

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 97**

[Docket No. 31238; Amdt. No. 3839]

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 February 20, 2019. 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 20, 2019.

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 Procedures and Airspace Group, Flight Technologies and Procedures Division, Flight Standards Service, Federal Aviation Administration. Mailing Address: FAA Mike Monroney Aeronautical Center, Flight Procedures and Airspace Group, 6500 South MacArthur Blvd., Registry Bldg. 29, Room 104, 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 February 8, 2019.

Rick Domingo,

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 28 March 2019

Lewisport, KY, Hancock Co-Ron Lewis Field, RNAV (GPS) RWY 5, Amdt 1B
Pittsfield, ME, Pittsfield Muni, NDB RWY 36, Amdt 4E

Effective 25 April 2019

Homer, AK, Homer, Takeoff Minimums and Obstacle DP, Amdt 3A
Kiana, AK, Bob Baker Memorial, RNAV (GPS) RWY 6, Orig-D
Kiana, AK, Bob Baker Memorial, RNAV (GPS) RWY 24, Orig-B
Kotlik, AK, Kotlik, RNAV (GPS) RWY 2, Orig-E
Oneonta, AL, Robbins Field, RNAV (GPS) RWY 6, Orig-C
Oneonta, AL, Robbins Field, RNAV (GPS) RWY 24, Orig-A
Oneonta, AL, Robbins Field, Takeoff Minimums and Obstacle DP, Orig-B
Russellville, AL, Bill Pugh Field, RNAV (GPS) RWY 2, Orig-C
Carlisle, AR, Carlisle Muni, RNAV (GPS) RWY 9, Amdt 1A
Carlisle, AR, Carlisle Muni, RNAV (GPS) RWY 27, Orig-A
Carlisle, AR, Carlisle Muni, VOR RWY 9, Amdt 2D
Crossett, AR, Z M Jack Stell Field, RNAV (GPS) RWY 23, Orig-B
Walnut Ridge, AR, Walnut Ridge Rgnl, LOC RWY 18, Amdt 3C
Jacksonville, FL, Jacksonville Intl, ILS OR LOC RWY 26, Amdt 2B
Key West, FL, Key West Intl, Takeoff Minimums and Obstacle DP, Amdt 2

Miami, FL, Miami Executive, ILS OR LOC RWY 9R, Amdt 11D
Miami, FL, Miami Executive, RNAV (GPS) RWY 9R, Amdt 2D
Miami, FL, Miami Executive, RNAV (GPS) RWY 27L, Amdt 2D
Jesup, GA, Jesup-Wayne County, NDB RWY 11, Amdt 2, CANCELED
Jesup, GA, Jesup-Wayne County, NDB RWY 29, Amdt 3, CANCELED
Macon, GA, Middle Georgia Rgnl, ILS OR LOC RWY 5, ILS RWY 5 SA CAT I, ILS RWY 5 SA CAT II, Amdt 3A
Macon, GA, Middle Georgia Rgnl, RNAV (GPS) RWY 5, Amdt 3A
Macon, GA, Middle Georgia Rgnl, RNAV (GPS) RWY 23, Amdt 2E
Shenandoah, IA, Shenandoah Muni, NDB RWY 4, Orig-D
Shenandoah, IA, Shenandoah Muni, RNAV (GPS) RWY 4, Orig-B
Sioux Center, IA, Sioux Center Muni, NDB RWY 18, Amdt 5, CANCELED
Waterloo, IA, Waterloo Rgnl, ILS OR LOC RWY 12, Amdt 10A
Peru, IL, Illinois Valley Rgnl-Walter A Duncan Field, LOC RWY 36, Amdt 4, CANCELED
Griffith, IN, Griffith-Merrillville, Takeoff Minimums and Obstacle DP, Amdt 4A
New Castle, IN, New Castle Henry County Marlatt Field, NDB RWY 10, Orig-B
New Castle, IN, New Castle Henry County Marlatt Field, RNAV (GPS) RWY 10, Orig-A
New Castle, IN, New Castle Henry County Marlatt Field, RNAV (GPS) RWY 28, Orig-A
New Castle, IN, New Castle Henry County Marlatt Field, Takeoff Minimums and Obstacle DP, Amdt 1A
South Bend, IN, South Bend Intl, RNAV (GPS) RWY 9R, Amdt 1A
Kingman, KS, Kingman Airport—Clyde Cessna Field, Takeoff Minimums and Obstacle DP, Orig-A
Rayville, LA, John H Hooks Jr Memorial, RNAV (GPS) RWY 18, Amdt 1B
Rayville, LA, John H Hooks Jr Memorial, RNAV (GPS) RWY 36, Amdt 2B
Shreveport, LA, Shreveport Downtown, RNAV (GPS) RWY 32, Orig-A
Falmouth, MA, Cape Cod Coast Guard Air Station, COPTER ILS Y OR LOC Y RWY 23, Amdt 2
Falmouth, MA, Cape Cod Coast Guard Air Station, ILS Z OR LOC Z RWY 23, Amdt 2
Falmouth, MA, Cape Cod Coast Guard Air Station, NDB RWY 23, Orig-A, CANCELED
Frederick, MD, Frederick Muni, VOR–A, Amdt 2D, CANCELED
Detroit, MI, Detroit Metropolitan Wayne County, ILS PRM Y RWY 22R (CLOSE PARALLEL), Amdt 1A
Detroit, MI, Detroit Metropolitan Wayne County, ILS PRM Z RWY 22R (CLOSE PARALLEL), ILS PRM Z RWY 22R (CLOSE PARALLEL) SA CAT I, ILS PRM Z RWY 22R (CLOSE PARALLEL) SA CAT II, Orig-A
Detroit, MI, Detroit Metropolitan Wayne County, ILS Y RWY 22R, Amdt 1A
Detroit, MI, Detroit Metropolitan Wayne County, ILS Z OR LOC RWY 22R, ILS Z RWY 22R SA CAT I, ILS Z RWY 22R SA CAT II, Amdt 4A

Drummond Island, MI, Drummond Island, RNAV (GPS) RWY 8, Orig-A
Drummond Island, MI, Drummond Island, RNAV (GPS) RWY 26, Orig-A
Sparta, MI, Paul C Miller-Sparta, RNAV (GPS) RWY 7, Orig-A
Sparta, MI, Paul C Miller-Sparta, RNAV (GPS) RWY 25, Orig-A
Sparta, MI, Paul C Miller-Sparta, VOR–A, Amdt 4A, CANCELED
International Falls, MN, Falls Intl-Einarson Field, ILS OR LOC RWY 31, Amdt 10C
New Ulm, MN, New Ulm Muni, RNAV (GPS) RWY 15, Orig-C
New Ulm, MN, New Ulm Muni, RNAV (GPS) RWY 33, Orig-B
Thief River Falls, MN, Thief River Falls Rgnl, ILS OR LOC RWY 31, Amdt 5A
Thief River Falls, MN, Thief River Falls Rgnl, VOR Y RWY 13, Amdt 9B
Thief River Falls, MN, Thief River Falls Rgnl, VOR Z RWY 13, Amdt 2D
Gideon, MO, Gideon Memorial, VOR RWY 15, Amdt 3A, CANCELED
Fayetteville, NC, Fayetteville Rgnl/Grannis Field, VOR RWY 4, Amdt 16C
Fayetteville, NC, Fayetteville Rgnl/Grannis Field, VOR RWY 22, Amdt 7C
Fayetteville, NC, Fayetteville Rgnl/Grannis Field, VOR RWY 28, Amdt 8C
Greensboro, NC, Piedmont Triad Intl, ILS OR LOC RWY 5L, ILS RWY 5L CAT II, ILS RWY 5L CAT III, Orig-C
Creighton, NE, Creighton Muni, RNAV (GPS) RWY 13, Orig-C
Creighton, NE, Creighton Muni, RNAV (GPS) RWY 31, Orig-C
McCook, NE, McCook Ben Nelson Rgnl, VOR RWY 30, Amdt 11C
North Platte, NE, North Platte Rgnl Airport Lee Bird Field, RNAV (GPS) RWY 12, Amdt 1B
North Platte, NE, North Platte Rgnl Airport Lee Bird Field, RNAV (GPS) RWY 30, Amdt 2B
North Platte, NE, North Platte Rgnl Airport Lee Bird Field, RNAV (GPS) RWY 35, Amdt 1B
Seward, NE, Seward Muni, Takeoff Minimums and Obstacle DP, Orig-B
Vincentown, NJ, Red Lion, RNAV (GPS) RWY 5, Orig-A, CANCELED
Vincentown, NJ, Red Lion, Takeoff Minimums and Obstacle DP, Amdt 1, CANCELED
Vincentown, NJ, Red Lion, VOR–A, Amdt 6A, CANCELED
Truth or Consequences, NM, Truth or Consequences Muni, Takeoff Minimums and Obstacle DP, Amdt 2
Lockport, NY, North Buffalo Suburban, RNAV (GPS) RWY 28, Orig, CANCELED
Lockport, NY, North Buffalo Suburban, Takeoff Minimums and Obstacle DP, Orig, CANCELED
New York, NY, John F Kennedy Intl, VOR RWY 4L, Amdt 1A
New York, NY, John F Kennedy Intl, VOR RWY 4R, Orig-A
New York, NY, LaGuardia, VOR–H, Amdt 3C, CANCELED
Schenectady, NY, Schenectady County, Takeoff Minimums and Obstacle DP, Amdt 6
Akron, OH, Akron Fulton Intl, NDB RWY 25, Amdt 15A

Cleveland, OH, Cuyahoga County, ILS OR LOC RWY 24, Amdt 16A

Columbus, OH, Rickenbacker Intl, NDB RWY 5R, Amdt 2A, CANCELED

Columbus, OH, Rickenbacker Intl, NDB RWY 23L, Amdt 2A, CANCELED

Youngstown-Warren, OH, Youngstown-Warren Rgnl, RADAR 1, Amdt 14

Tulsa, OK, Tulsa Intl, ILS OR LOC RWY 18L, Amdt 16A

Tulsa, OK, Tulsa Intl, RNAV (GPS) RWY 8, Amdt 2B

Clarion, PA, Clarion County, VOR-A, Amdt 3A, CANCELED

Corry, PA, Corry-Lawrence, NDB RWY 14, Amdt 5, CANCELED

Franklin, PA, Venango Rgnl, VOR RWY 3, Amdt 5B, CANCELED

Harrisburg, PA, Harrisburg Intl, ILS OR LOC RWY 31, Amdt 1E

Hazleton, PA, Hazleton Rgnl, Takeoff Minimums and Obstacle DP, Amdt 3

West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 9, Amdt 1A

West Chester, PA, Brandywine Rgnl, RNAV (GPS) RWY 27, Amdt 1A

West Chester, PA, Brandywine Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1A

West Chester, PA, Brandywine Rgnl, VOR-A, Amdt 4A

York, PA, York, RNAV (GPS) RWY 17, Amdt 2C

York, PA, York, RNAV (GPS) RWY 35, Amdt 1C

Greenville, SC, Greenville Downtown, ILS Y OR LOC Y RWY 1, Orig-B

Greenville, SC, Greenville Downtown, ILS Z OR LOC Z RWY 1, Amdt 30B

Orangeburg, SC, Orangeburg Muni, Takeoff Minimums and Obstacle DP, Amdt 4

Pierre, SD, Pierre Rgnl, ILS OR LOC RWY 31, Amdt 12D

Albany, TX, Albany Muni, RNAV (GPS) RWY 17, Amdt 1C

Albany, TX, Albany Muni, RNAV (GPS) RWY 35, Amdt 1C

Baytown, TX, RWJ Airpark, Takeoff Minimums and Obstacle DP, Amdt 1A

Borger, TX, Hutchinson County, VOR RWY 17, Amdt 9, CANCELED

Borger, TX, Hutchinson County, VOR/DME RWY 35, Amdt 4A, CANCELED

Fredericksburg, TX, Gillespie County, Takeoff Minimums and Obstacle DP, Amdt 2

Galveston, TX, Scholes Intl at Galveston, ILS OR LOC RWY 14, Amdt 12C

Galveston, TX, Scholes Intl at Galveston, VOR RWY 14, Amdt 4C

Haskell, TX, Haskell Muni, RNAV (GPS)-A, Orig-A

Houston, TX, Conroe-North Houston Rgnl, ILS OR LOC RWY 14, Amdt 3C

Houston, TX, Conroe-North Houston Rgnl, NDB RWY 14, Amdt 3C

Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 8L, ILS RWY 8L SA CAT I, ILS RWY 8L CAT II, ILS RWY 8L CAT III, Amdt 4D

Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 9, ILS RWY 9 SA CAT I, ILS RWY 9 SA CAT II, Amdt 10B

Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 26L, ILS RWY 26L SA CAT I, ILS RWY 26L CAT II, ILS RWY 26L CAT III, Amdt 21D

Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 26R, ILS RWY 26R SA CAT I, ILS RWY 26R CAT II, ILS RWY 26R CAT III, Amdt 4B

Houston, TX, George Bush Intercontinental/Houston, ILS OR LOC RWY 27, ILS RWY 27 SA CAT I, ILS RWY 27 CAT II, ILS RWY 27 CAT III, Amdt 11A

Houston, TX, Pearland Rgnl, VOR-B, Amdt 1A, CANCELED

Houston, TX, William P Hobby, ILS OR LOC RWY 4, ILS RWY 4 SA CAT I, ILS RWY 4 CAT II, ILS RWY 4 CAT III, Amdt 43A

Houston, TX, William P Hobby, ILS OR LOC RWY 13R, Amdt 12D

Houston, TX, William P Hobby, ILS OR LOC RWY 31L, Amdt 6D

La Porte, TX, La Porte Muni, VOR-A, Orig-B, CANCELED

Olney, TX, Olney Muni, RNAV (GPS) RWY 17, Amdt 1

Olney, TX, Olney Muni, RNAV (GPS) RWY 35, Amdt 1

Brookneal, VA, Brookneal/Campbell County, RNAV (GPS) RWY 24, Amdt 1B

Brookneal, VA, Brookneal/Campbell County, VOR-A, Amdt 2A

Norfolk, VA, Chesapeake Rgnl, VOR/DME RWY 23, Amdt 1A, CANCELED

Petersburg, VA, Dinwiddie County, Takeoff Minimums and Obstacle DP, Amdt 1

Burlington, WI, Burlington Muni, RNAV (GPS) RWY 11, Orig-C

Burlington, WI, Burlington Muni, RNAV (GPS) RWY 29, Amdt 1C

Park Falls, WI, Park Falls Muni, NDB RWY 36, Amdt 1A, CANCELED

Platteville, WI, Platteville Muni, RNAV (GPS) RWY 7, Orig-C

Platteville, WI, Platteville Muni, RNAV (GPS) RWY 25, Orig-A

Bluefield, WV, Mercer County, ILS OR LOC RWY 23, Amdt 15D

Rescinded: On February 7, 2019 (84 FR 2441), the FAA published an Amendment in Docket No. 31229, Amdt No. 3831, to Part 97 of the Federal Aviation Regulations under section 97.33. The following entry for College Station, TX, effective February 28, 2019, is hereby rescinded in its entirety:

College Station, TX, Easterwood Field, RNAV (GPS) RWY 29, Amdt 1B

[FR Doc. 2019-02679 Filed 2-19-19; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2019-N-0142]

Medical Devices; Dental Devices; Classification of the Auto Titration Device for Oral Appliances

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is

classifying the auto titration device for oral appliances into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the auto titration device for oral appliances' classification. We are taking this action because we have determined that classifying the device into class II (special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

DATES: This order is effective February 20, 2019. The classification was applicable on August 23, 2018.

FOR FURTHER INFORMATION CONTACT:

Anita Belani, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G314, Silver Spring, MD 20993-0002, 301-796-3944, Anita.Belani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the auto titration device for oral appliances as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate