms were exposed for 100 days to a temperature of 45 °C. Also, to accelerate the aging process of the latex, condoms were exposed to temperatures of 70 and 85 °C for up to 100 days (Refs. 7 through 9).

The study revealed that exposed condoms (i.e., condoms not protected by packaging) degraded to the point of being unusable within 1 year at room temperature, and at higher temperatures in as little as 10 days. The FDA/Washington study further shows that latex condoms stored in intact plastic packages also degrade over time, though at a much slower rate. The results of the FDA/Washington study demonstrate that aging and other conditions can significantly affect the integrity, strength, and quality of latex essential to maintaining a barrier against the transmission of disease.

Based upon these findings, using standards established by the American Society for Testing and Materials (ASTM), and following meetings with condom manufacturers, the agency published in the **Federal Register** of May 24, 1996 (61 FR 26140), a proposed rule that would require latex condoms to be labeled with an expiration date. Specifically, FDA proposed that, to ensure visibility of the expiration date by customers, an expiration date must appear on the primary packaging (i.e., the individual package), as well as higher levels of labeling, such as the case containing individually packaged products.

To establish the expiration date, FDA proposed that a manufacturer, before performing tests on products that demonstrate physical and mechanical integrity of the product, subject products from three discrete and random lots to each of the following conditions: (1) Storage unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged after manufacture, followed by storage of the packaged product at 70 °C (plus or minus 2 °C) for 7 days; (2) storage unpackaged for the maximum amount of time the manufacturer allows the product to remain unpackaged after manufacture, followed by storage of the packaged product at 40 to 50 °C (plus or minus