List of Subjects in 14 CFR Part 97

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

Issued in Washington, DC, on January 20, 2012.

John M. Allen,

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 establishing, amending, suspending, or revoking Standard Instrument Approach Procedures and/or Takeoff Minimums and/or Obstacle Departure Procedures effective at 0902 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 9 FEB 2012

Wilmington, DE, New Castle, VOR RWY 9, Amdt 7
Houston, TX, Ellington Field, TACAN RWY 4, Orig
Houston, TX, Ellington Field, TACAN RWY 35L, Orig

Effective 8 MAR 2012

Wilmington, DE, New Castle, ILS OR LOC RWY 1, Amdt 23A
New Castle, IN, New Castle-Henry Co Muni, Takeoff Minimums and Obstacle DP, Orig
Terre Haute, IN, Sky King, Takeoff Minimums and Obstacle DP, Amdt 3
Lewiston, ME, Auburn/Lewiston Muni, ILS OR LOC RWY 4, Amdt 10C
Brunswick, ME, Brunswick Executive, RNAV (GPS) RWY 1R, Amdt 1
Brunswick, ME, Brunswick Executive, RNAV (GPS) RWY 19L, Amdt 1
Sault Ste Marie, MI, Chippewa County Intl, ILS OR LOC RWY 16, Amdt 8A
Pine River, MN, Pine River Rgnl, Takeoff Minimums and Obstacle DP, Orig
Omaha, NE, Eppley Airfield, ILS OR LOC RWY 36, Orig-A
Wilmington, OH, Clinton Field, VOR–A, Amdt 2, CANCELLED
Erie, PA, Erie Intl/Tom Ridge Field, ILS OR LOC RWY 6, Amdt 16B
Greer, SC, Greenville Spartanburg Intl, ILS OR LOC/DME RWY 4, ILS RWY 4 (SA CAT I), ILS RWY 4 (CAT II), ILS RWY 4 (CAT III), Amdt 23A
Sioux Falls, SD, Joe Foss Field, ILS OR LOC RWY 21, Amdt 10A
Memphis, TN, General Dewitt Spain, Takeoff Minimums and Obstacle DP, Amdt 4
Racine, WI, John H Batten, ILS OR LOC RWY 4, Amdt 4C
Racine, WI, John H Batten, RNAV (GPS) RWY 22, Orig-A

Effective 5 APR 2012

Jacksonville, FL, Jacksonville Intl, RNAV (GPS) RWY 32, Amdt 2A
Titusville, FL, NASA Shuttle Landing Facility, TACAN RWY 15, Orig, CANCELLED
Titusville, FL, NASA Shuttle Landing Facility, TACAN RWY 33, Orig, CANCELLED
Dublin, GA, W H 'BUD' Barron, ILS OR LOC RWY 2, Amdt 2A
Concordia, KS, Blosser Muni, GPS RWY 17, Orig-B, CANCELLED
Concordia, KS, Blosser Muni, GPS RWY 35, Orig-A, CANCELLED
Concordia, KS, Blosser Muni, RNAV (GPS) RWY 17, Orig
Concordia, KS, Blosser Muni, RNAV (GPS) RWY 35, Orig
Crisfield, MD, Crisfield Muni, RNAV (GPS) RWY 32, Orig, CANCELLED
Crisfield, MD, Crisfield Muni, RNAV (GPS)-B, Orig
Rocky Mount, NC, Rocky Mount-Wilson Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2
Florence, SC, Florence Rgnl, RNAV (GPS) RWY 9, Orig-B
Greenville, TN, Greenville-Greene Co Muni, LOC RWY 5, Amdt 4, CANCELLED

RESCINDED: On January 9, 2012 (77 FR 1015), the FAA published an Amendment in Docket No. 30819, Amdt No. 3458 to Part 97 of the Federal Aviation Regulations under section 97.33. The following entries, effective 9 February 2012, are hereby rescinded in their entirety:

Pender, NE, Pender Muni, RNAV (GPS) RWY 15, Orig
Pender, NE, Pender Muni, RNAV (GPS) RWY 33, Orig
Pender, NE, Pender Muni, Takeoff Minimums and Obstacle DP, Orig

[FR Doc. 2012–2247 Filed 2–3–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30825; Amdt. No. 3463]

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 February 6, 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 February 6, 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 January 20, 2012.

John M. Allen,

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:

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:

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
8–Mar–12	AL	Birmingham	Birmingham-Shuttlesworth Intl	1/3755	1/12/12	LOC RWY 18, Amdt 2
8–Mar–12	AL	Birmingham	Birmingham-Shuttlesworth Intl	1/3759	1/12/12	RNAV (GPS) RWY 18, Amdt 1
8–Mar–12	CA	Atwater	Castle	1/4927	1/12/12	RNAV (GPS) RWY 31, Orig-B
8–Mar–12	CA	Atwater	Castle	1/4928	1/12/12	RNAV (GPS) RWY 13, Orig-B
8–Mar–12	NV	Las Vegas	McCarran Intl	1/5302	1/12/12	ILS OR LOC RWY 25L, Amdt 3B
8–Mar–12	NY	Syracuse	Syracuse Hancock Intl	2/1481	1/12/12	RNAV (GPS) RWY 15, Amdt 1

[FR Doc. 2012–2242 Filed 2–3–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 312, 314, 601, 610, 801, 807, 809, 812, and 814

[Docket No. FDA–2006–N–0364]

Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a final rule, without change, the interim final rule that issued regulations permitting FDA Center Directors to grant exceptions or alternatives to certain regulatory labeling requirements applicable to human drugs, biological products, or medical devices that are or will be included in the Strategic National Stockpile (SNS). FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective February 6, 2012.

FOR FURTHER INFORMATION CONTACT:

For information concerning biological products:

Melissa Reisman, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, (301) 827–6210.

For information concerning drug products:

Brad G. Leissa, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, rm. 2170, Silver Spring, MD 20993, (301) 796–1693.

For information concerning medical devices:

Larry Spears, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3412, Silver Spring, MD 20993, (301) 796–5517.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 28, 2007 (72 FR 73589), FDA issued an interim final rule entitled ''Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile'' (hereinafter referred to as the interim final rule).[1] This rule became effective upon the date of publication in the **Federal Register.**

We issued the interim final rule to facilitate the safety, effectiveness, and availability of appropriate medical countermeasures stored in the SNS in the event of a public health emergency. We also recognized that it may be appropriate for certain human drugs, biological products, or medical devices (hereinafter referred to collectively as medical products) that are or will be held in the SNS to be labeled in a manner that would not comply with certain FDA labeling requirements. However, noncompliance with these labeling requirements could render such products misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 352). Under this rule, the appropriate FDA Center Director may grant exceptions or alternatives to certain regulatory labeling requirements applicable to medical products that are or will be included in the SNS if he or she determines that compliance with the labeling requirements could adversely affect the safety, effectiveness, or availability of specified lots, batches, or other units of medical products that are or will be included in the SNS. An exception or alternative granted under this rule may include conditions or safeguards deemed appropriate by the FDA Center Director to ensure that the labeling for such products includes information necessary for the safe and effective use of the product given the product's anticipated circumstances of use.

For example, this rule applies to certain medical products that enter the SNS as investigational products in addition to medical products in the SNS that are approved, licensed, or cleared for marketing.[2] Labels on investigational products ordinarily would not contain all elements required on licensed, approved, or cleared product labels. Certain information, such as expiration dates, warnings for users, license numbers of manufacturers and other information, may not be available or finalized for an investigational product, and thus could not be included on a container label if the investigational product was added to the SNS. Prior to the implementation of this rule, when investigational products were ultimately approved for marketing, the products would have been returned to the manufacturer or sent to relabelers for relabeling, a potentially time-consuming, costly, and labor-intensive process. Further, requiring relabeling of such investigational products after approval, licensure or clearance could adversely affect the safety, effectiveness, or availability of the products. This rule allows the appropriate FDA Center Director to grant an exception or alternative to the relevant labeling requirements to enable the immediate use of a product in the event of a public health emergency.

For these reasons, as explained in the interim final rule and the following section of this document, this rule allows FDA Center Directors to grant exceptions or alternatives to certain labeling requirements not explicitly required by statute for medical products that are or will be included in the SNS.

II. Comments on the Interim Final Rule and FDA Responses

We received 7 comments on the proposed rule. These comments were received from hospitals, biologics manufacturers, law firms, other government agencies, and other interested persons. To make it easier to identify comments and our responses, the word ''Comment,'' in parentheses, will appear before the comment's description, and the word ''Response,'' in parentheses, will appear before our response. We have also numbered each comment to help distinguish between different comments. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value or importance or the order in which it was received. Certain comments were grouped together because the subject matter of the comments was similar.

(Comment 1) One comment applauded the efforts put forth by the Agency to provide industry with the opportunity for exceptions or alternatives to FDA labeling requirements for products held by the SNS. The comment also recognized the importance of facilitating rapid access to large quantities of medical products in the event of an act of terrorism or natural disaster. Another comment expressed general agreement with the interim final rule.

(Response) We appreciate these comments in support of the rule. Congress mandated the development of a SNS to provide for the emergency

[1] In the **Federal Register** of November 18, 2008 (73 FR 68332), FDA issued a technical amendment to reincorporate a regulation that was inadvertently revised by the interim final rule.

[2] As noted in the preamble to the interim final rule, medical products stockpiled in the SNS may also include products that will ultimately be used in an emergency under section 564 of the FD&C Act (21 U.S.C. 360bbb–3).