Issued in Renton, Washington, on September 26, 2005.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 05–19876 Filed 10–3–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2005–21166; Airspace Docket No. 05–AWP–4]

Establishment of Class E Airspace; Hana, HI

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes a Class E airspace area at Hana, HI. The establishment of an Area Navigation (RNAV) Global Positioning System (GPS) Instrument Approach Procedures (IAP) RNAV (GPS) to Runway (RWY) 26 IAP and a RNAV Departure Procedure (DP) at Hana Airport, Hana, HI has made this action necessary. Additional controlled airspace extending upward from 700 feet or more above the surface of the earth is needed to contain aircraft executing this RNAV (GPS) IAP and RNAV DP. The intended effect of this action is to provide adequate controlled airspace for Instrument Flight Rules operations at Hana Airport, Hana, HI.

DATES: Effective 0901 UTC October 27, 2005.

FOR FURTHER INFORMATION CONTACT: Debra Trindle, The Office of the Regional Western Terminal Operations, Federal Aviation Administration, at 15000 Aviation Boulevard, Lawndale, California 90261, telephone (310) 725–6613.

SUPPLEMENTARY INFORMATION:

History

On August 3, 2005, the FAA proposed to amend 14 CFR parts 71 by modifying the Class E airspace area at Hana Airport, HI (05 FR 15314). Additional controlled airspace extending upward from 700 feet or more above the surface is needed to contain aircraft executing the RNAV (GPS) (RWY) 26 IAP and RNAV DP at Hana Airport, Hana, HI. This action will provide adequate controlled airspace for aircraft executing the RNAV (GPS) (RWY) 26 IAP and RNAV DP at Hana Airport, Hana, HI.

Interested parties were invited to participate in this rulemaking, proceeding by submitting written comments on the proposal to the FAA. No comments to the proposal were received. Class E airspace designations for airspace extending from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9N, dated August September 1, 2005, and effective September 16, 2005, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 modifies the Class E airspace area at Hana Airport, HI. The establishment of a RNAV (GPS) (RWY) 26 IAP and RNAV DP at Hana Airport has made this action necessary. The effect of this action will provide adequate airspace for aircraft executing the RNAV (GPS) (RWY) 26 IAP and RNAV DP at Hana Airport, Hana, HI.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation—(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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; ROUTES; AND REPORTING POINTS.

■ 1. The authority citation for 14 CFR 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 7400.9N, Airspace Designations and Reporting Points, dated September 1, 2005, and effective September 16, 2005, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

AWP HI E5 Hana, HI [New]

Hana, HI

(Lat. 20°47′44″ N, long. 156°00′52″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of the Hana Airport.

* * * * *

Dated: Issued in Los Angeles, California, on September 21, 2005.

Leonard Mobley,

Acting Area Director, Western Terminal Operations.

[FR Doc. 05–19855 Filed 10–3–05; 8:45am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30458; Amdt. No. 3135]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: This rule is effective October 4, 2005. The compliance date for each SIAP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director

of the Federal Register as of October 4, 2005.

ADDRESSES: Availability of matter incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Ave, SW., Washington, DC 20591;

2. The FAA Regional Office of the region in which affected airport is located; or

3. The National Flight Procedures Office, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 or,

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call (202) 741–6030, or go to: *http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.*

For Purchase—Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA–200), FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591; or

2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald P. Pate, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd., Oklahoma City, OK 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to Title 14, Code of Federal Regulations, Part 97 (14 CFR Part 97) amends Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in the appropriate FAA Form 8260, as modified by the the National Flight Data Center (FDC)/Permanent Notice to Airmen (P–NOTAM), which is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Code of Federal Regulations. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form documents is unnecessary. The provisions of this amendment state the affected CFR sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP as modified by FDC/P–NOTAMs.

The SIAPs, as modified by FDC P–NOTAM, and contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these chart changes to SIAPs, the TERPS criteria were applied to only these specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for all these SIAP amendments requires making them effective in less than 30 days.

Further, the SIAPs contained in this amendment are based on the criteria contained in TERPS. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs are impracticable and contrary to the public interest and, where applicable, that good cause exists for making these SIAPs effective in less than 30 days.

Conclusion

The FAA has determined that this 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. For the same reason, the FAA certifies that this amendment will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, and Navigation (Air).

Issued in Washington, DC, on September 23, 2005.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, Title 14, Code of Federal regulations, Part 97, 14 CFR part 97, is amended by amending Standard Instrument Approach Procedures, effective at 0901 UTC on the dates specified, as follows:

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

■ 1. The authority citation for part 97 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

■ 2. Part 97 is amended to read as follows:

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33, and 97.35 [Amended]

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * Effective upon publication

FDC date	State	City	Airport	FDC No.	Subject
09/19/05	WY	Cheyenne	Cheyenne Regional/Jerry Olson Field.	5/8498	RNAV (GPS) Rwy 27, Orig-A

FDC date	State	City	Airport	FDC No.	Subject
09/19/05	ID	Idaho Falls	Idaho Falls Regional	5/8505	NDB Rwy 20, Amdt 10B
09/19/05	ID	Idaho Falls	Idaho Falls Regional	5/8520	ILS Rwy 20, Amdt 11C
09/19/05	UT	Cedar City	Cedar City Regional	5/8521	ILS OR LOC Rwy 20, Amdt 3C
09/19/05	UT	Provo	Provo Muni	5/8522	ILS OR LOC/DME Rwy 13, Orig-A
09/19/05	UT	Roosevelt	Roosevelt Muni	5/8523	RNAV (GPS) Rwy 25, Orig-A
09/19/05	UT	Roosevelt	Roosevelt Muni	5/8524	VOR/DME RNAV Rwy 25, Amdt 2A
09/19/05	UT	Provo	Provo Muni	5/8526	VOR/DME Rwy 13, Amdt 1A
09/19/05	UT	Provo	Provo Muni	5/8527	VOR Rwy 13, Amdt 3A
09/19/05	UT	Moab	Canyon Lands Field	5/8528	VOR–A, Amdt 10A

[FR Doc. 05–19745 Filed 10–3–05; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2005N–0341]

Medical Devices; Immunology and Microbiology Devices; Classification of AFP-L3% Immunological Test Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying AFP-L3% (alpha-fetoprotein L3 subfraction) immunological test systems into class II (special controls). The special control that will apply to the device is the guidance document entitled ''Class II Special Controls Guidance Document: AFP-L3% Immunological Test Systems.'' The agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a guidance document that will serve as the special control for the device.

DATES: This rule is effective November 3, 2005. The classification was effective May 19, 2005.

FOR FURTHER INFORMATION CONTACT: Maria Chan, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0496.

SUPPLEMENTARY INFORMATION:

I. What is the Background of this Rulemaking?

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of FDA's regulations.

Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification (section 513(f)(2) of the act).

In accordance with section 513(f)(1) of the act, FDA issued an order on April 1, 2005, classifying the Wako LBA (liquid-phase binding assay) AFP-L3 in class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device that was subsequently reclassified into class I or class II. On April 6, 2005, Wako Chemical USA, Inc., submitted a petition requesting classification of the Wako AFP-L3 Test System under section 513(f)(2) of the act. The manufacturer recommended that the device be classified into class II.

In accordance with 513(f)(2) of the act, FDA reviewed the petition in order to classify the device under the criteria for classification set forth in 513(a)(1) of the act. Devices are to be classified into class II if general controls, by themselves, are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the petition, FDA determined that the Wako LBA AFP-L3 Test System can be classified into class II with the establishment of special controls. FDA believes these special controls will provide reasonable assurance of the safety and effectiveness of the device.

The device is assigned the generic name AFP-L3% immunological test system and it is identified as an in vitro device that consists of reagents and an automated instrument used to quantitatively measure, by immunochemical techniques, AFP and AFP-L3 subfraction in human serum. The device is intended for in vitro diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma, in conjunction with other laboratory findings, imaging studies, and clinical assessment.

FDA has identified the risks to health associated with this type of device as inappropriate risk assessment and improper patient management. Failure of the system to perform as indicated, or error in interpretation of results, could lead to inappropriate risk assessment and improper management of patients with chronic liver diseases. Specifically, a falsely low AFP-L3% could result in a determination that the patient is at a lower risk of developing hepatocellular carcinoma, which could delay appropriate monitoring and treatment. A falsely high AFP-L3% could result in a determination that the patient is at a