South Bend, IN, KSBN, RNAV (GPS) RWY 27L, Orig-C
South Bend, IN, KSBN, RNAV (GPS) RWY 27R, Amdt 1A
South Bend, IN, KSBN, RNAV (GPS) RWY 36, Amdt 1B
South Bend, IN, South Bend Intl, Takeoff Minimums and Obstacle DP, Amdt 9A
Dodge City, KS, KDDC, VOR RWY 32, Amdt 5C
Hugoton, KS, KHQG, RNAV (GPS) RWY 2, Orig-B
Hugoton, KS, KHQG, RNAV (GPS) RWY 20, Orig-B
Hugoton, KS, KHQG, Takeoff Minimums and Obstacle DP, Amdt 2
Pittsburg, KS, KPTS, RNAV (GPS) RWY 4, Amdt 2
Pittsburg, KS, KPTS, VOR RWY 4, Amdt 3G, CANCELLED
Jackson, KY, KJKL, RNAV (GPS) RWY 1, Amdt 1
Lewisport, KY, KY8, RNAV (GPS) RWY 23, Amdt 2
Lewisport, KY, KY8, Takeoff Minimums and Obstacle DP, Amdt 1
Mayfield, KY, M25, RNAV (GPS) RWY 19, Amdt 2
New Orleans, LA, KMSY, ILS OR LOC RWY 2, Amdt 20A
New Orleans, LA, KMSY, RNAV (RNP) Z RWY 11, Amdt 1B
Frederick, MD, KFDK, RNAV (GPS) RWY 5, Amdt 1
Carrabassett, ME, B21, RNAV (GPS)–A, Amdt 1B
Majuro Atoll, MH, PKMJ, RNAV (GPS) RWY 7, Orig-F
Majuro Atoll, MH, PKMJ, RNAV (GPS) RWY 25, Orig-F
Detroit, MI, KYIP, ILS OR LOC RWY 5, Orig
Detroit, MI, KYIP, ILS OR LOC RWY 5R, Amdt 16, CANCELLED
Detroit, MI, KYIP, ILS OR LOC RWY 23, Orig
Detroit, MI, KYIP, ILS OR LOC RWY 23L, Amdt 8, CANCELLED
Detroit, MI, KYIP, RNAV (GPS) RWY 5, Orig
Detroit, MI, KYIP, RNAV (GPS) RWY 5R, Amdt 2, CANCELLED
Detroit, MI, KYIP, RNAV (GPS) RWY 23, Orig
Detroit, MI, KYIP, RNAV (GPS) RWY 23L, Amdt 2, CANCELLED
Detroit, MI, Willow Run, Takeoff Minimums and Obstacle DP, Amdt 11
Escanaba, MI, KESC, ILS OR LOC RWY 9, Amdt 3A
Iron Mountain Kingsford, MI, KIMT, RNAV (GPS) RWY 1, Orig-C
Iron Mountain Kingsford, MI, KIMT, RNAV (GPS) RWY 19, Orig-C
Iron Mountain Kingsford, MI, KIMT, VOR RWY 31. Amdt 16C
Menominee, MI, KMNM, ILS OR LOC RWY 3, Amdt 3A
Menominee, MI, KMNM, VOR–A, Amdt 3C, CANCELLED
Troy, MI, KVLL, RNAV (GPS) RWY 10, Amdt 3A
Troy, MI, KVLL, Takeoff Minimums and Obstacle DP, Amdt 4B
Detroit Lakes, MN, KDTL, VOR RWY 14, Amdt 2, CANCELLED
Cleveland, OH, KBKL, ILS OR LOC RWY 24R, Amdt 2
Columbus, OH, KOSU, Takeoff Minimums and Obstacle DP, Orig-A
Miami, OK, KMIO, VOR/DME–A, Amdt 2C, CANCELLED
La Grande, OR, KLGD, NDB–B, Amdt 2A
Sunriver, OR, S21, RNAV (GPS) RWY 18, Amdt 1
Erie, PA, KERI, RNAV (GPS) RWY 24, Amdt 2A
Conway, SC, KHYW, NDB RWY 4, Orig-C, CANCELLED
Conway, SC, KHYW, NDB RWY 22, Amdt 1A, CANCELLED
Canadian, TX, KHHF, RNAV (GPS) RWY 4, Amdt 2A
Dumas, TX, KDUX, RNAV (GPS) RWY 1, Amdt 1
Dumas, TX, KDUX, RNAV (GPS) RWY 19, Amdt 1
Gruver, TX, E19, RNAV (GPS) RWY 2, Orig-B
Gruver, TX, E19, RNAV (GPS) RWY 20, Orig-C
Pampa, TX, KPPA, RNAV (GPS) RWY 17, Orig-C
Pampa, TX, KPPA, VOR/DME–A, Amdt 3A, CANCELLED
Panhandle, TX, T45, RNAV (GPS) RWY 17, Orig-C
Perryton, TX, KPYX, RNAV (GPS) RWY 17, Orig-D
Spearman, TX, E42, VOR/DME RWY 2, Amdt 1, CANCELLED
Pasco, WA, KPSC, ILS OR LOC RWY 21R, Amdt 13C
Pasco, WA, KPSC, VOR RWY 30, Amdt 5C
Richland, WA, KRLD, LOC RWY 19, Amdt 9A
Sturgeon Bay, WI, KSUE, RNAV (GPS) RWY 20, Amdt 2
Sturgeon Bay, WI, KSUE, RNAV (GPS) RWY 28, Amdt 1

[FR Doc. 2022–10444 Filed 5–13–22; 8:45 am]
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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31428; Amdt. No. 4008]

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 May 16, 2022. 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 May 16, 2022.

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., Registry Bldg. 29, Room 104, Oklahoma City, OK 73169. Telephone: (405) 954–4164.

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 April 29, 2022.

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, Title 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	FDC No.	FDC date	Subject
16–Jun–22	UT	Provo	Provo Muni	2/0598	4/25/22	VOR/DME RWY 13, Amdt 2.
16–Jun–22	NE	Cozad	Cozad Muni	2/0746	4/25/22	VOR RWY 13, Amdt 2B.
16–Jun–22	KS	Atwood	Atwood-Rawlins County City-County	2/0749	4/25/22	Takeoff Minimums and Obstacle DP, Orig-A.
16–Jun–22	WI	Wautoma	Wautoma Muni	2/0751	4/21/22	Takeoff Minimums and Obstacle DP, Orig.
16–Jun–22	TX	Beaumont	Beaumont Muni	2/2086	4/18/22	VOR/DME RWY 13, Amdt 3D.
16–Jun–22	TX	Beaumont	Beaumont Muni	2/2087	4/18/22	VOR/DME RWY 31, Amdt 4D.
16–Jun–22	WI	Superior	Richard I Bong	2/3062	4/19/22	RNAV (GPS) RWY 4, Orig-C.
16–Jun–22	WI	Superior	Richard I Bong	2/3073	4/19/22	RNAV (GPS) RWY 14, Orig-C.
16–Jun–22	WI	Superior	Richard I Bong	2/3074	4/19/22	RNAV (GPS) RWY 22, Orig-B.
16–Jun–22	WI	Superior	Richard I Bong	2/3079	4/19/22	RNAV (GPS) RWY 32, Orig-C.
16–Jun–22	OR	Corvallis	Corvallis Muni	2/3151	4/7/22	VOR–A, Amdt 11.
16–Jun–22	IL	Decatur	Decatur	2/3252	4/13/22	RNAV (GPS) RWY 18, Amdt 1A.
16–Jun–22	NM	Grants	Grants-Milan Muni	2/4257	4/15/22	RNAV (GPS) RWY 31, Orig-B.
16–Jun–22	NM	Grants	Grants-Milan Muni	2/4258	4/15/22	RNAV (GPS) RWY 13, Orig-B.
16–Jun–22	GA	Atlanta	Hartsfield-Jackson Atlanta Intl	2/4353	4/14/22	ILS OR LOC RWY 10, ILS RWY 10 (SA CAT I), ILS RWY 10 (CAT II), ILS RWY 10 (CAT III), Amdt 5A.
16–Jun–22	CA	Visalia	Visalia Muni	2/4501	4/13/22	ILS OR LOC RWY 30, Amdt 9.
16–Jun–22	IA	Carroll	Arthur N Neu	2/7399	4/15/22	RNAV (GPS) RWY 13, Amdt 1B.
16–Jun–22	IA	Carroll	Arthur N Neu	2/7400	4/15/22	RNAV (GPS) RWY 31, Amdt 1B.
16–Jun–22	IA	Oelwein	Oelwein Muni	2/7413	4/15/22	RNAV (GPS) RWY 13, Orig-A.
16–Jun–22	PA	Johnstown	John Murtha Johnstown/Cambria County.	2/8118	4/21/22	RNAV (GPS) RWY 15, Amdt 1A.
16–Jun–22	MO	Lebanon	Floyd W Jones Lebanon	2/8522	4/19/22	RNAV (GPS) RWY 18, Orig-B.
16–Jun–22	MO	Lebanon	Floyd W Jones Lebanon	2/8523	4/19/22	RNAV (GPS) RWY 36, Orig-B.

AIRAC date	State	City	Airport	FDC No.	FDC date	Subject
16–Jun–22	OR	Redmond	Roberts Fld	2/8524	4/25/22	ILS OR LOC RWY 23, Amdt 5.
16–Jun–22	OR	Redmond	Roberts Fld	2/8525	4/25/22	RNAV (GPS) Z RWY 29, Amdt 1A.
16–Jun–22	TX	Austin	Austin Exec	2/8614	4/15/22	RNAV (GPS) RWY 13, Orig-A.
16–Jun–22	ID	Grangeville	Idaho County	2/8625	4/25/22	RNAV (GPS) RWY 26, Orig.
16–Jun–22	TX	Beaumont	Beaumont Muni	2/8948	4/18/22	RNAV (GPS) RWY 13, Amdt 1.
16–Jun–22	TX	Beaumont	Beaumont Muni	2/8953	4/18/22	RNAV (GPS) RWY 31, Amdt 1.
16–Jun–22	TX	Ennis	Ennis Muni	2/9668	4/21/22	VOR/DME–A, Amdt 1A.
16–Jun–22	PA	Butler	Pittsburgh/Butler Rgnl	2/9976	3/29/22	RNAV (GPS) RWY 26, Amdt 2.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 866

[Docket No. FDA–2019–N–5192]

Microbiology Devices; Reclassification of Human Immunodeficiency Virus Serological Diagnostic and Supplemental Tests and Human Immunodeficiency Virus Nucleic Acid Diagnostic and Supplemental Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is issuing a final order to reclassify certain human immunodeficiency virus (HIV) serological diagnostic and supplemental tests and HIV nucleic acid (NAT) diagnostic and supplemental tests, postamendments class III devices with the product code MZF, into class II (special controls), subject to premarket notification. Through this final order, FDA is also adding two new device classification regulations and identifying special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness for these device types. This final order will reduce the regulatory burdens associated with these device types, as manufacturers will no longer be required to submit a premarket approval application (PMA) but can instead submit a premarket notification (510(k)) and receive clearance before marketing their device.

DATES: This order is effective June 15, 2022.

FOR FURTHER INFORMATION CONTACT: Melissa Segal, Center for Biologics Evaluation and Review, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (general controls and special controls), and class III (general controls and premarket approval).

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f)(1) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until, (1) FDA reclassifies the device into class I or class II, or (2) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. FDA determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act and part 807 (21 CFR part 807), subpart E, of the regulations.

A postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA, acting by administrative order, can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide a reasonable assurance of the safety and effectiveness of the device for its intended use.

On February 21, 2020, FDA published in the **Federal Register** a proposed order (85 FR 10110) to reclassify certain HIV serological diagnostic and supplemental tests and HIV NAT diagnostic and supplemental tests from class III to class II (special controls), subject to premarket notification. The comment period on the proposed order closed on April 21, 2020.

II. Comments on the Proposed Order

In response to the February 21, 2020, proposed order, FDA received several comments from public health organizations, device manufacturers, and individuals by the close of the comment period, each containing one or more comments on one or more issues. We describe and respond to the comments in this section of the document. The order of response to the comments is purely for organizational purposes and does not signify the comment's value or importance nor the order in which the comments were received.

(Comment 1) Nearly all comments expressed general support for the proposed reclassification along with appropriate controls to assure safety and efficacy. The comments noted that reclassification could improve access to HIV testing, support earlier diagnosis and facilitate prevention of HIV, enhance laboratory efficiency and patient management, and strengthen public health surveillance.

(Response 1) We acknowledge and appreciate the supportive comments. We are reclassifying these devices and establishing the special controls published in the proposed order with some clarifications and modifications, as summarized in section III.

(Comment 2) Several comments recommended the reclassification of HIV viral load monitoring tests, which were not included within the scope of the proposed order. The comments expressed differing opinions regarding whether HIV viral load reclassification should be included in this final order. One comment also noted that, at the 119th meeting of the Blood Products Advisory Committee (BPAC) held on July 19, 2018 (the Panel), there was clear support from the committee for reclassification of HIV viral load monitoring tests.

(Response 2) We appreciate the comments and note that FDA published