

The VOR Federal airway amendments and revocation are described below.

V-36: V-36 extends between the Thunder Bay, ON, Canada, VOR/DME and the intersection of the Wiarton, ON, Canada, VOR/DME 150° radial and Toronto, ON, Canada, VOR/DME 304° radial (BIGBE fix); and between the Elmira, NY, VOR/DME and the intersection of the La Guardia, NY, VOR/DME 310° and Stillwater, NJ, VOR/DME 043° radials (NEION fix). The airspace within Canada is excluded. This action removes the airway segment between the Thunder Bay, ON, Canada, VOR/DME and Wawa, ON, Canada, VOR/DME; and the airway segment between the Sault Ste. Marie, MI, VOR/DME and the intersection of the Wiarton, ON, Canada, VOR/DME 150° radial and Toronto, ON, Canada, VOR/DME 304° radial (BIGBE fix). The resulting airway extends between the Wawa, ON, Canada, VOR/DME and the Sault Ste. Marie, MI, VOR/DME; and between the Elmira, NY, VOR/DME and the intersection of the La Guardia, NY, VOR/DME 310° and Stillwater, NJ, VOR/DME 043° radials (NEION fix). The airspace within Canada remains excluded.

V-316: V-316 currently extends between the Ironwood, MI, VOR/DME and the Sawyer, MI, VOR/DME; and between the Sault Ste. Marie, MI, VOR/DME and the Sudbury, ON, Canada, VOR/DME. The airspace in Canada is excluded. This action removes the airway segment between the Sault Ste. Marie, MI, VOR/DME and the Sudbury, ON, Canada, VOR/DME, and the exclusionary language. The resulting airway extends between the Ironwood, MI, VOR/DME and the Sawyer, MI, VOR/DME.

V-180: V-180 currently extends between the International Falls, MN, VOR/DME and the Dryden, ON, Canada, NDB. The airspace within Canada is excluded. The airway is revoked in its entirety.

All radials in the VOR Federal airway descriptions below are unchanged and stated in True degrees.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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 Department of

Transportation (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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of amending VOR Federal airways V-36 and V-316; and revoking VOR Federal airway V-180, to mirror changes being made by NAV CANADA in Canadian airspace in support of their Navigational Aid Modernization program, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5-6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5-2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. The FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA JO Order 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6010(a), Domestic VOR Federal airways.

* * * * *

V-36 [Amended]

From Wawa, ON, Canada; to Sault Ste. Marie, MI. From Elmira, NY; INT Elmira 110° and LaGuardia, NY, 310° radials; to INT LaGuardia 310° and Stillwater, NJ, 043° radials.

The airspace within Canada is excluded.

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V-180 [Removed]

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V-316 [Amended]

From Ironwood, MI; to Sawyer, MI.

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Issued in Washington, DC, on November 16, 2021.

Michael R. Beckles,
Acting Manager, Rules and Regulations Group.

[FR Doc. 2021-25484 Filed 11-22-21; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2021-0288; Airspace Docket No. 21-AGL-6]

RIN 2120-AA66

Amendment of Area Navigation (RNAV) T-348 and Establishment of T-409; Northcentral United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends RNAV route T-348 and establishes RNAV route T-409 in the northcentral United States. This action expands the availability of RNAV routing in support of transitioning the National Airspace

System (NAS) from ground-based to satellite-based navigation.

DATES: Effective date 0901 UTC, January 27, 2022. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: FAA Order JO 7400.11F, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at https://www.faa.gov/air_traffic/publications/. For further information, you can contact the Rules and Regulations Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783. FAA Order JO 7400.11F is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order JO 7400.11F at NARA, email: fr.inspection@nara.gov or go to <https://www.archives.gov/federal-register/cfr/ibr-locations.html>.

FOR FURTHER INFORMATION CONTACT: Jesse Acevedo, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it modifies the route structure as necessary to preserve the safe and efficient flow of air traffic within the NAS.

History

The FAA published a notice of proposed rulemaking for Docket No. FAA-2021-0288, in the **Federal Register** (86 FR 24798; May 10, 2021), amending T-348 and establishing T-409. The proposed action expands the availability of RNAV routing in support of transitioning the NAS from ground-based to satellite-based navigation. Interested parties were invited to

participate in this rulemaking effort by submitting written comments on the proposal. No comments were received.

United States Area Navigation T-routes are published in paragraph 6011 of FAA Order JO 7400.11F, dated August 10, 2021, and effective September 15, 2021, which is incorporated by reference in 14 CFR 71.1. The RNAV routes listed in this document will be published subsequently in FAA JO Order 7400.11.

Availability and Summary of Documents for Incorporation by Reference

This document amends FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021. FAA Order JO 7400.11F is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11F lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Rule

This action amends 14 CFR part 71 by amending RNAV route T-348 and establishing RNAV route T-409. This action is necessary to support the FAA's Next Generation Air Transportation System efforts to transition of the NAS from ground-based to satellite-based navigation.

The RNAV route actions are described below.

T-348: T-348 extends between the BRAIN, MN, waypoint (WP) and the LUNGS, WI, WP. This action extends the route between the LESNR, SD, WP and the BRAIN, MN, WP. As a result of this route segment addition, the BRAIN WP will remain in place, but will no longer be referenced in the legal description. The new route flows from the LESNR WP, through the TECUD, SD, fix and Sioux Falls, SD, VOR/Tactical Air Navigation (VORTAC), to the GRSIS, MN, WP, onward. The resulting RNAV route extends between the LESNR WP and the LUNGS WP.

T-409: T-409 is a new RNAV route that extends between the LLUKY, NE, WP and the Pierre, SD, VORTAC. For RNAV equipped aircraft, this route mitigates the loss of the V-71 airway segments removed on September 10, 2020, due to the decommissioning of the Winner, SD, VOR. Non-equipped aircraft can request ATC radar vectors to fly around or through the area or take advantage of any adjacent VOR Federal airways.

FAA Order JO 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

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 Department of Transportation (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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action of amending RNAV T-348 and establishing RNAV T-409, in support of efforts transitioning the NAS from ground-based to satellite-based navigation, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations at 40 CFR part 1500, and in accordance with FAA Order 1050.1F, Environmental Impacts: Policies and Procedures, paragraph 5-6.5a, which categorically excludes from further environmental impact review rulemaking actions that designate or modify classes of airspace areas, airways, routes, and reporting points (see 14 CFR part 71, Designation of Class A, B, C, D, and E Airspace Areas; Air Traffic Service Routes; and Reporting Points). As such, this action is not expected to result in any potentially significant environmental impacts. In accordance with FAA Order 1050.1F, paragraph 5-2 regarding Extraordinary Circumstances, the FAA has reviewed this action for factors and circumstances in which a normally categorically excluded action may have a significant environmental impact requiring further analysis. Accordingly, the FAA has determined that no extraordinary circumstances exist that warrant preparation of an environmental assessment or environmental impact study.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11F, Airspace Designations and Reporting Points, dated August 10, 2021, and effective September 15, 2021, is amended as follows:

Paragraph 6011 United States Area Navigation Routes.

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T-348 LESNR, SD to LUNGS, WI [Amended]

LESNR, SD	WP	(Lat. 43°29'16.49" N, long. 099°45'41.00" W)
TECUD, SD	FIX	(Lat. 43°32'54.48" N, long. 097°51'42.23" W)
Sioux Falls, SD (FSD)	VORTAC	(Lat. 43°38'58.14" N, long. 096°46'52.02" W)
GRSIS, MN	WP	(Lat. 43°38'45.54" N, long. 094°25'21.17" W)
FOOLS, MN	WP	(Lat. 43°46'58.20" N, long. 092°35'44.93" W)
GABDE, MN	WP	(Lat. 43°38'50.04" N, long. 092°18'26.46" W)
KRRTR, IA	WP	(Lat. 43°16'18.12" N, long. 091°22'30.62" W)
Madison, WI (MSN)	VORTAC	(Lat. 43°08'41.41" N, long. 089°20'22.91" W)
LUNGS, WI	WP	(Lat. 43°02'43.66" N, long. 088°56'54.86" W)

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T-409 LLUKY, NE to Pierre, SD (PIR) [New]

LLUKY, NE	WP	(Lat. 42°29'20.26" N, long. 098°38'11.44" W)
ADEDY, SD	FIX	(Lat. 43°03'05.06" N, long. 099°17'41.35" W)
LESNR, SD	WP	(Lat. 43°29'16.49" N, long. 099°45'41.00" W)
Pierre, SD (PIR)	VORTAC	(Lat. 44°23'40.40" N, long. 100°09'46.11" W)

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Issued in Washington, DC, on November 17, 2021.

Michael R. Beckles,
Acting Manager, Rules and Regulations Group.

[FR Doc. 2021–25469 Filed 11–22–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. FDA–2018–N–1913]

Medical Devices; General and Plastic Surgery Devices; Classification of the General Laparoscopic Power Morcellation Containment System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final amendment; final order.

SUMMARY: The Food and Drug Administration (FDA or we) is classifying the general laparoscopic power morcellation containment system 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 general laparoscopic power morcellation containment system’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 November 23, 2021. The classification was applicable on December 19, 2017.

FOR FURTHER INFORMATION CONTACT: Cal Rabang, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4633, Silver Spring, MD, 20993–0002, 301–796–6412, *Cal.Rabang@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Upon request, FDA has classified the general laparoscopic power morcellation containment system 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, in part 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 established the first procedure for De Novo classification (Pub. L. 105–115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112–144). 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