DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31240; Amdt. No. 3841]

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 March 14, 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 March 14, 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 22, 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 25 April 2019

Miami, FL, Miami Intl, ILS OR LOC RWY 9, Amdt 10C
Calhoun, GA, Tom B. David Fld, LOC–A, Orig-A, CANCELLED
Plymouth, IN, Plymouth Muni, RNAV (GPS) RWY 10, Orig-A
Plymouth, IN, Plymouth Muni, VOR RWY 10, Amdt 12A
Plymouth, IN, Plymouth Muni, VOR RWY 28, Amdt 11A
Hardinsburg, KY, Breckinridge County, RNAV (GPS) RWY 10, Orig
Hardinsburg, KY, Breckinridge County, RNAV (GPS) RWY 28, Orig
Hardinsburg, KY, Breckinridge County, Takeoff Minimums and Obstacle DP, Orig
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 4R, ILS RWY 4R SA CAT I, ILS RWY 4R CAT II, ILS RWY 4R CAT III, Amdt 11
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 15R, Amdt 2
Boston, MA, General Edward Lawrence Logan Intl, ILS OR LOC RWY 27, Amdt 3
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Amdt 3
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 15R, Amdt 2
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 27, Amdt 1
Grand Rapids, MN, Grand Rapids/Itasca Co-Gordon Newstrom Fld, RNAV (GPS) RWY 34, Orig-C
Engelhard, NC, Hyde County, RNAV (GPS) RWY 11, Orig
Engelhard, NC, Hyde County, Takeoff Minimums and Obstacle DP, Orig
Clovis, NM, Clovis Muni, RNAV (GPS) RWY 30, Orig-A
East Hampton, NY, East Hampton, VOR–A, Amdt 11B, CANCELLED
Ellenville, NY, Joseph Y Resnick, GPS RWY 4, Orig, CANCELLED
Ellenville, NY, Joseph Y Resnick, GPS RWY 22, Orig, CANCELLED
Ellenville, NY, Joseph Y Resnick, RNAV (GPS) RWY 4, Orig
Ellenville, NY, Joseph Y Resnick, RNAV (GPS) RWY 22, Orig
Hazelton, PA, Hazelton Rgnl, LOC RWY 28, Amdt 9
Hazelton, PA, Hazelton Rgnl, RNAV (GPS) RWY 10, Amdt 3
Hazelton, PA, Hazelton Rgnl, RNAV (GPS) RWY 28, Amdt 2
Honey Grove, PA, Stottle Memorial, COPTER RNAV (GPS) 086, Orig, CANCELLED

Rescinded: On February 20, 2019 (84 FR 4996), the FAA published an Amendment in Docket No. 31238, Amdt No. 3839, to Part 97 of the Federal Aviation Regulations under sections 97.29 and 97.37. The following entries for Key West, FL, and Pierre, SD, effective April 25, 2019, are hereby rescinded in their entirety:

Key West, FL, Key West Intl, Takeoff Minimums and Obstacle DP, Amdt 2
Pierre, SD, Pierre Rgnl, ILS OR LOC RWY 31, Amdt 12D

[FR Doc. 2019–04648 Filed 3–13–19; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2019–N–0360]

Medical Devices; Immunology and Microbiology Devices; Classification of the Device To Detect and Identify Microorganisms and Associated Resistance Marker Nucleic Acids Directly in Respiratory Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 March 14, 2019. The classification was applicable on April 3, 2018.

FOR FURTHER INFORMATION CONTACT: Dina Jerebitski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4450, Silver Spring, MD 20993–0002, 301–796–4221, *Dina.Jerebitski@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the device to detect and identify microorganisms and associated resistance marker nucleic acids directly in respiratory specimens 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 to a predicate device that does not require premarket approval (see 21 U.S.C. 360c(i)). We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) (21 U.S.C. 360(k)) of the FD&C