

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
20-May-21 ..	MS ..	Tunica	Tunica Muni	1/7505	3/10/21	ILS OR LOC RWY 35, Amdt 1
20-May-21 ..	TN ...	Dyersburg	Dyersburg Rgnl	1/7753	2/22/21	RNAV (GPS) RWY 4, Amdt 2C
20-May-21 ..	TN ...	Dyersburg	Dyersburg Rgnl	1/7754	2/22/21	VOR-A, Amdt 18A
20-May-21 ..	TN ...	Dyersburg	Dyersburg Rgnl	1/7755	2/22/21	RNAV (GPS) RWY 22, Amdt 1B
20-May-21 ..	MN ..	Alexandria	Chandler Fld	1/7812	2/19/21	RNAV (GPS) RWY 31, Amdt 1
20-May-21 ..	MN ..	Alexandria	Chandler Fld	1/7813	2/19/21	VOR RWY 22, Amdt 15A
20-May-21 ..	MN ..	Alexandria	Chandler Fld	1/7814	2/19/21	ILS OR LOC RWY 31, Orig-D
20-May-21 ..	TX ...	Stephenville	Stephenville Clark Rgnl	1/7893	3/25/21	RNAV (GPS) RWY 14, Orig-A
20-May-21 ..	TX ...	Stephenville	Stephenville Clark Rgnl	1/7894	3/25/21	RNAV (GPS) RWY 32, Orig-A
20-May-21 ..	MI	Dowagiac	Dowagiac Muni	1/8248	3/11/21	RNAV (GPS) RWY 9, Orig
20-May-21 ..	MI	Dowagiac	Dowagiac Muni	1/8249	3/11/21	RNAV (GPS) RWY 27, Orig
20-May-21 ..	WY ..	Worland	Worland Muni	1/8477	3/23/21	RNAV (GPS) RWY 16, Orig-B
20-May-21 ..	WY ..	Worland	Worland Muni	1/8478	3/23/21	RNAV (GPS) RWY 34, Orig-B
20-May-21 ..	WY ..	Worland	Worland Muni	1/8479	3/23/21	VOR RWY 16, Amdt 6B
20-May-21 ..	MT ..	Glendive	Dawson Community	1/8553	1/29/21	RNAV (GPS) RWY 12, Orig-B
20-May-21 ..	MT ..	Glendive	Dawson Community	1/8554	1/29/21	RNAV (GPS) RWY 30, Orig-B
20-May-21 ..	GA ..	Bainbridge	Decatur County Industrial Air Park	1/8590	2/22/21	ILS OR LOC RWY 27, Orig-A
20-May-21 ..	GA ..	Bainbridge	Decatur County Industrial Air Park	1/8595	2/22/21	VOR-A, Amdt 4
20-May-21 ..	GA ..	Bainbridge	Decatur County Industrial Air Park	1/8596	2/22/21	RNAV (GPS) RWY 27, Amdt 1
20-May-21 ..	GA ..	Bainbridge	Decatur County Industrial Air Park	1/8597	2/22/21	RNAV (GPS) RWY 9, Amdt 1
20-May-21 ..	KS ...	Salina	Salina Rgnl	1/9485	3/3/21	NDB RWY 35, Amdt 17B
20-May-21 ..	NC ..	Clinton	Clinton-Sampson County	1/9814	3/25/21	RNAV (GPS) RWY 6, Amdt 2B
20-May-21 ..	NC ..	Clinton	Clinton-Sampson County	1/9815	3/25/21	RNAV (GPS) Y RWY 24, Amdt 1B
20-May-21 ..	NC ..	Clinton	Clinton-Sampson County	1/9816	3/25/21	LOC RWY 6, Amdt 3B
20-May-21 ..	NC ..	Clinton	Clinton-Sampson County	1/9817	3/25/21	VOR/DME-A, Amdt 6A

[FR Doc. 2021-07849 Filed 4-16-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31364; Amdt. No. 3951]

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 April 19, 2021. 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 April 19, 2021.

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 Information Services, 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, email fedreg.legal@nara.gov or go to: <https://www.archives.gov/federal-register/cfr/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 73169. Telephone (405) 954-4164.

SUPPLEMENTARY INFORMATION: This rule amends 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 8260-3, 8260-4, 8260-5, 8260-15A, 8260-15B, when required by an entry on 8260-15A, and 8260-15C.

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 or 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 typed 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 flights 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.

Lists of Subjects in 14 CFR Part 97

Air Traffic Control, Airports, Incorporation by reference, Navigation (Air).

Issued in Washington, DC, on April 2, 2021.

Wade Terrell,

Aviation Safety, Manager, Flight Procedures & Airspace Group, Flight Technologies and Procedures Division.

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 17 June 2021

Fairbanks, AK, Fairbanks Intl, Takeoff Minimums and Obstacle DP, Amdt 6B
 Fort Smith, AR, KFSM, ILS OR LOC RWY 7, Amdt 1A
 St Johns, AZ, KSJN, VOR–A, Amdt 3
 Mammoth Lakes, CA, Mammoth Yosemite, NIKOL TWO Graphic DP
 San Jose, CA, KSJC, RNAV (RNP) Z RWY 30L, Amdt 3
 San Jose, CA, KSJC, RNAV (RNP) Z RWY 30R, Amdt 2
 Naples, FL, KAPF, RNAV (GPS) RWY 5, Amdt 2C
 Naples, FL, KAPF, RNAV (GPS) RWY 23, Amdt 1C
 Tampa, FL, KTPA, LOC RWY 1R, Amdt 4B
 Venice, FL, Venice Muni, Takeoff Minimums and Obstacle DP, Amdt 4
 Atlanta, GA, Atlanta Speedway, Takeoff Minimums and Obstacle DP, Amdt 2B

Hilo, HI, PHTO, ILS OR LOC RWY 26, Amdt 14A
 Honolulu, HI, PHNL, RNAV (GPS) RWY 8R, Amdt 1
 Carbondale/Murphysboro, IL, KMDH, ILS OR LOC RWY 18L, Amdt 13B
 Carbondale/Murphysboro, IL, KMDH, NDB RWY 18L, Amdt 13B
 Chicago, IL, KMDW, RNAV (GPS) Z RWY 4R, Amdt 4
 Chicago, IL, KMDW, RNAV (RNP) Y RWY 4R, Amdt 1
 Marion, IL, KMWA, ILS OR LOC RWY 20, Amdt 12C
 Marion, IL, KMWA, RNAV (GPS) RWY 2, Amdt 1D
 Marion, IL, KMWA, RNAV (GPS) RWY 20, Amdt 1D
 Marion, IL, KMWA, VOR RWY 2, Amdt 13E, CANCELLED
 Beverly, MA, KBVY, RNAV (GPS) RWY 16, Amdt 2
 Boston, MA, KBOS, ILS OR LOC RWY 33L, ILS RWY 33L (SA CAT I), ILS RWY 33L (CAT II), ILS RWY 33L (CAT III), Amdt 5F
 Ocean City, MD, KOXB, LOC RWY 14, Amdt 2B, CANCELLED
 Ocean City, MD, KOXB, LOC RWY 32, Orig
 Greenville, ME, Greenville Muni, Takeoff Minimums and Obstacle DP, Amdt 3
 Presque Isle, ME, KPQI, ILS OR LOC RWY 1, Amdt 7A
 Eveleth, MN, KEVM, VOR RWY 27, Amdt 1B, CANCELLED
 Preston, MN, KFKA, RNAV (GPS) RWY 29, Amdt 1E
 St Paul, MN, KSTP, RNAV (GPS) RWY 32, Amdt 1A
 Cuba, MO, KUBX, RNAV (GPS) RWY 36, Amdt 1
 Grain Valley, MO, 3GV, RNAV (GPS) RWY 9, Orig-A
 Potosi, MO, 8WC, RNAV (GPS) RWY 2, Amdt 2D
 Salem, MO, K33, VOR–A, Orig-A, CANCELLED
 Billings, MT, KBIL, ILS OR LOC RWY 28R, Amdt 3A
 Billings, MT, KBIL, RNAV (GPS) RWY 7, Amdt 2A
 Billings, MT, KBIL, RNAV (GPS) RWY 10L, Amdt 4A
 Billings, MT, KBIL, RNAV (GPS) RWY 25, Amdt 2A
 Billings, MT, KBIL, RNAV (GPS) Y RWY 28R, Amdt 4A
 Billings, MT, KBIL, RNAV (RNP) Z RWY 28R, Amdt 1A
 Williston, ND, KXWA, RNAV (GPS) RWY 4, Orig
 Williston, ND, KXWA, RNAV (GPS) RWY 22, Orig
 Williston, ND, Williston Basin Intl, Takeoff Minimums and Obstacle DP, Amdt 1
 Williston, ND, KXWA, VOR RWY 22, Orig
 Concord, NH, KCON, ILS OR LOC RWY 35, Amdt 2
 Concord, NH, KCON, RNAV (GPS) RWY 12, Amdt 1
 Concord, NH, KCON, RNAV (GPS) RWY 17, Amdt 1
 Concord, NH, KCON, RNAV (GPS) RWY 35, Amdt 1
 Concord, NH, KCON, VOR–A, Amdt 1
 Lebanon, NH, Lebanon Muni, Takeoff Minimums and Obstacle DP, Amdt 3

Manchester, NH, KMHT, RNAV (GPS) Y RWY 17, Amdt 1D

Pittstown, NJ, Alexandria, Takeoff Minimums and Obstacle DP, Amdt 3

Owyhee, NV, 10U, RNAV (GPS) RWY 5, Orig Owyhee, NV, Owyhee, Takeoff Minimums and Obstacle DP, Orig

New York, NY, KLGA, COPTER ILS OR LOC RWY 13, Amdt 1

Saranac Lake, NY, KSLK, ILS OR LOC RWY 23, Amdt 11

Saranac Lake, NY, KSLK, RNAV (GPS) RWY 23, Amdt 1

Athens/Albany, OH, KUNI, NDB RWY 25, Amdt 9D

Dayton, OH, 3I7, RNAV (GPS)-A, Orig Dayton, OH, 3I7, VOR OR GPS RWY 21, Amdt 3B, CANCELLED

Gallipolis, OH, KGAS, RNAV (GPS) RWY 23, Amdt 1

Springfield, OH, KSGH, NDB RWY 24, Amdt 17, CANCELLED

Wilmington, OH, KILN, ILS OR LOC RWY 4L, Amdt 4E

Wilmington, OH, KILN, ILS OR LOC RWY 4R, Orig-D

Wilmington, OH, KILN, ILS OR LOC RWY 22L, ILS RWY 22L (SA CAT I), ILS RWY 22L (CAT II), Orig-D

Wilmington, OH, KILN, ILS OR LOC RWY 22R, ILS RWY 22R (SA CAT I), ILS RWY 22R (CAT II), ILS RWY 22R (CAT III), Amdt 6A

Wilmington, OH, KILN, RNAV (GPS) RWY 4L, Orig-D

Hinton, OK, 2O8, RNAV (GPS) RWY 18, Amdt 1C

Hinton, OK, 2O8, RNAV (GPS) RWY 36, Amdt 1C

Hinton, OK, Hinton Muni, Takeoff Minimums and Obstacle DP, Orig-A

Abilene, TX, KABI, RNAV (GPS) RWY 22, Orig-B, CANCELLED

Abilene, TX, Abilene Rgnl, Takeoff Minimums and Obstacle DP, Amdt 4A

Austin, TX, KEDC, RNAV (GPS) RWY 31, Amdt 1A

Barre/Montpelier, VT, KMPV, RNAV (GPS) RWY 35, Amdt 2

Seattle, WA, KSEA, ILS OR LOC RWY 16L, ILS RWY 16L (SA CAT I), ILS RWY 16L (CAT II), ILS RWY 16L (CAT III), Amdt 8A

Green Bay, WI, KGRB, RNAV (GPS) RWY 6, Amdt 2B

Green Bay, WI, KGRB, RNAV (GPS) RWY 18, Amdt 1C

Green Bay, WI, KGRB, RNAV (GPS) RWY 36, Amdt 3B

Ravenswood, WV, I18, RNAV (GPS) RWY 4, Orig-B

Sheridan, WY, KSHR, RNAV (GPS) RWY 33, Amdt 1A

RESCINDED: On March 24, 2021 (86 FR 15583), the FAA published an Amendment in Docket No. 31359 Amdt No. 3947, to Part 97 of the Federal Aviation Regulations under section 97.23 and 97.25. The following entries for Beverly, MA, effective April 22, 2021, are hereby rescinded in their entirety: Beverly, MA, KBVY, LOC RWY 16, Amdt 8 Beverly, MA, Beverly Rgnl, VOR RWY 16, Amdt 5E, CANCELLED

[FR Doc. 2021-07853 Filed 4-16-21; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 866, 880, 884 and 892

[Docket No. FDA-2018-N-1440]

RIN 0910-AH67

Medical Devices; Medical Device Classification Regulations To Conform to Medical Software Provisions in the 21st Century Cures Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is amending certain classification regulations to reflect changes to the Federal Food, Drug, and Cosmetic Act (FD&C Act) made by the 21st Century Cures Act (the Cures Act). The Cures Act amended the definition of a device in the FD&C Act to exclude certain software functions. FDA is taking this action so that its regulations conform to the medical software provisions in the Cures Act.

DATES: This rule is effective on April 19, 2021.

FOR FURTHER INFORMATION CONTACT: Bakul Patel, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5528, Silver Spring, MD 20993, 301-796-5528, email: Bakul.Patel@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Executive Summary
 - A. Purpose of the Final Rule
 - B. Summary of the Major Provisions of the Final Rule
 - C. Legal Authority
- II. Table of Abbreviations and Acronyms Commonly Used in This Document
- III. Background
- IV. Legal Authority
- V. Description of the Final Rule
 - A. Scope
 - B. Calculator/Data Processing Module for Clinical Use
 - C. Continuous Glucose Monitor Secondary Display
 - D. Automated Indirect Immunofluorescence Microscope and Software-Assisted System
 - E. Medical Device Data Systems
 - F. Home Uterine Activity Monitor
 - G. Medical Image Storage Device
 - H. Medical Image Communications Device
 - I. Picture Archiving and Communications System
- VI. Effective Date
- VII. Economic Analysis of Impacts

- VIII. Analysis of Environmental Impact
- IX. Paperwork Reduction Act of 1995
- X. Federalism
- XI. Consultation and Coordination With Indian Tribal Governments
- XII. Reference

I. Executive Summary

A. Purpose of the Final Rule

On December 13, 2016, the Cures Act was enacted (Pub. L. 114-255). The Cures Act amended the FD&C Act to include descriptions of software functions that are excluded from the definition of device in the FD&C Act. The Cures Act amended the FD&C Act to state that the term device does not include the software functions excluded pursuant to section 520(o)(1) of the FD&C Act.

Among the software functions excluded from the definition of device by this provision, most relevant to this rule are the software functions intended to transfer, store, convert formats, or display clinical laboratory test or other device data, results, and findings and that do not interpret or analyze such clinical laboratory test or other device data, results, and findings. Because the provision only excludes certain software functions from the device definition, the regulatory status of device hardware remains unchanged. With this final rule, FDA is amending the “identification” description of eight classification regulations so that the regulations no longer include software functions that the Cures Act excluded from the device definition in the FD&C Act. In other words, in this action, FDA is amending eight classification regulations so that the regulations conform to the medical software provisions of the Cures Act and reflect FDA’s current statutory authority.

B. Summary of the Major Provisions of the Final Rule

This rule updates eight classification regulations by amending these regulations to exclude software functions that no longer fall within the device definition under 201(h) of the FD&C Act. Specifically, FDA is amending the following classification regulations:

- Amend the calculator/data processing module for clinical use “identification” description to remove non-device software functions that maintain and retrieve laboratory data;
- amend the continuous glucose monitor (CGM) secondary display “identification” description to remove receive and display software functions, and amend the title of the CGM secondary display regulation to