

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8174	7/10/18	ILS OR LOC RWY 10L, Amdt 24.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8183	7/10/18	ILS OR LOC RWY 10R, Amdt 1.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8189	7/10/18	ILS OR LOC RWY 28R, Amdt 11.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8201	7/10/18	RNAV (GPS) RWY 10R, Amdt 1.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8211	7/10/18	RNAV (GPS) RWY 28L, Amdt 1.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8232	7/10/18	RNAV (RNP) Y RWY 10L, Amdt 1A.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8240	7/10/18	RNAV (GPS) Y RWY 28R, Amdt 4.
13-Sep-18 .....	FL	Fort Lauderdale .....	Fort Lauderdale/Hollywood Intl.	8/8244	7/10/18	RNAV (GPS) Z RWY 10L, Amdt 4.
13-Sep-18 .....	GA	Calhoun .....	Tom B David Fld .....	8/8262	7/23/18	RNAV (GPS) RWY 35, Amdt 1B.
13-Sep-18 .....	GA	Calhoun .....	Tom B David Fld .....	8/8265	7/23/18	RNAV (GPS) RWY 17, Amdt 1A.
13-Sep-18 .....	AL	Mobile .....	Mobile Downtown .....	8/8670	7/10/18	RNAV (GPS) RWY 14, Amdt 2.
13-Sep-18 .....	NJ	Ocean City .....	Ocean City Muni .....	8/8675	7/10/18	GPS RWY 6, Orig-B.
13-Sep-18 .....	NJ	Ocean City .....	Ocean City Muni .....	8/8676	7/10/18	VOR-A, Orig-B.
13-Sep-18 .....	TX	Houston .....	David Wayne Hooks Memorial.	8/8861	7/25/18	RNAV (GPS) RWY 35L, Amdt 1C.
13-Sep-18 .....	TX	Houston .....	David Wayne Hooks Memorial.	8/8862	7/25/18	RNAV (GPS) RWY 17R, Amdt 1D.
13-Sep-18 .....	TX	Houston .....	David Wayne Hooks Memorial.	8/8863	7/25/18	LOC RWY 17R, Amdt 3D.
13-Sep-18 .....	OK	Oklahoma City .....	Will Rogers World .....	8/9620	7/23/18	VOR RWY 17L, Amdt 2.
13-Sep-18 .....	KS	Independence .....	Independence Muni .....	8/9691	7/23/18	RNAV (GPS) RWY 17, Amdt 2.
13-Sep-18 .....	MN	Moose Lake .....	Moose Lake Carlton County ..	8/9703	7/25/18	NDB RWY 4, Amdt 1.

[FR Doc. 2018-17616 Filed 8-16-18; 8:45 am]

BILLING CODE 4910-13-P

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

[Docket No. 31206; Amdt. No. 3811]

**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 August 17, 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 August 17, 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](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](http://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 July 27, 2018.

**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 13 September 2018

Ketchikan, AK, Ketchikan Intl, RNAV (GPS) RWY 29, Orig  
Ketchikan, AK, Ketchikan Intl, RNAV (GPS)-B, Amdt 1  
Geneva, AL, Geneva Muni, Takeoff Minimums and Obstacle DP, Amdt 1  
Fayetteville, AR, Drake Field, LDA RWY 34, Amdt 5

Fayetteville, AR, Drake Field, VOR/DME-B, Orig-B, CANCELED  
Oakland, CA, Metropolitan Oakland Intl, RNAV (RNP) Z RWY 12, Amdt 2  
San Francisco, CA, San Francisco Intl, ILS OR LOC RWY 19L, Amdt 22  
San Francisco, CA, San Francisco Intl, RNAV (GPS) RWY 19R, Amdt 3  
Watsonville, CA, Watsonville Muni, Takeoff Minimums and Obstacle DP, Amdt 5A  
Watsonville, CA, Watsonville Muni, WATSONVILLE FOUR, Graphic DP  
Augusta, GA, Daniel Field, RNAV (GPS) RWY 5, Orig  
Cedartown, GA, Polk County Airport—Cornelius Moore Field, RNAV (GPS) RWY 10, Orig-B  
Cedartown, GA, Polk County Airport—Cornelius Moore Field, RNAV (GPS) RWY 28, Orig-B  
Paris, ID, Bear Lake County, RNAV (GPS) RWY 10, Orig  
Paris, ID, Bear Lake County, RNAV (GPS) RWY 28, Orig  
Paris, ID, Bear Lake County, Takeoff Minimums and Obstacle DP, Orig  
Bolingbrook, IL, Bolingbrook’s Clow Intl, RNAV (GPS)-B, Amdt 1A  
Bolingbrook, IL, Bolingbrook’s Clow Intl, VOR-A, Amdt 1A  
Springfield, IL, Abraham Lincoln Capital, ILS OR LOC RWY 22, Amdt 9C  
French Lick, IN, French Lick Muni, RNAV (GPS) RWY 8, Amdt 1C  
French Lick, IN, French Lick Muni, RNAV (GPS) RWY 26, Orig-C  
Indianapolis, IN, Indianapolis Rgnl, RNAV (GPS) RWY 34, Amdt 1B  
Topeka, KS, Topeka Rgnl, TACAN RWY 13, Amdt 4B  
New Roads, LA, False River Rgnl, LOC RWY 36, Amdt 2  
New Roads, LA, False River Rgnl, NDB RWY 36, Amdt 2A, CANCELED  
New Roads, LA, False River Rgnl, RNAV (GPS) RWY 18, Amdt 1  
New Roads, LA, False River Rgnl, RNAV (GPS) RWY 36, Amdt 1  
Boston, MA, General Edward Lawrence Logan Intl, RNAV (GPS) RWY 4R, Amdt 2B  
Detroit, MI, Detroit Metropolitan Wayne County, ILS OR LOC RWY 4R, ILS RWY 4R SA CAT I, ILS RWY 4R CAT II, ILS RWY 4R CAT III, Amdt 19A  
Detroit, MI, Detroit Metropolitan Wayne County, ILS PRM RWY 4R (CLOSE PARALLEL), ILS PRM RWY 4R (CLOSE PARALLEL) SA CAT I, ILS PRM RWY 4R (CLOSE PARALLEL) CAT II, ILS PRM RWY 4R (CLOSE PARALLEL) CAT III, Amdt 3A  
Greenville, MI, Greenville Muni, Takeoff Minimums and Obstacle DP, Amdt 2B  
Marquette, MI, Sawyer Intl, ILS OR LOC RWY 1, Amdt 1  
Marquette, MI, Sawyer Intl, RNAV (GPS) RWY 1, Amdt 1  
Marquette, MI, Sawyer Intl, RNAV (GPS) RWY 19, Amdt 2  
Marquette, MI, Sawyer Intl, VOR RWY 19, Amdt 1  
Hinckley, MN, Field of Dreams, RNAV (GPS) RWY 24, Orig-A, CANCELED  
Red Wing, MN, Red Wing Rgnl, Takeoff Minimums and Obstacle DP, Amdt 2A  
Bismarck, ND, Bismarck Muni, ILS OR LOC RWY 31, Amdt 34A

Garrison, ND, Garrison Muni, RNAV (GPS) RWY 13, Amdt 2  
 Garrison, ND, Garrison Muni, RNAV (GPS) RWY 31, Amdt 2  
 Manchester, NH, Manchester, Takeoff Minimums and Obstacle DP, Amdt 10B  
 Mesquite, NV, Mesquite, RNAV (GPS) Y RWY 2, Orig  
 Mesquite, NV, Mesquite, RNAV (GPS) Z RWY 2, Orig  
 Mesquite, NV, Mesquite, Takeoff Minimums and Obstacle DP, Orig  
 Minden, NV, Minden-Tahoe, RNAV (GPS)-A, Amdt 1  
 Minden, NV, Minden-Tahoe, RNAV (GPS)-B, Amdt 1  
 Columbus, OH, Bolton Field, ILS OR LOC RWY 4, Amdt 5A  
 Columbus, OH, Bolton Field, NDB RWY 4, Amdt 7A  
 Columbus, OH, Bolton Field, RNAV (GPS) RWY 4, Orig-B  
 Lebanon, OH, Warren County/John Lane Field, NDB-A, Amdt 6  
 Idabel, OK, Mc Curtain County Rgnl, RNAV (GPS) RWY 2, Amdt 1  
 Idabel, OK, Mc Curtain County Rgnl, RNAV (GPS) RWY 20, Amdt 1  
 Corvallis, OR, Corvallis Muni, ILS OR LOC RWY 17, Amdt 5  
 Corvallis, OR, Corvallis Muni, RNAV (GPS) RWY 35, Amdt 3  
 Corvallis, OR, Corvallis Muni, VOR RWY 17, Amdt 8  
 Corvallis, OR, Corvallis Muni, VOR RWY 35, Amdt 12  
 Corvallis, OR, Corvallis Muni, VOR-A, Amdt 11  
 Borger, TX, Hutchinson County, RNAV (GPS) RWY 17, Amdt 1  
 Borger, TX, Hutchinson County, RNAV (GPS) RWY 35, Amdt 1  
 Dallas, TX, Dallas Love Field, ILS OR LOC RWY 31L, Amdt 22A  
 Dallas, TX, Dallas Love Field, ILS OR LOC RWY 31R, ILS RWY 31R SA CAT I, ILS RWY 31R SA CAT II, Amdt 7  
 Dallas, TX, Dallas Love Field, ILS Y OR LOC Y RWY 13L, Amdt 33A  
 Dallas, TX, Dallas Love Field, ILS Y OR LOC Y RWY 13R, Amdt 6A  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 13L, Amdt 1C  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 13R, Orig-B  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 31L, Amdt 1E  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Y RWY 31R, Amdt 3  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Z RWY 13L, Amdt 3B  
 Dallas, TX, Dallas Love Field, RNAV (GPS) Z RWY 13R, Amdt 2A  
 Dallas, TX, Dallas Love Field, RNAV (RNP) W RWY 13L, Orig-C  
 Dallas, TX, Dallas Love Field, RNAV (RNP) X RWY 13L, Orig-C  
 Houston, TX, West Houston, RNAV (GPS) RWY 15, Amdt 1C  
 Houston, TX, West Houston, RNAV (GPS) RWY 33, Amdt 1B  
 Houston, TX, West Houston, VOR-D, Amdt 1, CANCELED  
 La Grange, TX, Fayette Rgnl Air Center, Takeoff Minimums and Obstacle DP, Amdt 1

Port Lavaca, TX, Calhoun County, Takeoff Minimums and Obstacle DP, Orig-A  
**RESCINDED:** On July 16, 2018 (83 FR 32766), the FAA published an Amendment in Docket No. 31202, Amdt No. 3807, to Part 97 of the Federal Aviation Regulations under section 97.25, 97.29, 97.33, and 97.37. The following entries for Asheville, NC, and Cleveland, TN, effective September 13, 2018, are hereby rescinded in their entirety:  
 Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig  
 Asheville, NC, Asheville Rgnl, ILS OR LOC RWY 35, Orig, CANCELED  
 Asheville, NC, Asheville Rgnl, LOC RWY 17, Orig  
 Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig  
 Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 17, Orig, CANCELED  
 Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig  
 Asheville, NC, Asheville Rgnl, RNAV (GPS) RWY 35, Orig, CANCELED  
 Asheville, NC, Asheville Rgnl, Takeoff Minimums and Obstacle DP, Amdt 1  
 Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 3, Amdt 2  
 Cleveland, TN, Cleveland Rgnl Jetport, RNAV (GPS) RWY 21, Amdt 2  
 Cleveland, TN, Cleveland Rgnl Jetport, Takeoff Minimums and Obstacle DP, Amdt 2

[FR Doc. 2018-17619 Filed 8-16-18; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 803

[Docket No. FDA-2017-N-6730]

#### Medical Devices and Device-Led Combination Products; Voluntary Malfunction Summary Reporting Program for Manufacturers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification; order granting alternative.

**SUMMARY:** The Food and Drug Administration's (FDA, Agency, or we) Center for Devices and Radiological Health and Center for Biologics Evaluation and Research are announcing that the Agency is granting an alternative that permits manufacturer reporting of certain device malfunction medical device reports (MDRs) in summary form on a quarterly basis. We refer to this alternative as the "Voluntary Malfunction Summary Reporting Program." This voluntary program reflects goals for streamlining malfunction reporting outlined in the commitment letter agreed to by FDA

and industry and submitted to Congress, as referenced in the Medical Device User Fee Amendments of 2017 (MDUFA IV Commitment Letter).

**DATES:** This voluntary program applies only to reportable malfunction events that manufacturers become aware of on or after August 17, 2018. See further discussion in section IV.F. "Submission Schedule and Logistics."

**FOR FURTHER INFORMATION CONTACT:** Michelle Rios, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3222, Silver Spring, MD 20993, 301-796-6107, [MDRPolicy@fda.hhs.gov](mailto:MDRPolicy@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240-402-7911; or CBER, Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002; or by calling 1-800-835-4709 or 240-402-8010; or email: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Every year, FDA receives hundreds of thousands of MDRs of suspected device-associated deaths, serious injuries, and malfunctions. The Agency's MDR program is one of the postmarket surveillance tools FDA uses to monitor device performance, detect potential device-related safety issues, and contribute to benefit-risk assessments. Malfunction reports represent a substantial fraction of the MDRs FDA receives on an annual basis.

Medical device reporting requirements for manufacturers are set forth in section 519 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360i) and the regulations contained in part 803 (21 CFR part 803). Among other things, part 803 requires the submission of an individual MDR when a manufacturer becomes aware of information, from any source, which reasonably suggests that one of its marketed devices malfunctioned and the malfunction of the device or a similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur (§§ 803.10(c)(1) and 803.50(a)(2)). Throughout this document, we refer to such malfunctions as "reportable malfunctions" or "reportable malfunction events."

The Food and Drug Administration Amendments Act of 2007 (FDAAA)