

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 August 18, 2023.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 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 5 October 2023

Fairbanks, AK, PAFA, ILS OR LOC RWY 2L, ILS RWY 2L (SA CAT I), ILS RWY 2L (CAT II), ILS RWY 2L (CAT III), Amdt 11
 Fairbanks, AK, PAFA, RNAV (RNP) Z RWY 2L, Amdt 2
 Fairbanks, AK, PAFA, RNAV (RNP) Z RWY 20R, Amdt 2
 Shishmaref, AK, PASH, NDB RWY 5, Amdt 1A, CANCELED
 Shishmaref, AK, PASH, RNAV (GPS) RWY 5, Amdt 1
 Shishmaref, AK, PASH, RNAV (GPS) RWY 23, Amdt 1
 Shishmaref, AK, PASH, Takeoff Minimums and Obstacle DP, Amdt 1

Manila, AR, KMXA, RNAV (GPS) RWY 36, Amdt 1
 Lancaster, CA, KWJF, PALMDALE ONE, Graphic DP
 Lancaster, CA, KWJF, RNAV (GPS) RWY 24, Orig-B
 Lancaster, CA, KWJF, Takeoff Minimums and Obstacle DP, Amdt 1
 Colorado Springs, CO, KFLY, FALCON ONE, Graphic DP
 Colorado Springs, CO, KFLY, RNAV (GPS) RWY 15, Orig
 Colorado Springs, CO, KFLY, RNAV (GPS) RWY 33, Orig
 Colorado Springs, CO, KFLY, Takeoff Minimums and Obstacle DP, Orig
 Arcadia, FL, X06, RNAV (GPS)–A, Amdt 1
 Arcadia, FL, X06, RNAV (GPS)–B, Amdt 1
 Elberton, GA, KEBA, RNAV (GPS) RWY 11, Amdt 2
 Elberton, GA, KEBA, RNAV (GPS) RWY 29, Amdt 1B
 Elberton, GA, KEBA, VOR RWY 11, Amdt 5
 Nahunta, GA, 4J1, RNAV (GPS) RWY 1, Amdt 1
 Nahunta, GA, 4J1, RNAV (GPS) RWY 19, Amdt 1
 Nahunta, GA, 4J1, RNAV (GPS) Y RWY 1, Orig-B, CANCELED
 Nahunta, GA, 4J1, RNAV (GPS) Z RWY 19, Orig-B, CANCELED
 Kahului, HI, PHOG, ILS Y OR LOC Y RWY 2, Orig-A
 Kahului, HI, PHOG, ILS Z OR LOC Z RWY 2, Amdt 26A
 Kahului, HI, PHOG, NDB RWY 2, Orig-B, CANCELED
 Kahului, HI, PHOG, VOR Y RWY 20, Amdt 1, CANCELED
 South Bend, IN, KSBN, RNAV (GPS) RWY 9R, Amdt 1C
 South Bend, IN, KSBN, RNAV (GPS) RWY 36, Amdt 1C
 Vidalia, LA, 0R4, RNAV (GPS) RWY 14, Amdt 1
 Sandusky, MI, Y83, RNAV (GPS) RWY 10, Orig
 Sandusky, MI, Y83, RNAV (GPS) RWY 28, Orig
 Sandusky, MI, Y83, Takeoff Minimums and Obstacle DP, Orig
 Natchez, MS, KHEZ, ILS OR LOC RWY 14, Amdt 3
 Natchez, MS, KHEZ, VOR RWY 18, Amdt 11A, CANCELED
 Oxford, MS, KUOX, RNAV (GPS) RWY 9, Amdt 2
 Oxford, MS, KUOX, RNAV (GPS) RWY 27, Amdt 2
 Oxford, MS, KUOX, VOR–A, Amdt 5B
 Winnemucca, NV, KWMC, FESKO ONE, Graphic DP
 Winnemucca, NV, KWMC, Takeoff Minimums and Obstacle DP, Amdt 3
 Winnemucca, NV, KWMC, WINNEMUCCA ONE, Graphic DP, CANCELED
 Miller, SD, KMKA, RNAV (GPS) RWY 33, Amdt 1C
 Alice, TX, KALI, LOC/DME RWY 31, Orig-F
 Alice, TX, KALI, RNAV (GPS) RWY 31, Amdt 1G
 Alice, TX, KALI, VOR RWY 31, Amdt 13G
 Milwaukee, WI, KMKE, Takeoff Minimums and Obstacle DP, Amdt 9

Buckhannon, WV, W22, RNAV (GPS) RWY 11, Amdt 2E

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31504; Amdt. No. 4076]

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 amends, suspends, or removes Standard Instrument Approach Procedures (SIAPs) and associated Takeoff Minimums and Obstacle Departure Procedures 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 for the 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 28, 2023. 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 28, 2023.

ADDRESSES: Availability of matter 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

fr.inspection@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 online 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., STB Annex, Bldg 26, Room 217, Oklahoma City, OK 73099. Telephone: (405) 954-1139.

SUPPLEMENTARY INFORMATION: This rule amends 14 CFR part 97 by amending the referenced SIAPs. The complete regulatory description of each SIAP is listed on the appropriate FAA Form 8260, as modified by the National Flight Data Center (NFDC)/Permanent Notice to Airmen (P-NOTAM), and is incorporated by reference under 5 U.S.C. 552(a), 1 CFR part 51, and 14 CFR 97.20. The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but 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 contained on FAA form documents is unnecessary. This amendment provides the affected CFR sections, and specifies the SIAPs and 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 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 and Takeoff Minimums and ODP as amended in the transmittal. For safety and timeliness of change considerations, this amendment incorporates only specific changes contained for each SIAP and Takeoff Minimums and ODP as modified by FDC permanent NOTAMs.

The SIAPs and Takeoff Minimums and ODPs, as modified by FDC permanent NOTAM, and contained in this amendment are based on criteria contained in the U.S. Standard for Terminal Instrument Procedures (TERPS). In developing these changes to SIAPs and Takeoff Minimums and ODPs, the TERPS criteria were applied only to specific conditions existing at the affected airports. All SIAP amendments in this rule have been previously issued by the FAA in a FDC NOTAM as an emergency action of immediate flight safety relating directly to published aeronautical charts.

The circumstances that created the need for these SIAP and Takeoff Minimums and ODP amendments require making them effective in less than 30 days.

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 these 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 August 18, 2023.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me, 14 CFR part 97 is amended by amending Standard Instrument Approach Procedures and Takeoff Minimums and ODPs, 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:

By amending: § 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, MLS, MLS/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, Identified as follows:

* * * *Effective Upon Publication*

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
5-Oct-23	WV	Charleston	West Virginia Intl Yeager	3/0120	8/11/23	ILS OR LOC RWY 5, Orig-A.
5-Oct-23	PA	Reading	Reading Rgnl/Carl A Spaatz Fld.	3/2093	8/10/23	RNAV (GPS) RWY 31, Orig.
5-Oct-23	OH	Washington Court House.	Fayette County	3/2336	8/11/23	RNAV (GPS) RWY 23, Amdt 1A.
5-Oct-23	OH	Coshocton	Richard Downing	3/2817	8/11/23	RNAV (GPS) RWY 4, Orig.
5-Oct-23	WI	Mosinee	Central Wisconsin	3/3041	7/27/23	RNAV (GPS) RWY 17, Amdt 1C.
5-Oct-23	GA	Americus	Jimmy Carter Rgnl	3/3101	6/21/23	RNAV (GPS) RWY 23, Amdt 1C.
5-Oct-23	AR	Fayetteville	Drake Fld	3/7177	8/9/23	RNAV (GPS) RWY 16, Amdt 1B.

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
5-Oct-23	AR	Fayetteville	Drake Fld	3/7180	8/9/23	LOC RWY 16, Orig.
5-Oct-23	AR	Fayetteville	Drake Fld	3/7182	8/9/23	RNAV (GPS) RWY 34, Amdt 1C.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2023–D–1909]

Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled “Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.” This guidance describes FDA’s compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that will go into effect on November 27, 2023. FDA believes the compliance policies outlined in this guidance will help supply chain stakeholders, particularly trading partners, by accommodating the additional time that may be needed to continue to develop and refine appropriate systems and processes to conduct interoperable, electronic tracing at the package level, to achieve robust supply chain security under the Drug Supply Chain Security Act (DSCSA) while helping ensure continued patient access to prescription drugs.

DATES: The announcement of the guidance is published in the **Federal Register** on August 28, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2023–D–1909 for “Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm.