DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30562 Amdt. No. 3229]

Standard Instrument Approach Procedures, Weather Takeoff Minimums; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard **Instrument Approach Procedures** (SIAPs) and/or Weather Takeoff Minimums for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or 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 August 8, 2007. The compliance date for each SIAP and/or Weather Takeoff Minimums 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 August 8, 2007.

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

For Examination—

- 1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue, SW., Washington, DC 20591;
- 2. The FAA Regional Office of the region in which the affected airport is located;
- 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 and Weather Takeoff Minimums 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 and Weather Takeoff Minimums 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 of the Code of Federal Regulations, Part 97 (14 CFR part 97), establishes, amends, suspends, or revokes SIAPs and/or Weather Takeoff Minimums. The complete regulatory description of each SIAP and/or Weather Takeoff Minimums is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR part 97.20. The applicable FAA Forms are identified as FAA Forms 8260-3, 8260-4, 8260-5 and 8260-15A. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs and/or Weather Takeoff Minimums, 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 and/or Weather Takeoff Minimums but refer to their 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 and/ or Weather Takeoff Minimums 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 and/or Weather Takeoff Minimums. 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 and/or Weather Takeoff Minimums as contained in the transmittal. Some SIAP and/or Weather Takeoff Minimums amendments may have been previously issued by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP, and/or Weather Takeoff Minimums amendments may require making them effective in less than 30 days. For the remaining SIAPs and/or Weather Takeoff Minimums, an effective date at least 30 days after publication is provided.

Further, the SIAPs and/or Weather Takeoff Minimums contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these SIAPs and/or Weather Takeoff Minimums, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and/or Weather Takeoff Minimums and safety in air commerce, I find that notice and public procedure before adopting these SIAPs and/or Weather Takeoff Minimums are impracticable and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs and/or Weather Takeoff Minimums 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 July 27, 2007. **James J. Ballough**,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, under Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and Weather Takeoff Minimums 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:

Effective 30 AUG 2007

Grand Canyon, AZ, Grand Canyon National Park, Takeoff Minimums and Obstacle DP, Orig

Phoenix, AZ, Phoenix Deer Valley, RNAV (GPS)-B, Orig-A

Phoenix, AZ, Phoenix Deer Valley, RNAV (GPS) RWY 25L, Orig-B

Sylvania, GA, Plantation Airpark, NDB RWY 23, Amdt 2

Westfield/Springfield, MA, Barnes Muni, ILS OR LOC RWY 20, Amdt 6

Westfield/Springfield, MA, Barnes Muni, RNAV (GPS) RWY 20, Orig

Westfield/Springfield, MA, Barnes Muni, GPS RWY 20, Orig-A, CANCELLED

Lee's Summit, MO, Lee's Summit Municipal, Takeoff Minimums and Obstacle DP, Orig Aberdeen/Amory, MS, Monroe County,

RNAV (GPS) RWY 18, Orig Aberdeen/Amory, MS, Monroe County,

RNAV (GPS) RWY 36, Orig Aberdeen/Amory, MS, Monroe County, Takeoff Minimums and Obstacle DP, Orig

Erwin, NC, Harnett County, Takeoff Minimums and Obstacle DP, Orig

Laconia, NH, Laconia, Muni, NDB RWY 8, Amdt 9

Laconia, NH, Laconia, Muni, ILS OR LOC RWY 8, Amdt 1

Laconia, NH, Laconia, Muni, RNAV (GPS) RWY 8, Orig

Laconia, NH, Laconia, Muni, RNAV (GPS) RWY 26, Orig Laconia, NH, Laconia, Muni, GPS RWY 26,

Orig-A, CANCELLED

New York, NY, LaGuardia, ILS OR LOC RWY 4, Amdt 35

New York, NY, LaGuardia, RNAV (RNP) Z RWY 4, Orig New York, NY, LaGuardia, RNAV (RNP) Z

New York, NY, LaGuardia, RNAV (RNP) Z RWY 22, Orig New York, NY, LaGuardia, RNAV (GPS) Y RWY 4, Amdt 2

New York, NY, LaGuardia, RNAV (GPS) Y RWY 22, Amdt 2

Sioux Falls, SD, Joss Foss Field, Takeoff Minimums and Obstacle DP, Amdt 7 Houston, TX, Houston Executive, RNAV (GPS) RWY 18, Orig

Houston, TX, Houston Executive, RNAV (GPS) RWY 36, Orig

Houston, TX, Houston Executive, Takeoff Minimums and Obstacle DP, Orig Menomonie, WI, Menomonie Municipal-

Score Field, RNAV (GPS) RWY 27, Orig Menomonie, WI, Menomonie Municipal-Score Field, RNAV (GPS) RWY 9, Orig

Norfolk, VA, Hampton Roads Executive, NDB RWY 2, Amdt 7

Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 10, Orig

Norfolk, VA, Hampton Roads Executive, RNAV (GPS) RWY 28, Orig

Norfolk, VA, Hampton Roads Executive, GPS RWY 10, Orig-A, CANCELLED

Norfolk, VA, Hampton Roads Executive, GPS RWY 28, Orig-A, CANCELLED

Norfolk, VA, Hampton Roads Executive, Takeoff Minimums and Obstacle DP, Amdt 1

Effective 27 SEP 2007

Chicago, IL, Chicago-O'Hare Intl, RNAV (GPS) RWY 32L, Amdt 2A

The FAA published several Amendments in Docket No. 30558, Amdt No. 3225 to Part 97 Of the Federal Aviation Regulations (Vol. 72, FR No. 135, Page 38755; dated Monday, July 16, 2007) under section 97.33, effective 30 August 2007, which is hereby RESCINDED as follows:

Miami, FL, Miami Intl, RNAV (RNP) Y RWY 9, Orig

Miami, FL, Miami Intl, RNAV (GPS) Z RWY 9, Amdt 1

Miami, FL, Miami Intl, ILS OR LOC RWY 9, Amdt 10

[FR Doc. E7–15134 Filed 8–7–07; 8:45 am] BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. 2007N-0294]

Medical Devices: Immunology and Microbiology Devices: Classification of In Vitro Human Immunodeficiency Virus Drug Resistance Genotype Assay

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying an in vitro human immunodeficiency virus (HIV) drug resistance genotype assay into class II (special controls). The special control that will apply to this device is the guidance document entitled "Class II Special Controls Guidance Document: In Vitro HIV Drug Resistance Genotype Assay." FDA is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of this device. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device.

DATES: This rule becomes effective September 7, 2007. The classification of this device into class II became effective on September 26, 2001.

FOR FURTHER INFORMATION CONTACT:

Nathaniel L. Geary, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

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, 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. FDA 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 part 807 (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.

In accordance with section 513(f)(1) of the act, FDA issued an order on June 27, 2001, classifying into class III the