

Greenwood, MS, Greenwood-LeFlore, VOR/DME RNAV RWY 18, Amdt 6A
 Wahpeton, ND, Harry Stern, RNAV (GPS) RWY 15, Orig
 Wahpeton, ND, Harry Stern, RNAV (GPS) RWY 33, Orig
 Wahpeton, ND, Harry Stern, NDB RWY 33, Amdt 5
 Wahpeton, ND, Harry Stern, GPS RWY 33, Orig-A, CANCELLED
 Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 13, Amdt 1
 Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 17, Amdt1
 Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 31, Amdt1
 Grand Island, NE, Central Nebraska Regional, RNAV (GPS) RWY 35, Amdt1
 Hobbs, NM, Lea County Rgnl, RNAV (GPS) RWY 3, Orig
 Hobbs, NM, Lea County Rgnl RNAV (GPS) RWY 21, Orig
 Hobbs, NM, Lea County Rgnl RNAV (GPS) RWY 30, Orig
 Hobbs, NM, Lea County Rgnl ILS OR LOC RWY 3, Amdt 6
 Hobbs, NM, Lea County Rgnl LOC/DME BC RWY 21, Amdt 6
 Hobbs, NM, Lea County Rgnl VOR/DME OR TACAN RWY 21, Amdt 9
 Hobbs, NM, Lea County Rgnl VOR OR TACAN RWY 3, Amdt 21
 Hobbs, NM, Lea County Rgnl GPS RWY 3, Orig-B, CANCELLED
 Hobbs, NM, Lea County Rgnl GPS RWY 21, Orig-B, CANCELLED
 Hobbs, NM, Lea County Rgnl GPS RWY 30, Orig-B, CANCELLED
 Las Vegas, NV, Henderson Executive, VOR-C, Orig
 Las Vegas, NV, North Las Vegas, ILS OR LOC RWY 12L, Orig
 Fort Worth, TX, Fort Worth Spinks, RNAV (GPS) RWY 17R, Orig
 Fort Worth, TX, Fort Worth Spinks, RNAV (GPS) RWY 35L, Orig
 Fort Worth, TX, Fort Worth Spinks, VOR/DME RNAV RWY 35L, Orig-B, CANCELLED
 Houston, TX, George Bush Intercontinental/Houston, RNAV (GPS) Z RWY 8L, Amdt 1
 Houston, TX, George Bush Intercontinental/Houston, RNAV (GPS) Z RWY 9, Amdt 2
 Houston, TX, George Bush Intercontinental/Houston, RNAV (GPS) Z RWY 27, Amdt 1
 Houston, TX, George Bush Intercontinental/Houston, RNAV (GPS) Z RWY 26R, Amdt 1
 Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 8L, ILS RWY 8L, (CAT II), ILS RWY 8L (CAT III), Amdt 1
 Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 9, Amdt 7
 Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 27, ILS RWY 27, (CAT II), ILS RWY 27 (CAT III), Amdt 6
 Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 26R, ILS RWY 26R, (CAT II), ILS RWY 26R (CAT III), Amdt 1
 Longview, TX, East Texas Regional, ILS OR LOC RWY 13, Amdt 12
 Longview, TX, East Texas Regional, VOR/DME OR TACAN RWY 31, Amdt 7

Longview, TX, East Texas Regional, VOR/DME OR TACAN RWY 13, Amdt 1
 Wichita Falls, TX, Kickapoo Downtown Airpark, RNAV (GPS) RWY 35, Orig
 Wichita Falls, TX, Kickapoo Downtown Airpark, NDB RWY 35, Amdt 4
 Wichita Falls, TX, Kickapoo Downtown Airpark, NDB-A, Amdt 6A
 Wichita Falls, TX, Kickapoo Downtown Airpark, VOR/DME RNAV OR GPS RWY 35, Amdt 3A, CANCELLED
 Sutton, WV, Braxton County, RNAV (GPS) RWY 1, Orig
 Sutton, WV, Braxton County, RNAV (GPS) RWY 19, Orig
 Sutton, WV, Braxton County, Takeoff Minimums and Textual DP, Orig

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BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 30465; Amdt. No. 3141]

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 November 15, 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 November 15, 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 November 4, 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:

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 No.
10/21/05	AK	IGIUGIG	IGIUGIG	5/9658	RNAV (GPS) RWY 5, ORIG-A.
10/21/05	AK	IGIUGIG	IGIUGIG	5/9659	RNAV (GPS) RWY 23, ORIG-A.
10/21/05	AK	KING SALMON	KING SALMON	5/9660	RNAV (GPS) Z RWY 29, ORIG-A.
10/21/05	AK	KING SALMON	KING SALMON	5/9661	RNAV (GPS) RWY 11, ORIG-A.
10/21/05	AK	SHUNGNAK	SHUNGNAK	5/9662	RNAV (GPS) RWY 9, ORIG-A.
10/24/05	WA	BELLINGHAM	BELLINGHAM INTL	5/9652	ILS RWY 16, AMDT 4B.
10/24/05	WA	BELLINGHAM	BELLINGHAM INTL	5/9653	NDB RWY 16, AMDT 1B.
10/25/05	MN	MINNEAPOLIS	MINNEAPOLIS-ST. PAUL INTL/WOLD CHAMBERLAIN.	5/9764	ILS PRM RWY 12R, AMDT 3A.
10/26/05	IL	QUINCY	QUINCY REGIONAL-BALDWIN FIELD	5/9835	ILS OR LOC RWY 4, AMDT 17A.
10/28/05	MN	MINNEAPOLIS	MINNEAPOLIS-ST. PAUL INTL/WOLD CHAMBERLAIN.	5/9978	ILS PRM RWY 30R, AMDT 6B.
10/28/05	MN	MINNEAPOLIS	MINNEAPOLIS-ST. PAUL INTL/WOLD CHAMBERLAIN.	5/9979	ILS PRM RWY 30L, AMDT 5B.
10/31/05	FL	BUNNELL	FLAGLER COUNTY	5/9990	RNAV (GPS) RWY 29, ORIG-A.
10/31/05	IL	CHICAGO	CHICAGO-O'HARE INTL	5/0115	ILS RWY 27L (CATII), AMDT 13A.
10/31/05	IL	CHICAGO	CHICAGO-O'HARE INTL	5/0116	ILS RWY 27L (CATIII), AMDT 13A.
10/31/05	IL	CHICAGO	CHICAGO-O'HARE INTL	5/0117	ILS OR LOC RWY 27L, AMDT 13A.
10/28/05	FL	MELBOURNE	MELBOURNE INTL	5/0032	RNAV (GPS) RWY 9R, ORIG-A.
10/28/05	FL	BUNNELL	FLAGLER COUNTY	5/9988	VOR-A, AMDT 1A.
10/28/05	FL	BUNNELL	FLAGLER COUNTY	5/9989	RNAV (GPS) RWY 6, ORIG-A.
10/28/05	FL	BUNNELL	FLAGLER COUNTY	5/9991	RNAV (GPS) RWY 11, ORIG-A.
10/28/05	FL	BUNNELL	FLAGLER COUNTY	5/9992	RNAV (GPS) RWY 24, ORIG-A.
10/28/05	FL	ORLANDO	ORLANDO INTL	5/9993	RNAV (GPS) RWY 36R, ORIG-B.
10/24/05	UT	LOGAN	LOGAN-CACHE	5/9717	RNAV (GPS) RWY 17, ORIG-A.
10/24/05	UT	LOGAN	LOGAN-CACHE	5/9720	RNAV (GPS) RWY 35, AMDT 1A.
10/31/05	UT	OGDEN	ODGEN-HINCKLEY	5/9940	VOR RWY 7, AMDT 5C.
10/28/05	WA	SEATTLE	SEATTLE-TACOMA INTL	5/0133	VOR RWY 34L/R, AMDT 9B.
10/28/05	WA	MOSES LAKE	GRANT COUNTY INTL	5/0136	VOR RWY 32R, AMDT 20A.
10/28/05	WA	MOSES LAKE	GRANT COUNTY INTL	5/0138	RNAV (GPS) RWY 32R, ORIG-B.

FDC Date	State	City	Airport	FDC No.	Subject No.
11/01/05	OH	MARYSVILLE	UNION COUNTY	5/0174	NDB RWY 27, AMDT 5B.
11/01/05	WA	YAKIMA	YAKIMA AIR TERMINAL/MCALLISTER FIELD.	5/0181	ILS RWY 27, AMDT 26C.
11/01/05	WA	PORT ANGELES ...	WILLIAM R. FAIRCHILD INTL	5/0187	ILS-1 RWY 8, AMDT 1C.
11/02/05	MN	ALEXANDRIA	CHANDLER FIELD	5/0218	ILS OR LOC RWY 31, ORIG-A.
10/27/05	TX	AUSTIN	AUSTIN-BERGSTROM INTL	5/9947	ILS OR LOC RWY 35L, AMDT 3A.
11/02/05	OK	ARDMORE	ARDMORE MUNI	5/0226	ILS RWY 31, AMDT 4A.
11/02/05	SC	MYRTLE BEACH ...	MYRTLE BEACH INTL	5/0232	ILS OR LOC RWY 36, AMDT 1C.
11/02/05	SC	MYRTLE BEACH ...	MYRTLE BEACH INTL	5/0233	RNAV (GPS) RWY 36, AMDT 1A.
11/02/05	SC	MYRTLE BEACH ...	MYRTLE BEACH INTL	5/0234	RADAR-1, AMDT 1C.
11/02/05	SC	MYRTLE BEACH ...	MYRTLE BEACH INTL	5/0235	ILS OR LOC RWY 18, AMDT 1F.
11/02/05	SC	MYRTLE BEACH ...	MYRTLE BEACH INTL	5/0236	RNAV (GPS) RWY 18, 1C.

[FR Doc. 05-22493 Filed 11-14-05; 8:45 am]
 BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. 2004N-0461]

Environmental Assessment; Categorical Exclusions

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of humanitarian device exemptions (HDEs) and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an environmental assessment (EA) nor an environmental impact statement (EIS) is required. FDA is taking this action in accordance with the National Environmental Policy Act (NEPA).

DATES: This rule is effective December 15, 2005.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2346.

SUPPLEMENTARY INFORMATION:

I. Introduction

In the **Federal Register** of November 24, 2004 (69 FR 68280), FDA published a proposed rule (the November 2004 proposed rule) to amend its regulation on environmental impact considerations to expand existing categorical exclusions to include approvals of HDEs

and establishment of special controls as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required. Interested persons were given until December 27, 2004, to comment on the proposal. FDA received two comments on the proposed rule.

II. Summary of Comments and FDA's Response

(Comment 1) One comment opposed FDA's proposal to expand existing categorical exclusions to include approvals of HDEs and establishment of special controls on the basis that a more rigorous standard should be applied before approval of "dangerous devices."

(Response) This comment seemed to misunderstand the proposed rule. FDA is not excluding any products from the statutorily required safety review under the Federal Food, Drug, and Cosmetic Act. The rule excludes certain categories of actions from the need to prepare an EA or EIS under the NEPA.

(Comment 2) This comment did not express an opinion on the proposed rule.

III. Background and Regulatory Authorities

NEPA requires all Federal agencies to assess the environmental impacts of its actions and to ensure that the interested and affected public is informed of environmental analyses. The Counsel on Environmental Quality (CEQ) is responsible for overseeing Federal efforts to comply with NEPA. Both CEQ and FDA have issued regulations governing agency obligations and responsibilities under NEPA. CEQ's regulations implementing the procedural requirements of NEPA can be found at 40 CFR parts 1500 through 1508 and FDA's NEPA policies and procedures can be found at 21 CFR part 25.

CEQ's and FDA's regulations, 40 CFR 1508.4 and 21 CFR 25.5(a)(1), respectively, define "categorical

exclusion" to mean a category of actions which have been found by procedures adopted by the Federal agency not to individually or cumulatively have a significant effect on the human environment and for which, therefore, neither an EA nor an EIS is required. When categorically excluding an action, an agency must determine that there are no extraordinary circumstances related to the action that may result in the action having significant environmental effects.

FDA published final regulations governing compliance with NEPA as implemented by the CEQ regulations in the **Federal Register** of July 29, 1997 (62 FR 40570). The July 29, 1997, final rule listed certain device actions as categories of actions that do not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor an EIS is required.

IV. Summary of the Final Rule

FDA received two comments on the proposed rule, however, neither comment related to the statutory and regulatory authority of that proposal. Therefore, the discussion of the statutory and regulatory authority set out in the preamble of the proposed rule (69 FR 68280 at 68281 through 68282) remains relevant to this final rule and will not be repeated here.

A. Special Controls

FDA is amending its environmental impact regulations under § 25.34 to include as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required, classification or reclassification of a device, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes. FDA issues special controls in order to assure that class II devices provide a reasonable assurance of safety and effectiveness.