List of Subjects in 14 CFR Part 97

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

Issued in Washington, DC on April 11, 2003.

James J. Ballough,

Director, Flight Standards Service.

Adoption of the Amendment

■ Accordingly, pursuant to the authority delegated to me, part 97 of the Federal Aviation Regulations (14 CFR part 97) is amended by establishing, amending, suspending, or revoking Standard Instruction 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, 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, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

Effective May 15, 2003

Akron, CO, Colorado Plains Regional, RNAV (GPS) RWY 11, Orig
Akron, CO, Colorado Plains Regional, RNAV (GPS) RWY 29, Orig
Akron, CO, Colorado Plains Regional, GPS RWY 11, Orig, (CANCELLED)
Akron, CO, Colorado Plains Regional, GPS RWY 29, Orig, (CANCELLED)
Agana, Guam, Guam International, RNAV (GPS) RWY 6L, Orig
Gibson City, IL, Schertz Field, VOR OR GPS–A, Amdt 4 (CANCELLED)
Caruthersville, MO, Caruthersville Mem, VOR/DME RWY 18, Orig
Caruthersville, MO, Caruthersville Mem, RNAV (GPS) RWY 18, Orig
Caruthersville, MO, Caruthersville Mem, RNAV (GPS) RWY 36, Orig
Glen Falls, NY, Floyd Bennett Memorial, VOR/DME or GPS RWY 19, AMDT 6B (CANCELLED)
Glen Falls, NY, Floyd Bennett Memorial, RNAV (GPS) RWY 1, ORIG
Glen Falls, NY, Floyd Bennett Memorial, RNAV (GPS) RWY 12, ORIG
Glen Falls, NY, Floyd Bennett Memorial, RNAV (GPS) RWY 19, ORIG
Glen Falls, NY, Floyd Bennett Memorial, RNAV (GPS) RWY 30, ORIG
Kinston, NC, Kinston Rgnl Jetport at Stallings Fld, RNAV (GPS) RWY 23, Amdt 1
Bellefontaine, OH, Bellefontaine Muni, VOR/DME RNAV RWY 22, Amdt 5A, (CANCELLED)
Bellefontaine, OH, Bellefontaine Muni, NDB OR GPS RWY 22, Amdt 6, (CANCELLED)
Salt Lake City, UT, Salt Lake City Intl, ILS RWY 16R, Amdt 1B
Salt Lake City, UT, Salt Lake City Intl, ILS RWY 34R, Amdt 1B

Effective June 12, 2003

Anahuac, TX, Chambers County, NDB RWY 12, Amdt 2

** * * Effective July 10, 2003*

Aurora, NE, Aurora Muni, NDB RWY 16, Amdt 3A (CANCELLED)
Crete, NE, Crete Muni, NDB RWY 17, Amdt 2A (CANCELLED)
Crete, NE, Crete Muni, NDB RWY 35, Amdt 2A (CANCELLED)

The FAA published the following procedures in Docket No. 30359; Amdt. No. 3049 to Part 97 of the Federal Aviation Regulations (Vol. 68, FR No. 54, Page 13622; dated Friday, March 20, 2003) under section 97.33 effective May 15, 2003 which are hereby rescinded:

Akron, CO, Colorado Springs Regional, RNAV (GPS) RWY 11, Orig
Akron, CO, Colorado Springs Regional, RNAV (GPS) RWY 29, Orig
Akron, CO, Colorado Springs Regional, GPS RWY 11, Orig, (CANCELLED)
Akron, CO, Colorado Springs Regional, GPS RWY 29, Orig, (CANCELLED)

The FAA published the following procedures in Docket No. 30360; Amdt. No. 3051 to Part 97 of the Federal Aviation Regulations (Vol. 68, FR No. 65, Page 16413; dated Friday, April 4, 2003) under section 97.33 effective May 15, 2003 which are hereby rescinded:

Agana, Guam, Guam International, RNAV (GPS) Y RWY 6L, Orig
Agana, Guam, Guam International, RNAV (GPS) Z RWY 6L, Orig

[FR Doc. 03–9724 Filed 4–21–03; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No.30364; Amdt. No. 3054]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes 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 April 22, 2003. 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 April 22, 2003.

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 affected airport is located; or

3. The Flight Inspection Area Office which originated the SIAP.

4. The Office of the Federal Register, 800 North Capitol Street, NW., Suite 700, Washington, DC

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 (AMCAFS–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 part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes Standard Instrument Approach

Procedures (SIAPs). The complete regulatory description on each SIAP is contained in the appropriate FAA Form 8260 and the National Flight Data Center (FDC)/Permanent (P) Notices to Airmen (NOTAM) which are incorporated by reference in the amendment under 5 U.S.C. 552(a), 1 CFR part 51, and § 97.20 of the Federal Aviation's Regulations (FAR). 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 of 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 (and FAR) 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 part 97 of the Federal Aviation Regulations (14 CFR part 97) establishes, amends, suspends, or revokes SIAPs. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained in the content of the following FDC/P NOTAMs for each SIAP. The SIAP information in some previously designated FDC/Temporary (FDC/T) NOTAMs is of such duration as to be permanent. With conversion to FDC/P NOTAMs, the respective FDC/T NOTAMs have been canceled.

The FDC/P NOTAMs for the SIAPs 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 by FDC/P NOTAMs, 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 National 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 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 the 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.

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Issued in Washington, DC on April 11, 2003.

James J. Ballough,

Director, Flight Standards Service.

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§ 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
03/26/03 ...	OK	Sand Springs	William R. Pogue Muni	3/2388	NDB Rwy 35, Amdt 2B
03/27/03 ...	IL	Chicago	Chicago Midway	3/2415	ILS Rwy 4R, Amdt 9B
03/27/03 ...	GA	Newnan	Newnan Coweta County	3/2432	GPS Rwy 32, Orig
03/28/03 ...	CO	Denver	Centennial	3/2448	VOR/DME RNAV Rwy 28, Amdt 1
03/28/03 ...	WY	Riverton	Riverton Regional	3/2465	VOR Rwy 10, Amdt 8A
03/31/03 ...	OH	Bellefontaine	Bellefontaine Regional	3/2499	RNAV (GPS) Rwy 25, Orig
03/31/03 ...	OK	Sand Springs	William R. Pogue Muni	[1] 3/2504	GPS Rwy 35, Orig-A
04/01/03 ...	LA	Lake Charles	Chennault Intl	3/2534	ILS Rwy 15, Amdt 4B
04/02/03 ...	WV	Bluefield	Mercer County	3/2571	VOR Rwy 23, Amdt 8A
04/02/03 ...	WV	Bluefield	Mercer County	3/2572	VOR/DME or GPS Rwy 23, Amdt 4A
04/02/03 ...	WV	Bluefield	Mercer County	3/2573	ILS Rwy 23, Amdt 14D
04/02/03 ...	IL	Decatur	Decatur	3/2577	NDB Rwy 6, Amdt 6

FDC date	State	City	Airport	FDC No.	Subject
04/02/03 ...	IL	Decatur	Decatur	3/2578	LOC BC Rwy 24, Amdt 10
04/02/03 ...	IL	Decatur	Decatur	3/2581	ILS Rwy 6, Amdt 13A
04/02/03 ...	IL	Decatur	Decatur	3/2582	VOR Rwy 36, Amdt 15
04/02/03 ...	TX	San Antonio	San Antonio Intl	3/2595	ILS Rwy 12R (Cat I, II), Amdt 13
04/03/03 ...	OH	Cleveland	Cleveland-Hopkins Intl	3/2609	ILS Rwy 6L, Orig-B
04/04/03 ...	NY	Newburgh	Newburgh/Stewart Intl	3/2641	VOR Rwy 27, Amdt 4A
04/04/03 ...	PA	Franklin	Venango Regional	3/2654	ILS Rwy 20, Amdt 4B
04/07/03 ...	VT	Burlington	Burlington Intl	3/2624	ILS/DME Rwy 33, Orig-D
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2735	RADAR–1, Amdt 1
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2736	ILS Rwy 18, Amdt 1C
04/09/03 ...	SC	Myrtle Beach	Myrtle Beach Intl	3/2737	RNAV (GPS) Rwy 18, Amdt 1
04/09/03 ...	TN	Dickson	Dickson Muni	3/2754	VOR/DME Rwy 17, Amdt 4B
04/09/03 ...	TN	Dickson	Dickson Muni	03/2755	RNAV (GPS) Rwy 17, Orig
04/09/03 ...	TN	Dickson	Dickson Muni	3/2756	NDB Rwy 17, Amdt 2A

[1] Replaces 3/2370.

[FR Doc. 03–9725 Filed 4–21–03; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. 02P–0494]

Medical Devices; Exemption From Premarket Notification; Class II Devices; Optical Impression Systems for Computer Assisted Design and Manufacturing

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is publishing an order granting a petition requesting exemption from the premarket notification requirements for data acquisition units for ceramic dental restoration systems. This rule exempts from premarket notification data acquisition units for ceramic dental restoration systems and establishes a guidance document as a special control for this device. FDA is publishing this order in accordance with the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: This rule is effective April 22, 2003.

FOR FURTHER INFORMATION CONTACT: Kevin Mulry, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–827–5283, ext 185.

SUPPLEMENTARY INFORMATION:

I. Statutory Background

Under section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c), FDA must classify devices into one of three regulatory classes: Class I, Class II, or Class III. FDA classification of a device is determined by the amount of regulation necessary to provide a reasonable assurance of safety and effectiveness. Under the Medical Device Amendments of 1976 (the 1976 amendments (Public Law 94–295)), as amended by the Safe Medical Devices Act of 1990 (the SMDA (Public Law 101–629)), devices are to be classified into Class I (general controls) if there is information showing that the general controls of the act are sufficient to assure safety and effectiveness; into Class II (special controls), 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 such assurance; and into Class III (premarket approval), if there is insufficient information to support classifying a device into Class I or Class II and the device is a life-sustaining or life-supporting device or is for a use that is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury.

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices), are classified through the premarket notification process under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations (21 CFR part 807) require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is ''substantially equivalent'' within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

On November 21, 1997, the President signed into law FDAMA (Public Law 105–115). Section 206 of FDAMA, in part, added a new section 510(m) to the act. Section 510(m)(1) of the act requires FDA, within 60 days after enactment of FDAMA, to publish in the **Federal Register** a list of each type of Class II device that does not require a report under section 510(k) of the act to provide reasonable assurance of safety and effectiveness. Section 510(m) of the act further provides that a 510(k) will no longer be required for these devices upon the date of publication of the list in the **Federal Register**. FDA published