300–103–0, 335–300–105–0, 335–300–106–0, 335–300–107–0, 335–300–108–0, 335–300–109–0, or 335–300–110–0, installed.

(2) For CFM56–7B20, CFM56–7B20/2, CFM56–7B20/3, CFM56–7B22, CFM56–7B22/2, CFM56–7B22/3, CFM56–7B22/3B1, CFM56–7B22/B1, CFM56–7B24, CFM56–7B24/2, CFM56–7B24/3, CFM56–7B24/3B1, CFM56–7B24/B1, CFM56–7B26, CFM56–7B26/2, CFM56–7B26/3, CFM56–7B26/3B1, CFM56–7B26/3B2, CFM56–7B26/3B2F, CFM56–7B26/3F, CFM56–7B26/B1, CFM56–7B26/B2, CFM56–7B27, CFM56–7B27/2, CFM56–7B27/3, CFM56–7B27/3B1, CFM56–7B27/3B1F, CFM56–7B27/3B3, CFM56–7B27/3F, CFM56–7B27/B1, and CFM56–7B27/B3 model turbofan engines, AGB P/N: 340–046–503–0, 340–046–504–0, or 340–046–505–0, installed.

(3) For CFM56–7B27A, CFM56–7B27A/3, or CFM56–7B27AE model turbofan engines, AGB P/N: 340–188–601–0, 340–188–603–0, or 340–188–605–0, installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 7260, Turbine Engine Accessory Drive.

(e) Unsafe Condition

This AD was prompted by a dual engine loss of oil event and 42 prior events of total loss of engine oil during flight. The FAA is issuing this AD to prevent loss of engine oil while in flight. The unsafe condition, if not addressed, could result in engine failure, loss of thrust control, reduced control of the aircraft, and damage to the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Required Actions

(1) After the effective date of this AD, after any maintenance that involves removal and re-installation of the AGB handcranking pad cover, perform an independent inspection to verify re-installation of the AGB handcranking pad cover; or

(2) Prior to the next removal of the AGB handcranking pad cover from the engine, insert the independent inspection required by paragraph (g)(1) of this AD as a required inspection item in the existing approved continuous airworthiness maintenance program for the aircraft.

(h) Mandatory Terminating Action

As a mandatory terminating action to the requirements of paragraph (g) of this AD:

(1) For affected CFM56–3, CFM56–3B, and CFM56–3C model turbofan engines, at the next engine shop visit, or before December 31, 2026, whichever occurs first after the effective date of this AD, replace the affected AGB with a part eligible for installation.

(2) For affected CFM56–7B model turbofan engines, except for CFM56–7B27A, CFM56–7B27A/3, and CFM56–7B27AE model turbofan engines, at the next engine shop visit, or before December 31, 2024, whichever occurs first after the effective date of this AD, replace the affected AGB with a part eligible for installation.

(i) Definition

(1) For the purpose of this AD, an ''engine shop visit'' is the induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine case flanges, except for the following situations, which do not constitute an engine shop visit:

(i) Separation of engine flanges solely for the purposes of transportation of the engine without subsequent maintenance; or

(ii) Separation of engine flanges solely for the purpose of replacing the fan or propulsor without subsequent maintenance.

(2) For the purpose of this AD, for affected CFM56–3, CFM56–3B, and CFM56–3C model turbofan engines, a part eligible for installation is:

(i) An AGB with a P/N other than 335–300–103–0, 335–300–105–0, 335–300–106–0, 335–300–107–0, 335–300–108–0, 335–300–109–0, 335–300–110–0; or

(ii) An AGB that, using an FAA-approved procedure, has been re-worked with a dynamic oil seal in the handcranking pad cover assembly and re-identified with a new P/N not listed in paragraph (i)(2)(i) of this AD.

Note 1 to paragraph (i)(2)(ii): Procedures to install a dynamic oil seal in the handcranking pad cover assembly can be found in CFM International SB CFM56–3 S/B 72–1129, Revision 7, dated May 6, 2020.

(3) For the purpose of this AD, for affected CFM56–7B model turbofan engines, except for CFM56–7B27A, CFM56–7B27A/3, and CFM56–7B27AE model turbofan engines, a part eligible for installation is:

(i) An AGB with a P/N other than 340–046–503–0, 340–046–504–0, or 340–046–505–0; or

(ii) An affected AGB that, using an FAA-approved procedure, has been re-worked with a dynamic oil seal in the handcranking pad cover assembly and re-identified with a new P/N not listed in paragraph (i)(3)(i) of this AD.

Note 2 to paragraph (i)(3)(ii): Procedures to install a dynamic oil seal in the handcranking pad cover assembly can be found in CFM International SB CFM56–7B S/B 72–0879, Revision 7, dated February 10, 2021, CFM56–7B S/B 72–0564, Revision 9, dated December 3, 2021, or CFM56–7B S/B 72–1071, initial issue, dated December 3, 2021.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, ECO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k) of this AD. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

For more information about this AD, contact Kevin Clark, Aviation Safety Engineer, ECO Branch, FAA, 1200 District Avenue, Burlington, MA 01803; phone: (781) 238–7088; fax: (781) 238–7199; email: *kevin.m.clark@faa.gov.*

(l) Material Incorporated by Reference

None.

Issued on February 23, 2022.

Derek Morgan,

Acting Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2022–04149 Filed 2–28–22; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31417; Amdt. No. 564]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This document adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: 0901 UTC, effective March 24, 2022.

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 73125. Telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for

Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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 95

Airspace, Navigation (air).

Issued in Washington, DC, on February 18, 2022.

Thomas J. Nichols,

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

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, March 24, 2022.

PART 95—IFR ALTITUDES

■ 1. The authority citation for part 95 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, and 14 CFR 11.49(b)(2).

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 564 Effective Date, March 24, 2022]

From	To	MEA	MAA
§ 95.3000 Low Altitude RNAV Routes			
§ 95.3302 RNAV Route T302			
Is Amended by Adding			
LLUKY, NE WP	ROKKK, IA WP	4400	17500
ROKKK, IA WP	WATERLOO, IA VOR/DME	3000	17500
WATERLOO, IA VOR/DME	DUBUQUE, IA VORTAC	2900	17500
DUBUQUE, IA VORTAC	JOOLZ, IL WP	*2900	17500
*2500–MOCA			
JOOLZ, IL WP	GRIFT, IL WP	3000	17500
§ 95.3411 RNAV Route T411			
Is Added to Read			
RAZORBACK, AR VORTAC	DROOP, MO WP	3200	17500
DROOP, MO WP	BUTLER, MO VORTAC	2800	17500
BUTLER, MO VORTAC	TOPEKA, KS VORTAC	3100	17500
TOPEKA, KS VORTAC	LINCOLN, NE VORTAC	3200	17500
§ 95.3413 RNAV Route T413			
Is Added to Read			
RAZORBACK, AR VORTAC	DROOP, MO WP	3200	17500
DROOP, MO WP	EMPORIA, KS VORTAC	3100	17500
EMPORIA, KS VORTAC	SALINA, KS VORTAC	3300	17500
SALINA, KS VORTAC	GRAND ISLAND, NE VOR/DME	3900	17500
GRAND ISLAND, NE VOR/DME	ISTIQ, NE WP	3800	17500
ISTIQ, NE WP	LLUKY, NE WP	4000	17500
LLUKY, NE WP	MMINI, NE WP	4000	17500
MMINI, NE WP	JMBAG, SD WP	4300	17500
JMBAG, SD WP	PIERRE, SD VORTAC	4200	17500

From	To	MEA
§ 95.6001 Victor Routes-U.S.		
§ 95.6013 VOR Federal Airway V13 Is Amended To Delete		
RAZORBACK, AR VORTAC	*PINNE, MO WP	3000

From	To	MEA
*4500–MRA		
PINNE, MO WP	NEOSHO, MO VOR/DME	3000
NEOSHO, MO VOR/DME	NASHE, MO FIX	2900
NASHE, MO FIX	DIZZI, MO WP	2700
DIZZI, MO WP	BUTLER, MO VORTAC	*2600
*2000–MOCA		
§ 95.6014 VOR Federal Airway V14 Is Amended To Delete		
TULSA, OK VORTAC	ADAIR, OK FIX	2500
ADAIR, OK FIX	NEOSHO, MO VOR/DME	3000
NEOSHO, MO VOR/DME	SPRINGFIELD, MO VORTAC	3000
§ 95.6015 VOR Federal Airway V15 Is Amended To Delete		
OKMULGEE, OK VOR/DME	MALTS, OK FIX	3500
MALTS, OK FIX	*PRYOR, OK FIX	**2900
*2900–MRA		
**2200–MOCA		
PRYOR, OK FIX	NEOSHO, MO VOR/DME	3000
§ 95.6027 VOR Federal Airway V27 Is Amended To Read in Part		
GAVIOTA, CA VORTAC	*ORCUT, CA FIX	6000
*6000–MCA	ORCUT, CA FIX, SE BND.	
§ 95.6037 VOR Federal Airway V37 Is Amended To Delete		
ELLWOOD CITY, PA VOR/DME	ERIE, PA TACAN	3000
§ 95.6043 VOR Federal Airway V43 Is Amended To Delete		
YOUNGSTOWN, OH VORTAC	ERIE, PA TACAN	*5000
*3000–GNSS MEA		
§ 95.6270 VOR Federal Airway V270 Is Amended To Delete		
ERIE, PA VORTAC	JAMESTOWN, NY VOR/DME	4000
§ 95.6307 VOR Federal Airway V307 Is Amended To Delete		
HARRISON, AR VOR/DME	NEOSHO, MO VOR/DME	*3400
*2800–MOCA		
NEOSHO, MO VOR/DME	OSWEGO, KS VOR/DME	3000
§ 95.6506 VOR Federal Airway V506 Is Amended To Delete		
TULSA, OK VORTAC	VINTA, OK FIX	2700
VINTA, OK FIX	NEOSHO, MO VOR/DME	3000
NEOSHO, MO VOR/DME	BILIE, MO FIX	3000
BILIE, MO FIX	SPRINGFIELD, MO VORTAC	3000

From	To	MEA	MAA
§ 95.7001 Jet Routes **§ 95.7181 Jet Route J181**			
Is Amended To Delete			
OKMULGEE, OK VOR/DME	NEOSHO, MO VOR/DME	18000	45000
NEOSHO, MO VOR/DME	HALLSVILLE, MO VORTAC	18000	45000

Airway Segment		Changeover Points	
From	To	Distance	From
§ 95.8005 Jet Route Changeover Points **J181 Is Amended To Delete Changeover Point**			
OKMULGEE, OK VOR/DME	NEOSHO, MO VOR/DME	58	OKMULGEE.
NEOSHO, MO VOR/DME	HALLSVILLE, MO VORTAC	130	NEOSHO.

[FR Doc. 2022–04022 Filed 2–28–22; 8:45 a.m.]
BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2022–N–0114]

Medical Devices; Orthopedic Devices; Classification of the Screw Sleeve Bone Fixation Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is classifying the screw sleeve bone fixation device 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 screw sleeve bone fixation device's classification. 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 March 1, 2022. The classification was applicable on May 1, 2020.

FOR FURTHER INFORMATION CONTACT: Jesse Muir, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4508, Silver Spring, MD 20993–0002, 240–402–6679, *Jesse.Muir@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the screw sleeve bone fixation device as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, by placing the device into a lower device class than the automatic class III assignment.

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 (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. 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 less-burdensome 510(k) process, when necessary, to market their device.

II. De Novo Classification

On December 13, 2018, FDA received Woven Orthopedic Technologies, LLC's request for De Novo classification of the OGmend® Implant System. 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, provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 U.S.C. 360c(a)(1)(B)). After review of the information submitted in the request, we determined that the device can be classified into class II with the establishment of special controls. FDA has determined that these special controls, in addition to the general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 1, 2020, FDA issued an order to the requester classifying the device into class II. In this final order, FDA is codifying the classification of the device by adding 21 CFR 888.3043.[1] We have named the generic type of device ''screw sleeve bone fixation device,'' and it is intended to be implanted in conjunction with a non-resorbable, metallic bone screw where the screw has lost purchase due to loosening, backout, or breakage. The device fits between the screw threads and surrounding bone and provides increased surface area to create an

[1] FDA notes that the ''ACTION'' caption for this final order is styled as ''Final amendment; final order,'' rather than ''Final order.'' Beginning in December 2019, this editorial change was made to indicate that the document ''amends'' the Code of Federal Regulations. The change was made in accordance with the Office of Federal Register's (OFR) interpretations of the Federal Register Act (44 U.S.C. chapter 15), its implementing regulations (1 CFR 5.9 and parts 21 and 22), and the Document Drafting Handbook.