

Subtitle VII, Part A, Subpart III, Section 44701: General requirements. Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

- (1) Is not a “significant regulatory action” under Executive Order 12866,
- (2) Would not affect intrastate aviation in Alaska, and
- (3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by adding the following new airworthiness directive:

Centerpointe Aerospace Inc.: Docket No. FAA–2023–1891; Project Identifier AD–2023–00612–R.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by November 17, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Centerpointe Aerospace Inc, Model S–58BT, S–58DT, S–58ET, S–58FT, S–58HT, and S–58JT helicopters, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC) Code 6300, Main Rotor Drive System.

(e) Unsafe Condition

This AD was prompted by the discovery of a fatigue crack on the angle gearbox mount (AGBM). The FAA is issuing this AD to detect fatigue cracking of the AGBM. The unsafe condition, if not addressed, could lead to loss of the angle gearbox, resulting in loss of main rotor drive and subsequent loss of control of the helicopter.

(f) Compliance

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

(g) Required Actions

(1) Within 250 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 250 hours TIS, perform a fluorescent penetrant inspection (FPI) to inspect for any crack on the AGBM in the eight areas depicted in the Accomplishment Instructions, Figures 1A and 1B, of Centerpointe Aerospace Service Bulletin No. 58B75, dated April 26, 2023. This FPI must be accomplished by a Level II or Level III inspector certified in the FAA-acceptable standards for nondestructive inspection personnel.

(2) If there is any crack, before further flight, remove the AGBM from service.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Central Certification 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 (i) of this AD.

(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.

(i) Additional Information

Jacob Fitch, Aviation Safety Engineer, FAA, 10101 Hillwood Pkwy., Fort Worth, TX 76177; phone: (817) 222–4130; email: jacob.fitch@faa.gov.

(j) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Centerpointe Aerospace Service Bulletin No. 58B75, dated April 26, 2023.

(ii) [Reserved]

(3) For Centerpointe service information identified in this NPRM, contact Centerpointe Aerospace Inc. at 279 Blackland Road, Fate, TX 75189; (972) 636–9601; email Operations@avnresources.com; <https://www.californiahelicopter.com>.

(4) You may view this service information at the FAA, Office of the Regional Counsel, Southwest Region, 10101 Hillwood Pkwy., Room 6N–321, Fort Worth, TX 76177. For information on the availability of this material at the FAA, call (817) 222–5110.

(5) You may view this service information that is incorporated by reference at 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: www.archives.gov/federal-register/cfr/ibr-locations.html.

Issued on September 22, 2023.

Victor Wicklund,

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

[FR Doc. 2023–21684 Filed 10–2–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–1957; Airspace Docket No. 23–AAL–28RIN 2120–AA66]

Amendment of Jet Route J–133 and Establishment of Area Navigation Route Q–801 in the Vicinity of Anchorage, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Jet Route J–133 by revoking a portion of the airway and establishing Canadian Area Navigation Route (RNAV) Q–801 in the vicinity of Anchorage, AK. The proposed amendment of J–133 is due to the pending decommissioning of several Navigational Aids (NAVAID) that provide course guidance along the airway. The proposed establishment of RNAV route Q–801 serves as a mitigation to J–133 and provides additional routing to the southeast for aircraft traveling to Canada or to the Pacific Northwest United States.

DATES: Comments must be received on or before November 17, 2023.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–1957 and Airspace Docket No. 23–AAL–28 using any of the following methods:

* *Federal eRulemaking Portal*: Go to www.regulations.gov and follow the online instructions for sending your comments electronically.

* *Mail*: Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier*: Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

* *Fax*: Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at www.regulations.gov at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FAA Order JO 7400.11H, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Steven Roff, 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 would modify the airway structure as necessary to preserve the safe and efficient flow of air traffic within the National Airspace System.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at www.regulations.gov. Recently published rulemaking documents can also be accessed through the FAA's web page at www.faa.gov/air_traffic/publications/airspace_amendments/.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during normal business hours at the office of the Western Service Center, Federal Aviation Administration, 2200 South 216th St., Des Moines, WA 98198.

Incorporation by Reference

Jet Routes are published in paragraph 2004 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. Canadian Area Navigation Routes are published in paragraph 2007 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

In 2003, Congress enacted the Vision 100-Century of Aviation Reauthorization Act (Pub. L. 108–176), which established a joint planning and development office in the FAA to manage the work related to the Next Generation Air Transportation System (NextGen). Today, NextGen is an ongoing FAA-led modernization of the nation's air transportation system to make flying safer, more efficient, and more predictable.

In support of NextGen, this proposal is part of an ongoing, large, and comprehensive airway modernization project in the state of Alaska. Part of this project is to transition the Alaskan en route navigation structure away from dependency on Nondirectional Radio Beacons (NDB) and move to develop and improve the RNAV route structure. The FAA is planning to decommission the Orca Bay, Yakataga, and Sitka NDBs in the state of Alaska. As a result, portions of Jet Route J–133 will become unusable.

The FAA proposes to amend Jet Route J–133 by revoking the portion between the Anchorage, AK, Very High Frequency Omnidirectional Range/Distance Measuring Equipment (VOR/DME) and the Sitka, AK, NDB. This portion of J–133 would be replaced by the proposed RNAV route Q–801. Q–801 would extend between Anchorage, AK, VOR/DME and HARPR, OR, waypoint (WP).

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend Jet Route J–133 and to establish Canadian RNAV route Q–801 in United States airspace.

NAV CANADA is amending RNAV route Q-801 in their airspace to ensure continuity and cross-border connectivity with the new RNAV route Q-801 proposed in this NPRM. The proposed Air Traffic Service (ATS) route actions are described below.

J-133: Jet route J-133 currently extends between Galena, AK, VOR/DME and Sitka, AK, NDB. The FAA proposes to revoke the portion between the Anchorage, AK, VOR/DME and the Sitka, AK, NDB. As amended, Jet route J-133 would extend between Galena, AK, VOR/DME and Anchorage, AK, VOR/DME.

Q-801: Q-801 would extend between the Anchorage, AK, VOR/DME and the HARPR, OR, WP. The new route would remain within United States airspace between the Anchorage VOR/DME and the EEVER, AK, Fix and between the CYVIC, WA, WP and the HARPR WP. The new EEVER route point is being established on the Alaska/Canada border north of the MOCHA, AK, Fix. The new CYVIC route point is being established on the United States/Canada border in Washington state replacing the CFPXC computer navigation fix (CNF) currently charted. This action is part of an ongoing FAA initiative to replace CNF and unpronounceable border fix/waypoint names with standard, pronounceable, five-letter names. This proposed action would establish RNAV route Q-801 within the

United States and exclude the airspace in Canada.

Regulatory Notices and Analyses

The FAA has determined that this proposed 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. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed 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

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 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 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 2004 Jet Routes

* * * * *

J-133 [Amended]

From Galena, AK to Anchorage, AK.

* * * * *

Paragraph 2007 Canadian Area Navigation Routes.

Q-801 HARPR, OR to Anchorage, AK (TED) [NEW]

Table with 3 columns: Name, Type, and Coordinates. Includes entries for HARPR, OR, FELIX, OR, ECTOF, OR, WAPTO, WA, TATOOSH, WA (TOU), CYVIC, WA, GOVAD, Canada, FINGS, Canada, SIMSU, Canada, CAFTA, Canada, EEVER, AK, MACIE, AK, LAIRE, AK, FROZN, AK, JOHNSTONE POINT, AK (JOH), and ANCHORAGE, AK (TED).

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Issued in Washington, DC, on September 28, 2023.

Karen L. Chiodini,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023-21811 Filed 10-2-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA-2023-N-2177]

RIN 0910-AI85

Medical Devices; Laboratory Developed Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, FDA is proposing a policy under which FDA intends to phase out its general enforcement discretion approach for laboratory developed tests