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 October 27, 2023.

Thomas J. Nichols,

Manager, Aviation Safety, Flight Standards Service, 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 30 November 2023

Noatak, AK, WTK/PAWN, RNAV (GPS) RWY 1, Orig–B
Noatak, AK, WTK/PAWN, RNAV (GPS) RWY 19, Orig–B
Lake Wales, FL, X07, RNAV (GPS) RWY 6, Amdt 2
Lake Wales, FL, X07, RNAV (GPS) RWY 24, Amdt 2
Sterling/Rockfalls, IL, KSQI, RNAV (GPS) RWY 7, Amdt 1A
Sterling/Rockfalls, IL, KSQI, RNAV (GPS) RWY 25, Amdt 1A
Calvert City, KY, M34, RNAV (GPS) RWY 28, Orig
Calvert City, KY, M34, Takeoff Minimums and Obstacle DP, Orig
Marion, KY, KGDA, RNAV (GPS) RWY 7, Amdt 4
Marion, KY, KGDA, RNAV (GPS) RWY 25, Amdt 3A
Prestonsburg, KY, SJS, RNAV (GPS) RWY 3, Amdt 2
Prestonsburg, KY, KSJS, RNAV (GPS) RWY 21, Amdt 3
Prestonsburg, KY, KSJS, Takeoff Minimums and Obstacle DP, Amdt 3
Boston, MA, KBOS, RNAV (GPS) X RWY 22L, Amdt 1E
Boston, MA, KBOS, RNAV (GPS) Y RWY 22L, Orig
Ocean City, MD, KOXB, LOC RWY 32, Orig
Ocean City, MD, KOXB, LOC RWY 32, Orig, CANCELED
Ocean City, MD, KOXB, RNAV (GPS) RWY 14, Orig
Ocean City, MD, KOXB, RNAV (GPS) RWY 14, Orig–H, CANCELED
Ocean City, MD, KOXB, RNAV (GPS) RWY 32, Orig
Ocean City, MD, KOXB, RNAV (GPS) RWY 32, Orig–D, CANCELED
Ocean City, MD, KOXB, Takeoff Minimums and Obstacle DP, Amdt 4
Greenville, ME, 3B1, RNAV (GPS) RWY 32, Orig
Lincoln, ME, KLRG, RNAV (GPS) RWY 16, Amdt 1
Lincoln, ME, LRG, RNAV (GPS) RWY 34, Amdt 2
Lincoln, ME, KLRG, Takeoff Minimums and Obstacle DP, Amdt 4
Hancock, MI, CMX, ILS OR LOC RWY 32, Amdt 15C
Hancock, MI, CMX, LOC BC RWY 14, Amdt 12C
Hancock, MI, KCMX, RNAV (GPS) RWY 14, Amdt 1B
Hancock, MI, KCMX, RNAV (GPS) RWY 32, Orig–C
Hancock, MI, KCMX, Takeoff Minimums and Obstacle DP, Amdt 3B
Hancock, MI, KCMX, VOR RWY 25, Amdt 17E
Traverse City, MI, KTVC, ILS OR LOC RWY 10, Orig
Mankato, MN, MKT, COPTER ILS Z OR LOC Z RWY 33, Amdt 1
Mankato, MN, MKT, ILS Y OR LOC Y RWY 33, Amdt 2
Mankato, MN, MKT, RNAV (GPS) RWY 4, Amdt 1
Mankato, MN, MKT, RNAV (GPS) RWY 15, Amdt 1
Mankato, MN, MKT, RNAV (GPS) RWY 22, Amdt 1
Mankato, MN, MKT, RNAV (GPS) RWY 33, Amdt 1
Mankato, MN, MKT, VOR RWY 15, Amdt 7B, CANCELED
Owatonna, MN, KOWA, ILS OR LOC RWY 30, Amdt 4
Owatonna, MN, KOWA, RNAV (GPS) RWY 12, Amdt 2
Waseca, MN, ACQ, RNAV (GPS) RWY 15, Amdt 2
Statesville, NC, KSVH, RNAV (GPS) RWY 10, Amdt 2
Statesville, NC, KSVH, Takeoff Minimums and Obstacle DP, Amdt 1
Readington, NJ, N51, RNAV (GPS) RWY 4, Amdt 1
Readington, NJ, N51, Takeoff Minimums and Obstacle DP, Amdt 2
Readington, NJ, N51, VOR RWY 4, Amdt 2
Hamilton, OH, HAO, RNAV (GPS) RWY 11, Amdt 1C
Hamilton, OH, HAO, RNAV (GPS) RWY 29, Amdt 2A
Johnstown, PA, KJST, ILS OR LOC RWY 33, Amdt 7C
Johnstown, PA, KJST, VOR Z RWY 15, Amdt 7B
Shamokin, PA, N79, RNAV (GPS) RWY 8, Amdt 1
Shamokin, PA, N79, RNAV (GPS) RWY 26, Amdt 1
Shamokin, PA, N79, VOR RWY 8, Amdt 4

[FR Doc. 2023–24659 Filed 11–8–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31515; Amdt. No. 4086]

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 November 9, 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 November 9, 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 October 27, 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
30–Nov–23	TX	Jasper	Jasper County/Bell Fld	3/0837	10/2/23	RNAV (GPS) RWY 18, Orig–A.
30–Nov–23	TX	Jasper	Jasper County/Bell Fld	3/0838	10/2/23	RNAV (GPS) RWY 36, Orig–C.

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
30–Nov–23	CT	Bridgeport	Bridgeport/Sikorsky	3/3119	10/11/23	ILS OR LOC RWY 6, Amdt 10B.
30–Nov–23	CT	Bridgeport	Bridgeport/Sikorsky	3/3122	10/11/23	RNAV (GPS) RWY 29, Amdt 2B.
30–Nov–23	CT	Bridgeport	Bridgeport/Sikorsky	3/3123	10/11/23	RNAV (GPS) RWY 24, Amdt 1B.
30–Nov–23	CT	Bridgeport	Bridgeport/Sikorsky	3/3125	10/11/23	RNAV (GPS) RWY 6, Amdt 1B.
30–Nov–23	MI	Hancock	Houghton County Meml	3/6218	10/16/23	RNAV (GPS) RWY 25, Amdt 1B.
30–Nov–23	KS	Manhattan	Manhattan Rgnl	3/6770	10/19/23	ILS OR LOC RWY 3, Amdt 8.
30–Nov–23	MA	Plymouth	Plymouth Muni	3/8906	10/20/23	RNAV (GPS) RWY 33, Amdt 1.
30–Nov–23	MA	Plymouth	Plymouth Muni	3/8908	10/20/23	RNAV (GPS) RWY 15, Orig–A.

[FR Doc. 2023–24660 Filed 11–8–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[Docket No. FDA–2023–N–4487]

Medical Devices; Hematology and Pathology Devices; Classification of the Container System for the Processing and Storage of Red Blood Cell Components Under Reduced Oxygen Conditions

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

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions 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 classification of the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions. 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.

DATES: This order is effective November 9, 2023. The classification was applicable on September 15, 2023.

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

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the container system for the processing and storage of Red Blood Cell components under reduced oxygen conditions as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. 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 (see 21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate device by means of the procedures for premarket notification under section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

FDA may also classify a device through ''De Novo'' classification, a common name for the process authorized under section 513(f)(2) of the FD&C Act; (see also 21 CFR part 860, subpart D). Section 207 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) established the first procedure for De Novo classification. Section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) modified the De Novo application process by adding a second procedure. A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see section 513(f)(2)(B)(i) of the FD&C Act). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application to market a substantially equivalent device (see section 513(i) of the FD&C Act, defining ''substantial equivalence''). Instead, sponsors can use the 510(k) process, when necessary, to market their device.

II. De Novo Classification

On January 5, 2022, FDA received Hemanext, Inc.'s request for De Novo classification of the Hemanext One. FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act.

We classify devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls that, in combination with the general controls,