

Range/Distance Measuring Equipment (VOR/DME); replacing the Ambler, AK (AMF), NDB with the new TOMPY, AK, waypoint (WP); removing the KORKY, AK, WP as it is no longer a turn point; extending the route westward from the TOMPY WP to the Kotzebue, AK (OTZ), VOR/DME; and adding the new CIBDU, AK, WP between the TOMPY WP and the Kotzebue, AK, VOR/DME to enable a lower minimum enroute altitude between the two route points. Lastly, the route is described in a West to East orientation.

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 reguLat.on only involves an established body of technical reguLat.ons for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a “significant reguLat.ry action” under Executive Order 12866; (2) is not a “significant rule” under Department of Transportation (DOT) ReguLat.ry Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a reguLat.ry evaluation as the anticipated impact is so minimal. Since this is a routine matter that only affects air traffic procedures and air navigation, it is certified that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the ReguLat.ry Flexibility Act.

Environmental Review

The FAA has determined that this airspace action of amending RNAV route T–233 in the vicinity of Kotzebue, AK, qualifies for categorical exclusion under the National Environmental Policy Act (42 U.S.C. 4321 et seq.) and its implementing reguLat.ons 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), and paragraph 5–6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. 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.

* * * * *

T–233 Kotzebue, AK (OTZ) to Bettles, AK (BTT) [Amended]

| | | |
|--------------------|---------|--|
| Kotzebue, AK (OTZ) | VOR/DME | (Lat. 66°53'08.46" N, long. 162°32'23.77" W) |
| CIBDU, AK | WP | (Lat. 66°52'57.45" N, long. 161°03'44.52" W) |
| TOMPY, AK | WP | (Lat. 67°06'18.81" N, long. 157°51'52.03" W) |
| ENCOR, AK | WP | (Lat. 66°55'58.35" N, long. 152°19'54.35" W) |
| Bettles, AK (BTT) | VOR/DME | (Lat. 66°54'18.03" N, long. 151°32'09.18" W) |

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Issued in Washington, DC, on August 10, 2022.

Scott M. Rosenbloom,

Manager, Airspace Rules and ReguLat.ons.

[FR Doc. 2022–17512 Filed 8–16–22; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–1083; Airspace Docket No. 19–AAL–62]

RIN 2120–AA66

Amendment of United States Area Navigation (RNAV) Route T–229; Point Hope, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends United States Area Navigation (RNAV) route T–

229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska.

DATES: Effective date 0901 UTC, November 3, 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 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.

FOR FURTHER INFORMATION CONTACT:

Colby Abbott, 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 expands the availability of RNAV in Alaska and improves the efficient flow of air traffic within the National Airspace System by lessening the dependency on ground-based navigation.

History

The FAA published a notice of proposed rulemaking (NPRM) for Docket No. FAA-2021-1083 in the **Federal Register** (86 FR 70783; December 13, 2021), amending RNAV route T-229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. Interested parties were invited to participate in this rulemaking effort by submitting comments on the proposal. No comments were received.

United States Area Navigation 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 route listed in this document will be published subsequently in FAA Order JO 7400.11.

Differences From the NPRM

In "The Proposal" section of the NPRM, the SURGE waypoint (WP) name identified in the T-229 proposed action was incorrect. The correct WP name is SUGRE WP. This action corrects the WP name to the SUGRE, AK, WP in The Rule section of the preamble. The WP name correction is editorial only and the latitude/longitude coordinates remain the same so there is no change to the alignment of T-229.

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-229 in the vicinity of Point Hope, AK, in support of a large and comprehensive T-route modernization project for the state of Alaska. The route amendment is described below.

T-229: T-229 extends between the Fairbanks, AK, VOR/Tactical Air Navigation (VORTAC) and the Point Hope, AK, Non-Directional Beacon (NDB). The Point Hope NDB is replaced by the new VANTY, AK, waypoint (WP) to provide a lowered Global Navigation Satellite System (GNSS) Minimum Enroute Altitude (MEA), from 4,000 feet Mean Sea Level (MSL) to 3,000 feet MSL, between the SUGRE, AK, WP and the new VANTY WP. The unaffected segments of the route remain unchanged.

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 airspace action of amending RNAV route T-229 in the vicinity of Point

Hope, AK, 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), and paragraph 5-6.5i, which categorically excludes from further environmental review the establishment of new or revised air traffic control procedures conducted at 3,000 feet or more above ground level (AGL); procedures conducted below 3,000 feet AGL that do not cause traffic to be routinely routed over noise sensitive areas; modifications to currently approved procedures conducted below 3,000 feet AGL that do not significantly increase noise over noise sensitive areas; and increases in minimum altitudes and landing minima. 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

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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.
* * * * *

T-229 Fairbanks, AK (FAI) to VANTY, AK [Amended]

| | | |
|---------------------|---------|--|
| Fairbanks, AK (FAI) | VORTAC | (Lat. 64°48'00.25" N, long. 148°00'43.11" W) |
| Tanana, AK (TAL) | VOR/DME | (Lat. 65°10'37.65" N, long. 152°10'39.18" W) |
| Huslia, AK (HSL) | VOR/DME | (Lat. 65°42'28.35" N, long. 156°21'47.11" W) |
| Selawik, AK (WLK) | VOR/DME | (Lat. 66°35'58.11" N, long. 159°59'26.98" W) |
| Kotzebue, AK (OTZ) | VOR/DME | (Lat. 66°53'08.46" N, long. 162°32'23.77" W) |
| VANTY, AK | WP | (Lat. 68°20'40.68" N, long. 166°47'53.61" W) |

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Issued in Washington, DC, on August 10, 2022.

Scott M. Rosenbloom,
Manager, Airspace Rules and Regulations.
[FR Doc. 2022-17513 Filed 8-16-22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 800, 801, 808, and 874

[Docket No. FDA-2020-D-1380]

Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products; Guidance for Industry and Food and Drug Administration Staff; Availability

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

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products.” This guidance document is intended to describe hearing aids, personal sound amplification products (PSAPs), their respective intended uses, and the regulatory requirements that apply to these products. The FDA Reauthorization Act of 2017 (FDARA) directed FDA to update and finalize the draft guidance entitled “Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” issued on November 7, 2013. This final guidance fulfills this FDARA requirement and supersedes “Guidance for Industry and FDA Staff: Regulatory Requirements for Hearing Aid Devices and Personal Sound Amplification Products,” dated February 25, 2009.

DATES: The announcement of the guidance is published in the **Federal Register** on August 17, 2022.

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-2020-D-1380 for “Regulatory Requirements for Hearing Aid Devices

and Personal Sound Amplification Products.” 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 docket, 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.