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NUCLEAR REGULATORY COMMISSION

10 CFR Part 13

RIN 3150–AD71

Program Fraud Civil Remedies; Technical Amendment

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule: technical amendment.

SUMMARY: This document corrects a paragraph numbering error contained in the Nuclear Regulatory Commission (NRC) regulations implementing the Program Fraud Civil Remedies Act of 1986.

EFFECTIVE DATE: July 29, 1997.

FOR FURTHER INFORMATION CONTACT: Susan Fonner, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone (301) 415–1634.

SUPPLEMENTARY INFORMATION: As published, the NRC's Program Fraud Civil Remedies regulations contain a numbering error in the definition of ''Claim'' contained in 10 CFR 13.2. Paragraph (b)(3) of the definition should have been numbered as paragraph (c). That this was an inadvertent error is evident both from the internal wording of the definition and from the definition of ''claim'' in the Act contained at 31 U.S.C. 3801. The definition of ''claim'' in the regulation is virtually identical to the definition in the Act, except for this numbering error.

List of Subjects in 10 CFR Part 13

Claims, Fraud, Organization and function (government agencies), Penalties.

Accordingly, 10 CFR part 13 is amended by making the following corrective amendment.

PART 13—PROGRAM FRAUD CIVIL REMEDIES

1. The authority citation for Part 13 continues to read as follows:

Authority: Public Law 99–509, secs. 6101–6104, 100 Stat. 1874 (31 U.S.C. 3801–3812). Sections 13.13 (a) and (b) also issued under section Pub. L. 101–410, 104 Stat. 890, as amended by section 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2161 note).

§ 13.2 [Amended]

2. In the definition of ''Claim'' in § 13.2, paragraph (b)(3) is redesignated as paragraph (c).

Dated at Rockville, MD, this 17th day of July, 1997.

For the Nuclear Regulatory Commission.

L. Joseph Callan,

Executive Director for Operations.

[FR Doc. 97–19929 Filed 7–28–97; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 25

[Docket No. NM–143; Special Conditions No. 25–ANM–130]

Special Conditions: International Aviation Services, Ltd.; Boeing Model 747–SP Airplane; High Intensity Radiated Fields (HIRF)

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions, request for comments.

SUMMARY: These special conditions are issued for Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. 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.

DATES: The effective date of these special conditions is July 17, 1997. Comments must be received on or before August 28, 1997.

ADDRESSES: Comments on these special conditions may be mailed in duplicate to: Federal Aviation Administration, Office of the Assistant Chief Counsel, Attn: Rules Docket (ANM–7), Docket No. NM–143, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; or delivered in duplicate to the Office of the Assistant Chief Counsel at the above address. Comments must be marked: Docket No. NM–143. 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: Tom Groves, FAA, Standardization Branch, ANM–113, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington, 98055–4056; telephone (425) 227–1503; facsimile (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA has determined that good cause exists for making these special conditions effective upon issuance; however, interested persons are invited to submit such written data, views, or arguments as they may desire. Communications should identify the regulatory docket and special condition 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. These special conditions may be changed in light of the comments received. All comments submitted 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 request must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. NM–143.'' The postcard will be date stamped and returned to the commenter.

Background

On August 8, 1996, International Aviation Services, Ltd. applied for a supplemental type certificate (STC) to modify Boeing Model 747–SP airplanes

listed on Type Certificate A20WE. The modification includes the installation of a 5-tube electronic flight instrument system (EFIS) that will replace the existing electro-mechanical horizontal situation indicator (HSI) and attitude director indicator (ADI). These systems, which display flight critical information, are vulnerable to high-intensity radiated fields (HIRF) external to the airplane.

Type Certification Basis

Under the provisions of 14 CFR § 21.101, International Aviation Services, Ltd. must show that the Boeing Model 747–SP, as changed, continues to meet the applicable provisions of the regulations incorporated by reference in Type Certificate A20WE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly referred to as the ''original type certification basis.'' The certification basis for the modified Model 747–SP includes 14 CFR part 25, as amended by Amendments 25–1 through 25–8 and certain later amendments, special conditions, exemptions, and optional requirements listed in the type certificate data sheet that are not relevant to these special conditions. In addition, the certification basis for the modifications, and for areas affected by the modifications, will be amended to include the following sections:

Section	Amendment	Title
25.779(a)	25–72	Motion and effect of cockpit controls.
25.1303	25–38	Flight and navigation instruments.
25.1307	25–72	Miscellaneous equipment.
25.1309	25–41	Equipment, systems, and installations.
25.1316	25–80	System lightning protection.
25.1321	25–41	Arrangement and visibility.
25.1322	25–38	Warning, caution, and advisory lights.
25.1329	25–46	Automatic pilot system.
25.1331	25–41	Instruments using a power supply.
25.1333	25–41	Instrument systems.
25.1335	25–41	Flight director systems.
25.1381	25–72	Instrument lights.
25.1501	25–42	General.
25.1529	25–54	Instructions for Continued Airworthiness.
25.1581	25–72	General.
25.1583	25–72	Operating limitations.

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 747–SP airplane because of novel or unusual design features, special conditions are prescribed under the provisions of § 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 §§ 11.28 and 11.29, 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 International Aviation Services, Ltd. apply at a later date for an STC to modify any other model already included on the same type certificate 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 Boeing Model 747–SP will incorporate a new electronic flight instrument system that performs critical functions. This system may be vulnerable to HIRF external to the airplane.

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, special conditions are needed for the Boeing Model 747–SP, which require that new electrical and electronic systems, such as the EFIS, 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.

High-Intensity Radiated Fields (HIRF)

With the trend toward increased power levels from ground-based transmitters, plus the advent of space and satellite communications, couples 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 HGz–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

Applicability

As discussed above, these special conditions are applicable to Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. Should International Aviation Services, Ltd. apply at a later date for a supplemental type certificate to modify any other model included on Type Certificate A20WE to incorporate 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 design features on Boeing Model 747–SP airplanes modified by International Aviation Services, Ltd. 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.

The substance of the special conditions for this airplane has been subjected to the notice and comment procedure in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. For this reason, and because a delay would significantly affect the certification of the airplane, which is imminent, the FAA has determined that prior public notice and comment are unnecessary and impracticable, and good cause exists for adopting these special conditions immediately. Therefore, these special conditions are being made effective upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

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 747–SP airplanes modified by International Aviation Services, Ltd.

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 these special conditions, 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.

Issued in Renton, Washington, on July 17, 1997.

Gary L. Killion,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–19858 Filed 7–28–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 1270

[Docket No. 93N–0453]

RIN 0910–AA40

Human Tissue Intended for Transplantation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require certain infectious disease testing, donor screening, and recordkeeping to help prevent the transmission of the human immunodeficiency virus (HIV), and hepatitis viruses through human tissue used in transplantation. In response to comments received, FDA has clarified and modified many of the provisions of the interim rule on human tissue intended for transplantation which was published in the **Federal Register** of December 14, 1993. The final rule requires facilities engaged in the recovery, screening, testing, processing, storing, or distributing of human tissues to ensure that specified minimum required medical screening and infectious disease testing has been performed and that records documenting such screening and testing for each human tissue are available for inspection by FDA. The regulations also contain provisions for the inspection of such facilities and for retaining, recalling, or destroying human tissue for which appropriate documentation is not available.

DATES: The regulation is effective January 26, 1998. This effective date is applicable to all human tissue intended for transplantation procured on or after this date. Written comments on the information collection requirements should be submitted by September 29, 1997.

ADDRESSES: Submit written comments on the information collection requirements to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

A. Background

In the **Federal Register** of December 14, 1993 (58 FR 65514), FDA issued an interim rule on human tissue intended for transplantation (hereinafter referred to as the interim rule). These regulations became effective upon the date of publication in the **Federal Register** and required human tissue in storage as of that date to be in compliance. The interim rule was issued because of evidence indicating an immediate need to protect the public health from the transmission of HIV infection and hepatitis infection through transplantation of human tissue from known donors infected with or at risk for these diseases. The movement towards regulating human tissue was accelerated by a hearing on appropriate oversight for human tissue banking chaired by Senator (then Representative) Wyden before the Subcommittee on Regulation, Business Opportunities and Technology of the Committee on Small Business held on October 15, 1993. At the hearing, representatives of persons involved in human tissue banking advocated that legislation setting forth regulatory requirements for human tissue banking be passed. There was testimony that human tissues from foreign sources were being offered for sale in the United States with little documentation as to the source of the human tissue, the cause of death, the medical conditions of the donor, or the results of donor screening and testing. This raised significant concerns about the safety and quality of some of the human tissue available for transplantation. As a result of a number of similar allegations, the agency initiated inquiries into the possibility that human tissues intended for transplantation were being supplied without appropriate infectious disease testing and medical screening. In a relatively brief period of time, the agency was able to confirm the availability for importation and distribution to the United States of