

mixer valve/main air valve assemblies and associated hot air ducting; in accordance with Hawker Service Bulletin SB. 49-45, dated May 15, 1995.

(1) If no discrepancy is detected, no further action is required by this AD.

(2) If any overheating or degradation is detected, prior to further flight, replace the hose assembly with a new assembly, ensuring proper clearance and routing exists, in accordance with the service bulletin.

(3) If any hose assembly is improperly routed, prior to further flight, re-route the assembly maintaining proper clearance, in accordance with the service bulletin.

(4) If the clearance of the hose assembly is inadequate and the hose assembly is properly routed, prior to further flight, adjust the hose assembly to achieve the 0.5-inch clearance, in accordance with the service bulletin.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM-113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM-113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM-113.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on December 18, 1995.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

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14 CFR Part 71

[Airspace Docket No. 95-AWP-38]

Proposed Establishment of Class D and E Airspace Areas; Saipan Island, CQ

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would establish Class D and E airspace areas at Saipan Island, CQ. The Class D airspace area would be established because an airport traffic control tower (ATCT) at Saipan International Airport, Saipan Island, CQ, has been commissioned. The FAA is proposing to establish the Class E airspace area to provide adequate controlled airspace for aircraft executing

instrument approach operations at Saipan International Airport.

DATES: Comments must be received on or before February 2, 1996.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, AWP-500, Docket No. 95-AWP-38, Federal Aviation Administration, P. O. Box 92007, Worldway Postal Center, Los Angeles, CA 90009.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, Room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Patricia Crawford, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-3075.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made:

"Comments to Airspace Docket No. 95-AWP-38." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both

before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3485.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish Class D and E airspace areas at Saipan Island, CQ. The Class D airspace area would be established because an ATCT at Saipan International Airport, Saipan Island, CQ, has been commissioned. The FAA is proposing to establish the Class E airspace area to provide adequate controlled airspace for aircraft executing instrument approach operations at Saipan International Airport. Class D and E airspace designations are published in paragraphs 5000 and 6004, respectively, of FAA Order 7400.9C dated August 17, 1995, and effective September 16, 1995, which is incorporated by reference in 14 CFR 71.1. The Class D and E airspace designations listed in this document would be published subsequently in this Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

ICAO Considerations

As part of this proposal relates to navigable airspace outside the United States, this notice is submitted in accordance with the International Civil Aviation Organization (ICAO) International Standards and Recommended Practices.

Applicability of International Standards and Recommended Practices by the Air Traffic Rules and Procedures Service, FAA, in areas outside domestic airspace of the United States is governed by Article 12 of, and Annex 11 to, the Convention on International Civil Aviation, which pertains to the establishment of air navigational facilities and services necessary to promote the safe, orderly, and expeditious flow of civil air traffic. Their purpose is to ensure that civil aircraft operations on international air routes are carried out under uniform conditions designed to improve the safety and efficiency of air operations.

The International Standards and Recommended Practices in Annex 11 apply in those parts of the airspace under the jurisdiction of a contracting state, derived from ICAO, wherein air traffic services are provided and also whenever a contracting state accepts the responsibility of providing air traffic services over high seas or in airspace of undetermined sovereignty. A contracting state accepting such responsibility may apply the International Standards and Recommended Practices in a manner consistent with that adopted for airspace under its domestic jurisdiction.

In accordance with Article 3 of the Convention on International Civil Aviation, Chicago, 1944, state aircraft are exempt from the provisions of Annex 11 and its Standards and Recommended Practices. As a contracting state, the United States agreed by Article 3(d) that its state aircraft will be operated in international airspace with due regard for the safety of civil aircraft.

Since this action involves, in part, the designation of navigable airspace outside the United States, the Administrator is consulting with the Secretary of State and the Secretary of Defense in accordance with the provisions of Executive Order 10854.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9C, Airspace Designations and Reporting Points, dated August 17, 1995, and effective September 16, 1995, is amended as follows:

Paragraph 5000—Class D Airspace

* * * * *

AWP CQ D Saipan Island, CQ [New]

Saipan International Airport, CQ

(Lat. 15°07'08"N, long. 145°43'46"E)

Saipan RBN (lat. 15°06'41"N, long. 145°42'37"E)

That airspace extending upward from the surface to and including 2,500 feet MSL within a 4.3-mile radius of Saipan International Airport. This Class D airspace area is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory, Pacific Chart Supplement.

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Paragraph 6004—Class E airspace areas designated as an extension to a Class D surface area

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AWP CQ E4 Saipan Island, CQ [New]

Saipan International Airport, CQ

(Lat. 15°07'08"N, long. 145°43'46"E)

Saipan RBN (lat. 15°06'41"N, long. 145°42'37"E)

That airspace extending upward from the surface within a 4.3-mile radius of Saipan International Airport and within 2.6 miles each side of the Saipan RBN 264° bearing, extending from the 4.3-mile radius to 7.4 miles west of the Saipan RBN and within 1.8 miles each side of the Saipan RBN 248° radial, extending from the 4.3-mile radius to 7.4 miles west of the Saipan RBN and within 1.8 miles each side of the Saipan RBN 068° radial, extending from the 4.3-mile radius to 6.5 miles east of the Saipan International Airport. This Class E airspace area is effective during the specific dates and times established in advanced by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory, Pacific Chart Supplement.

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Issued in Washington, DC, on December 12, 1995.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 95–31202 Filed 12–21–95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 50 and 312

[Docket No. 95N–0359]

Protection of Human Subjects; Informed Consent

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its current informed consent regulations to require that the written consent form signed by the subject or the subject's legally authorized representative, be dated by the subject or the subject's legally authorized representative at the time consent is given. FDA is proposing this requirement because the agency has had problems on occasion verifying that informed consent was obtained from a research subject prior to participation in a study because the consent document was not dated. The agency believes that by explicitly requiring that the consent form be dated at the time it is signed, the agency will be able to help ensure that informed consent was, in fact, obtained prior to entry into the study as required by FDA regulations. FDA is also proposing to amend its regulation on case histories to clarify what adequate case histories include.

DATES: Written comments by March 21, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Glen D. Drew, Office of Health Affairs (HFY–20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1382.

SUPPLEMENTARY INFORMATION:

I. Description of the Proposed Rule

Except as provided in FDA regulations, no investigator may involve a human being as a subject in research covered by part 50 (21 CFR part 50) unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. Section 50.20 requires the investigator to seek informed consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that