

replacement, replace the fuel injector manifolds and the privilege injector with parts eligible for installation.

(g) Arrius 2F Turboshaft Engines

(1) Replace the privilege injector with a privilege injector eligible for installation before exceeding 400 operating hours TSN or since last inspection on the privilege injector, whichever occurs first.

(2) Borescope-inspect the flame tube and the high-pressure turbine area for turbine distress.

(3) Thereafter, within every 400 operating hours TIS since last privilege injector replacement, replace the privilege injector with parts eligible for installation.

(h) Definition

For the purposes of this AD, time-in-service (TIS) is defined as the number of engine operating hours on the manifolds since the manifolds were new or since the manifolds were last cleaned, whichever is more.

(i) Installation Prohibitions

(1) For Arrius 2B1 turboshaft engines, after the effective date of this AD, do not install fuel injector manifolds or a privilege injector on an engine, or an engine on a helicopter, unless the fuel injection manifold and privilege injector have accumulated fewer than 200 operating hours since new, or since last inspection.

(2) For Arrius 2F turboshaft engines, after the effective date of this AD, do not install a privilege injector on an engine, or an engine on a helicopter, unless the privilege injector has accumulated fewer than 400 operating hours since new, or since last inspection.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

(1) For more information about this AD, contact James Lawrence, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7176; fax: 781-238-7199; email: james.lawrence@faa.gov.

(2) See European Aviation Safety Agency AD 2012-0150, dated August 8, 2012, and AD 2012-0249, dated November 21, 2012, Turbomeca S.A. Alert Mandatory Service Bulletin (MSB) No. A319 73 2012, Version I, dated November 12, 2012, and Turbomeca S.A. Alert MSB No. A319 73 4001, Version K, dated February 10, 2012, for related information.

(3) For service information identified in this AD, contact Turbomeca, 40220 Tarnos, France; phone: 33 (0)5 59 74 40 00; telex: 570 042; fax: 33 (0)5 59 74 45 15. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

Issued in Burlington, Massachusetts, on January 30, 2013.

Colleen M. D'Alessandro,

Assistant Manager, Engine & Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA-2012-1004; Airspace Docket No. 12-ANM-21]

RIN 2120-AA66

Proposed Amendment of VOR Federal Airway V-595; OR

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Supplemental notice of proposed rulemaking (SNPRM); reopening of comment period.

SUMMARY: This SNPRM amends the notice of proposed rulemaking (NPRM) published on October 22, 2012 which proposed to amend VHF omnidirectional range (VOR) Federal airway V-595 in Oregon. This SNPRM proposes to remove an additional segment of the airway due to high terrain and navigation aid coverage issues.

DATES: Comments must be received on or before March 25, 2013.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001; telephone: (202) 366-9826. You must identify FAA Docket No. FAA-2012-1004 and Airspace Docket No. 12-ANM-21 at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy and ATC Procedures Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis

supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA-2012-1004 and Airspace Docket No. 12-ANM-21) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at <http://www.regulations.gov>.

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA-2012-1004 and Airspace Docket No. 12-ANM-21." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

An electronic copy of this document may be downloaded through the Internet at <http://www.regulations.gov>.

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 1601 Lind Ave. SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267-9677, for a copy of Advisory Circular No. 11-2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

Background

On October 22, 2012, the FAA published in the **Federal Register** a NPRM to remove a segment of VOR Federal airway V-595 due to the planned decommissioning of the Portland, OR, VOR/DME (77 FR 64444). No comments were received.

The NPRM would have terminated V-595 at the HARZL navigation fix, which is approximately 29 NM southeast of the Portland VOR/DME. Subsequent to the publication, further study showed that mountainous terrain in the area would limit the service volume of the Deschutes, OR, VORTAC to a degree that the Deschutes VORTAC could not be used to identify the entire length of the proposed segment between Deschutes and the HARZL fix. In addition, the decommissioning of the Portland VOR/DME would require raising the IFR minimum enroute altitude (MEA) along that segment to an unusable height.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to further modify the description of VOR Federal airway V-595. Instead of removing that segment of V-595 between the Portland, OR, VOR/DME and the HARZL fix, as originally proposed, the FAA is now proposing to remove the entire V-595 segment between the Deschutes VORTAC and the Portland VOR/DME. Consequently, the amended V-595 would extend only between the Rogue Valley, OR, VORTAC and the Deschutes VORTAC. This action is necessary because the Portland, OR, VOR/DME, which currently serves as the northern end point of the route, is scheduled to be decommissioned. Further, due to high terrain issues, the Deschutes VORTAC service volume is not adequate to support the originally proposed segment between Deschutes and the HARZL fix. By separate rulemaking action, the FAA is proposing to establish new area navigation routes (T-routes) in the area.

Since this change expands the scope of the originally proposed rule, the FAA has determined that it is necessary to reopen the comment period to provide additional opportunity for public comment.

VOR Federal airways are published in paragraph 6010, of FAA Order 7400.9W dated August 8, 2012, and effective September 15, 2012, which is incorporated by reference in 14 CFR 71.1. The VOR Federal airway listed in this document would be subsequently published in the Order.

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. Therefore, this proposed regulation: (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 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.

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 an Oregon route structure as required to preserve the safe and efficient flow of air traffic.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1E, “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 part 71 continues to read as follows:

Authority: 49 U.S.C. 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 7400.9W, Airspace Designations and Reporting Points, Dated August 8, 2012 and effective September 15, 2012, is amended as follows:

* * * * *

Paragraph 6010 Domestic VOR Federal airways.

V-595 [Amended]

From Rogue Valley, OR, to Deschutes, OR.

Issued in Washington, DC, on January 31, 2013.

Alan Wilkes,

Acting Manager, Airspace Policy and ATC Procedures Group.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2012-N-1239]

Dental Devices; Reclassification of Temporary Mandibular Condyle Prosthesis

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed order to reclassify temporary mandibular condyle prosthesis, a preamendments class III device, into class II (special controls), and rename the device “temporary mandibular condyle reconstruction plate.” FDA is also issuing the draft special controls guideline, “Class II Special Controls Guideline: Temporary Mandibular Condyle Reconstruction Plate,” which sets forth the special controls that the Agency believes are necessary to provide a reasonable assurance of the safety and effectiveness of the device.

DATES: Submit either electronic or written comments on this proposed order or on the draft guideline by May 8, 2013. See section XIII of this document for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-1239, by any of the following methods: