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.

* * * * *

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]

BILLING CODE 4910–13–P

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