

Lago Vista, TX, Lago Vista TX—Rusty Allen, RNAV (GPS) RWY 15, Orig
 Robstown, TX, Nueces County, GPS RWY 13, Orig-C, CANCELED
 Robstown, TX, Nueces County, RNAV (GPS) RWY 13, Orig
 Robstown, TX, Nueces County, Takeoff Minimums and Obstacle DP, Amdt 1
 Clarksville, VA, Lake Country Regional, VOR/DME-A, Orig-A, CANCELED
 Richland, WA, Richland, LOC RWY 19, Amdt 8
 Richland, WA, Richland, RNAV (GPS) Y RWY 19, Amdt 1
 Richland, WA, Richland, RNAV (GPS) Z RWY 19, Orig
 Wenatchee, WA, Pangborn Memorial, ILS X RWY 12, Orig
 Yakima, WA, Yakima Air Terminal/McAllister Field, RNAV (GPS) X RWY 27, Amdt 1A
 Medford, WI, Taylor County, RNAV (GPS) RWY 16, Orig
 Medford, WI, Taylor County, RNAV (GPS) RWY 34, Orig
 Mineral Point, WI, Iowa County, NDB RWY 22, Amdt 6
 Mineral Point, WI, Iowa County, RNAV (GPS) RWY 4, Amdt 1
 Mineral Point, WI, Iowa County, RNAV (GPS) RWY 11, Amdt 1
 Mineral Point, WI, Iowa County, RNAV (GPS) RWY 22, Amdt 1
 Mineral Point, WI, Iowa County, RNAV (GPS) RWY 29, Amdt 1
 Superior, WI, Richard I Bong, GPS RWY 3, Orig, CANCELED
 Superior, WI, Richard I Bong, GPS RWY 13, Orig, CANCELED
 Superior, WI, Richard I Bong, GPS RWY 31, Orig, CANCELED
 Superior, WI, Richard I Bong, RNAV (GPS) RWY 4, Orig
 Superior, WI, Richard I Bong, RNAV (GPS) RWY 14, Orig
 Superior, WI, Richard I Bong, RNAV (GPS) RWY 22, Orig
 Superior, WI, Richard I Bong, RNAV (GPS) RWY 32, Orig
 Casper, WY, Casper/Natrona County Intl, Takeoff Minimums and Obstacle DP, Amdt 4
 Cheyenne, WY, Cheyenne Rgnl/Jerry Olson Field, Takeoff Minimums and Obstacle DP, Amdt 4

[FR Doc. 2012-18521 Filed 8-1-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30854; Amdt. No. 3489]

Standard Instrument Approach Procedures, and Takeoff Minimums and Obstacle Departure Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This rule establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures 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, adding new obstacles, or changing 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 2, 2012. The compliance date for each SIAP, associated Takeoff Minimums, and ODP 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 2, 2012.

ADDRESSES: Availability of matter 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.

*Availability—*All SIAPs are available online free of charge. Visit nfdc.faa.gov to register. Additionally, individual SIAP and Takeoff Minimums and ODP 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.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham III, 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 rule amends Title 14, Code of Federal Regulations, Part 97 (14 CFR part 97) by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (FDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of Title 14 of the Code of Federal Regulations.

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. This amendment provides the affected CFR sections and specifies the types of SIAP and the corresponding effective dates. This amendment also identifies the airport and its location, the procedure 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 changes to SIAPs, the TERPS criteria were applied only to 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.

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 July 20, 2012.

John Duncan,

Deputy 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.

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

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

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, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

Effective Upon Publication

AIRAC Date	State	City	Airport	FDC No.	FDC Date	Subject
23-Aug-12	KS	Wichita	Wichita Mid-Continent	2/0134	7/11/12	RNAV (GPS) RWY 1R, Amdt 1.
23-Aug-12	NE	North Platte	North Platte Rgnl Airport Lee Bird Field.	2/0484	7/11/12	ILS OR LOC RWY 30, Amdt 6.
23-Aug-12	NE	North Platte	North Platte Rgnl Airport Lee Bird Field.	2/0485	7/11/12	VOR RWY 35, Amdt 18A.
23-Aug-12	TX	Dallas	Dallas Love Field	2/0613	7/11/12	ILS RWY 13R, Amdt 4D.
23-Aug-12	TX	Dallas	Dallas Love Field	2/0617	7/11/12	ILS RWY 13L, Amdt 31B.
23-Aug-12	CA	Santa Ana	John Wayne Airport-Orange County.	2/1446	7/11/12	RNAV (GPS) Y RWY 19R, Amdt 1B.
23-Aug-12	KS	Hutchinson	Hutchinson Muni	2/3180	7/11/12	RNAV (GPS) RWY 31, Amdt 1.
23-Aug-12	MA	Orange	Orange Muni	2/3482	7/11/12	VOR A, Amdt 7.
23-Aug-12	MA	Worcester	Worcester Rgnl	2/3525	7/11/12	ILS OR LOC RWY 29, Amdt 4.
23-Aug-12	IA	Des Moines	Des Moines Intl	2/3637	7/11/12	ILS OR LOC RWY 13, Amdt 9A.
23-Aug-12	OK	Tulsa	Tulsa Intl	2/3664	7/11/12	RNAV (RNP) Z RWY 26, Orig-A.
23-Aug-12	OK	Tulsa	Tulsa Intl	2/3666	7/11/12	RNAV (GPS) Y RWY 26, Amdt 3.
23-Aug-12	NC	Jacksonville	Albert J Ellis	2/4274	7/11/12	RNAV (GPS) RWY 5, Amdt 1.
23-Aug-12	MN	Luverne	Quentin Aanenson Field	2/5558	7/11/12	RNAV (GPS) RWY 36, Orig.
23-Aug-12	OK	Tulsa	Tulsa Intl	2/6222	7/11/12	VOR OR TACAN RWY 26, Amdt 24.
23-Aug-12	AL	Huntsville	Huntsville Intl-Carl T Jones Field.	2/6348	7/11/12	ILS OR LOC RWY 18R, Amdt 24C.
23-Aug-12	TX	George West	Live Oak County	2/7921	7/11/12	RNAV (GPS) RWY 13, Orig.
23-Aug-12	TX	George West	Live Oak County	2/7922	7/11/12	VOR/DME A, Amdt 2.
23-Aug-12	MN	Owatonna	Owatonna Degner Rgnl	2/7931	7/11/12	ILS OR LOC RWY 30, Amdt 2A.
23-Aug-12	WI	Boyceville	Boyceville Muni	2/7936	7/11/12	RNAV (GPS) RWY 26, Amdt 1.
23-Aug-12	WI	Boyceville	Boyceville Muni	2/7937	7/11/12	RNAV (GPS) RWY 8, Amdt 1.
23-Aug-12	MO	Mountain Grove	Mountain Grove Memorial	2/7942	7/11/12	VOR/DME OR GPS Rwy 8, Orig-A.
23-Aug-12	MI	Fremont	Fremont Muni	2/8257	7/11/12	RNAV (GPS) RWY 18, Amdt 1B.
23-Aug-12	NY	Williamson/Sodus ...	Williamson-Sodus	2/8598	7/11/12	RNAV (GPS) RWY 10, Amdt 1.
23-Aug-12	NY	Williamson/Sodus ...	Williamson-Sodus	2/8599	7/11/12	RNAV (GPS) RWY 28, Amdt 2.
23-Aug-12	FL	Miami	Miami Intl	2/8600	7/11/12	ILS OR LOC RWY 26L, Amdt 15B.
23-Aug-12	LA	New Orleans	Louis Armstrong New Orleans Intl.	2/8632	7/11/12	ILS OR LOC RWY 1, Amdt 17.
23-Aug-12	CA	Santa Ana	John Wayne Airport-Orange County.	2/8703	7/11/12	ILS OR LOC RWY 19R, Amdt 12A.
23-Aug-12	TX	Austin	Lakeway Airpark	2/8777	7/11/12	RNAV (GPS) RWY 16, Orig.

[FR Doc. 2012-18516 Filed 8-1-12; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF COMMERCE**Bureau of Industry and Security****15 CFR Part 774****The Commerce Control List***CFR Correction*

In Title 15 of the Code of Federal Regulations, Parts 300 to 799, revised as of January 1, 2012, in supplement no. 1 to part 774, in Category 6, make the following corrections:

- 1. In 6A001:
 - A. On page 807, in the note following paragraph 6A001.a.1, add “equipment as follows” after “6A001.a.1 does not control”.
 - B. On page 807, in paragraph a.1.a.1.a, remove “20” and add “20°” in its place.
 - C. On page 810, designating the notes following 6A001.b.2 as “Note 1” and “Note 2”.
 - D. On page 810, removing the note to 6A001.a.2 following the N.B. at the end of the section.
- 2. In 6A992, on page 826, in the table for “License Requirements”, remove the entry for RS and place it below the table as an indented paragraph.
- 3. In 6B108, on page 830, remove “Unit: r” and add “Unit: Number” in its place.
- 4. In 6C005, on page 831, add “License Requirements” above “Reason for Control”.
- 5. In 6D001, on page 831, remove “CIV: * * *” and add “CIV: N/A” in its place.
- 6. In 6D003:
 - A. On page 832, in “Reason for Control”, after “NS”, add “RS,”.
 - B. On page 833, remove paragraphs h.1.a and h.1.b.
- 7. In 6E001, on page 834, add “License Requirements” above “Reason for Control”.
- 8. In 6E002, on page 835, add “License Requirements” above “Reason for Control”.

[FR Doc. 2012-18967 Filed 8-1-12; 8:45 am]

BILLING CODE 1505-01-D

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 807**

[Docket No. FDA-2009-N-0114]

RIN 0910-AF88

Implementation of Device Registration and Listing Requirements Enacted in the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, the Medical Device User Fee and Modernization Act of 2002, and Title II of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to reflect recent statutory amendments to the device registration and listing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Food and Drug Administration Amendments Act of 2007 (FDAAA), enacted on September 27, 2007, amended the FD&C Act by requiring domestic and foreign device establishments to begin submitting their registration and device listing information to FDA by electronic means rather than on paper forms, and also specified the timeframes when establishments are required to submit such information. In addition, this final rule would facilitate FDA's collection of additional registration information from foreign establishments as required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). The final rule will update certain provisions in the regulations to improve the quality of registration and listing information available to FDA. FDA relies on having complete and accurate registration and listing information in order to accomplish a number of important public health objectives.

DATES: This final rule is effective October 1, 2012.

FOR FURTHER INFORMATION CONTACT:

Ann Ferriter, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2680, Silver Spring, MD 20993-0002, 301-796-5686; and

Stephen Ripley, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401

Rockville Pike, Suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:**Table of Contents**

- I. Background
- II. Overview of the Final Rule
- III. Comments on the Proposed Rule
- IV. Legal Authority
- V. Analysis of Economic Impacts
- VI. Paperwork Reduction Act of 1995
- VII. Environmental Impact
- VIII. Federalism
- IX. References

I. Background

We originally published establishment registration regulations for medical devices in the **Federal Register** of September 3, 1976 (41 FR 37458) (proposed rule) and August 23, 1977 (42 FR 42520) (final rule), and device listing regulations in the **Federal Register** of September 30, 1977 (42 FR 52808) (proposed rule), and August 25, 1978 (43 FR 37990) (final rule).

These regulations called for establishment registration and device listing information to be submitted to the Center for Devices and Radiological Health (CDRH) on several paper forms: FDA 2891, Registration of Device Establishment; FDA 2891a, Annual Registration of Device Establishment; and FDA 2892, Device Listing. Once these forms were completed and submitted to FDA, FDA then forwarded them to a data entry contractor who entered the information into FDA's device registration and listing database.

In June 2002, section 321 of the Bioterrorism Act (Pub. L. 107-188) amended section 510(i) of the FD&C Act (21 U.S.C. 360(i)) to require those foreign establishments who are required to register with FDA to do so by electronic means, and to include additional information identifying certain parties involved in the importation of the foreign establishment's devices into the United States as part of their registration. Subsequently, in October 2002, section 207 of the Medical Device User Fee and Modernization Act (MDUFMA) (Pub. L. 107-250) further amended section 510 of the FD&C Act by extending the requirement for electronic submission of registration information to include domestic firms as well as foreign firms. However, when adding these new electronic submission requirements, which appear in section 510(p) of the FD&C Act, Congress chose to delay their implementation so that FDA would have an opportunity to first put systems in place to accommodate the electronic receipt of registration information. This was accomplished by including a