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### DEPARTMENT OF TRANSPORTATION

# **Federal Aviation Administration**

## 14 CFR Part 97

[Docket No. 31195; Amdt. No. 3801]

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 removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures (ODPs) 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 June 5, 2018. 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 June 5, 2018.

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

### For Examination

- 1. U.S. Department of Transportation, Docket Ops-M30, 1200 New Jersey Avenue SE, West Bldg., Ground Floor, Washington, DC 20590–0001.
- 2. The FAA Air Traffic Organization Service Area in which the affected airport is located:
- 3. The office of Aeronautical Navigation Products, 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 and Takeoff Minimums and ODPs are available online free of charge. Visit the National Flight Data Center at *nfdc.faa.gov* to register. Additionally, individual SIAP and Takeoff Minimums and ODP copies may be obtained from the FAA Air Traffic Organization Service Area in which the affected airport is located.

## FOR FURTHER INFORMATION CONTACT:

Thomas J. Nichols, Flight Procedure Standards Branch (AFS–420), Flight Technologies and Programs Divisions, 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 of the Code of Federal Regulations, Part 97 (14 CFR part 97), by establishing, amending, suspending, or removes SIAPS, Takeoff Minimums and/or ODPS. The complete regulatory description of each SIAP and its associated Takeoff Minimums or ODP for an identified airport is listed on 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 FAA Forms 8260-3, 8260-4, 8260-5, 8260-15A, and 8260-15B when required by an entry on 8260-15A.

The large number of SIAPs, Takeoff Minimums and ODPs, their complex nature, and the need for a special format make publication in the Federal Register expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, Takeoff Minimums or ODPs, but instead 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, Takeoff Minimums and ODP listed on FAA form documents is unnecessary. This amendment provides the affected CFR sections and specifies the types of SIAPs, Takeoff Minimums and ODPs with their applicable effective dates. This amendment also identifies the airport and its location, the procedure, and the amendment number.

# Availability and Summary of Material Incorporated by Reference

The material incorporated by reference is publicly available as listed in the **ADDRESSES** section.

The material incorporated by reference describes SIAPS, Takeoff Minimums and/or ODPS as identified in the amendatory language for part 97 of this final rule.

### The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as Amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously 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 that created the need for some SIAP and Takeoff Minimums and ODP amendments may require making them effective in less than 30 days. For the remaining SIAPs and Takeoff Minimums and ODPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs and Takeoff Minimums and ODPs 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 Takeoff Minimums and ODPs, 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, Takeoff Minimums and ODPs, and safety in air commerce, I find that notice and public procedure under 5 U.S.C. 553(b) are impracticable and contrary to the public interest and. where applicable, under 5 U.S.C 553(d), good cause exists for making some SIAPs effective in less than 30 days.

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, Navigation (air).

Issued in Washington, DC, on May 18, 2018.

#### John S. Duncan,

Executive 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 removing Standard Instrument Approach Procedures and/or Takeoff Minimums and Obstacle Departure 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(f), 106(g), 40103, 40106, 40113, 40114, 40120, 44502, 44514, 44701, 44719, 44721–44722.

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

Effective 21 June 2018

Fort Madison, IA, Fort Madison Muni, RNAV (GPS) RWY 17, Amdt 1A

Big Rapids, MI, Roben-Hood, Takeoff Minimums and Obstacle DP, Amdt 6A

Detroit, MI, Detroit Metropolitan Wayne County, ILS OR LOC RWY 22L, ILS RWY 22L SA CAT I, Amdt 32A

Detroit, MI, Detroit Metropolitan Wayne County, RNAV (RNP) W RWY 22R, Orig-A

Detroit, MI, Detroit Metropolitan Wayne County, RNAV (RNP) X RWY 3R, Orig-A

Detroit, MI, Detroit Metropolitan Wayne County, RNAV (RNP) X RWY 21L, Orig-A St Paul, MN, St Paul Downtown Holman Fld,

St Paul, MN, St Paul Downtown Holman Fld ILS OR LOC RWY 32, Amdt 6A

Omaha, NE, Eppley Airfield, RNAV (GPS) Y RWY 18, Amdt 4A

Saranac Lake, NY, Adirondack Rgnl, Takeoff Minimums and Obstacle DP, Amdt 8

Cleveland, OH, Cleveland-Hopkins Intl, RNAV (GPS) Y RWY 6L, Amdt 2A

Ottawa, OH, Putnam County, VOR RWY 27, Amdt 2C

Effective 19 July 2018

Manley Hot Springs, AK, Manley Hot Springs, RNAV (GPS) RWY 18, Orig Manley Hot Springs, AK, Manley Hot

Springs, RNAV (GPS) RWY 36, Orig Manley Hot Springs, AK, Manley Hot

Manley Hot Springs, AK, Manley Hot Springs, Takeoff Minimums and Obstacle DP, Orig

Fayetteville/Springdale/Rogers, AR, Northwest Arkansas Rgnl, ILS OR LOC RWY 34, Amdt 4 Auburn, CA, Auburn Muni, RNAV (GPS) RWY 7, Orig-B

Long Beach, CA, Long Beach/Daugherty Field/, ILS OR LOC RWY 30, Amdt 34

Long Beach, CA, Long Beach/Daugherty Field/, RNAV (RNP) RWY 26R, Amdt 1A

Long Beach, CA, Long Beach/Daugherty Field/, Takeoff Minimums and Obstacle DP, Amdt 6A

Long Beach, CA, Long Beach/Daugherty Field/, VOR OR TACAN RWY 30, Amdt 9 Oakland, CA, Metropolitan Oakland Intl, RNAV (RNP) Z RWY 12, Amdt 2

Palm Springs, CA, Jacqueline Cochran Rgnl, RNAV (GPS) RWY 30, Amdt 1

Palm Springs, CA, Jacqueline Cochran Rgnl, VOR RWY 30, Amdt 2

Palm Springs, CA, Jacqueline Cochran Rgnl, VOR–A, Amdt 1

Panama City, FL, Northwest Florida Beaches Intl, ILS OR LOC RWY 16, ILS RWY 16 SA CAT I, ILS RWY 16 SA CAT II, Amdt 3

Douglas, GA, Douglas Muni, ILS OR LOC RWY 4, Amdt 2C

Kahului, HI, Kahului, ILS OR LOC RWY 2, Amdt 25A

Springfield, IL, Abraham Lincoln Capital, VOR RWY 4, Orig-C

Sterling/Rockfalls, IL, Whiteside Co Arpt-Jos H Bittorf Fld, ILS OR LOC RWY 25, Amdt 11

Sterling/Rockfalls, IL, Whiteside Co Arpt-Jos H Bittorf Fld, LOC BC RWY 7, Amdt 6

Sterling/Rockfalls, IL, Whiteside Co Arpt-Jos H Bittorf Fld, NDB RWY 7, Amdt 6, CANCELED

Sterling/Rockfalls, IL., Whiteside Co Arpt-Jos H Bittorf Fld, RNAV (GPS) RWY 7, Amdt 1

Sterling/Rockfalls, IL., Whiteside Co Arpt-Jos H Bittorf Fld, RNAV (GPS) RWY 25, Amdt 1

Howell, MI, Livingston County Spencer J Hardy, RNAV (GPS) RWY 31, Amdt 1B Howell, MI, Livingston County Spencer J Hardy, VOR RWY 31, Amdt 11A, CANCELED

Menominee, MI, Menominee Rgnl, ILS OR LOC RWY 3, Amdt 3

Menominee, MI, Menominee Rgnl, RNAV (GPS) RWY 3, Orig-A

Menominee, MI, Menominee Rgnl, RNAV (GPS) RWY 21, Orig-C

Menominee, MI, Menominee Rgnl, RNAV (GPS) RWY 32, Amdt 1C

Menominee, MI, Menominee Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3A Menominee, MI, Menominee Rgnl, VOR–A,

Amdt 3C Cabool, MO, Cabool Memorial, RNAV (GPS) RWY 21, Orig-B

Cabool, MO, Cabool Memorial, VOR/DME RWY 21, Amdt 2A, CANCELED

Ithaca, NY, Ithaca Tompkins Rgnl, ILS OR LOC RWY 32, Amdt 7

Ithaca, NY, Ithaca Tompkins Rgnl, RNAV (GPS) RWY 32, Orig-B

Ithaca, NY, Ithaca Tompkins Rgnl, VOR RWY 14, Amdt 14A, CANCELED

Ogdensburg, NY, Ogdensburg Intl, RNAV (GPS) RWY 9, Amdt 1

Watertown, NY, Watertown Intl, Takeoff Minimums and Obstacle DP, Amdt 3 Tiffin, OH, Seneca County, NDB RWY 24, Amdt 7D

Tiffin, OH, Seneca County, RNAV (GPS) RWY 6, Orig-B Tiffin, OH, Seneca County, RNAV (GPS) RWY 24, Amdt 1C

Tiffin, OH, Seneca County, VOR RWY 6, Amdt 9B

Anderson, SC, Anderson Rgnl, RNAV (GPS) RWY 23, Amdt 2

Weslaco, TX, Mid Valley, RNAV (GPS) RWY 14, Orig-A

Weslaco, TX, Mid Valley, VOR–A, Orig-B Eastsound, WA, Orcas Island, RNAV (GPS) RWY 16. Amdt 2

Port Angeles, WA, William R Fairchild Intl, ILS OR LOC RWY 8, Amdt 3A

Port Angeles, WA, William R Fairchild Intl, RNAV (GPS) RWY 8, Amdt 1A

Port Angeles, WA, William R Fairchild Intl, RNAV (GPS) RWY 26, Amdt 1B

Port Angeles, WA, William R Fairchild Intl, Takeoff Minimums and Obstacle DP, Amdt

Port Angeles, WA, William R Fairchild Intl, WATTR SEVEN, Graphic DP New Holstein, WI, New Holstein Muni

New Holstein, WI, New Holstein Muni, RNAV (GPS) RWY 14, Orig-B

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# DEPARTMENT OF HEALTH AND HUMAN SERVICES

# **Food and Drug Administration**

# 21 CFR Parts 862, 866, 876, 880, and 884

[Docket No. FDA-2017-N-1129]

# Medical Devices; Exemptions From Premarket Notification: Class II Devices

**AGENCY:** Food and Drug Administration,

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is publishing an order to exempt a list of class II devices from premarket notification (510(k)) requirements, subject to certain limitations. This exemption from 510(k), subject to certain limitations, is immediately in effect for the listed class II devices. This exemption will decrease regulatory burdens on the medical device industry and will eliminate private costs and expenditures required to comply with certain Federal regulations. FDA is also amending the codified language for the listed class II devices to reflect this final determination. FDA is publishing this order in accordance with the section of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permitting the exemption of a device from the requirement to submit a 510(k).

**DATES:** This order is effective June 5, 2018.

# FOR FURTHER INFORMATION CONTACT:

Scott McFarland, Center for Devices and