

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2011-0016; Airspace
Docket No. 11-ANM-1]

**Modification of Class E Airspace;
Poplar, MT**

AGENCY: Federal Aviation
Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class E airspace at Poplar Municipal Airport, Poplar, MT. The airport was moved 1.5 Nautical Miles (NM) to the northeast. Controlled airspace is necessary to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) standard instrument approach procedures at Poplar Municipal Airport, Poplar, MT. This improves the safety and management of Instrument Flight Rules (IFR) operations at the airport. This also corrects the airport name from Poplar Airport.

DATES: Effective date, 0901 UTC, August 25, 2011. 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 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Eldon Taylor, Federal Aviation Administration, Operations Support Group, Western Service Center, 1601 Lind Avenue SW., Renton, WA 98057; telephone (425) 203-4537.

SUPPLEMENTARY INFORMATION:**History**

On February 16, 2011, the FAA published in the **Federal Register** a notice of proposed rulemaking to establish additional controlled airspace at Poplar, MT (76 FR 8921). Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. The FAA received one comment suggesting omitting language in the legal description relating to Federal airways and the Wolf Point, MT, Class E airspace area. The FAA found merit in this comment, and will make the change to the legal description. With the exception of editorial changes and the changes described above, this rule is the same as that proposed in the NPRM.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9U dated August 18, 2010, and effective September 15, 2010, which is incorporated by reference in 14 CFR

Part 71.1. The Class E airspace designations listed in this document will be published subsequently in that Order.

The Rule

This action amends Title 14 Code of Federal Regulations (14 CFR) Part 71 by amending Class E airspace at Poplar Municipal Airport, Poplar, MT. The airport was moved 1.5 nautical miles to the northeast, and controlled airspace extending upward from 700 feet above the surface is necessary to accommodate IFR aircraft executing new RNAV (GPS) standard instrument approach procedures at Poplar Municipal Airport. This enhances the safety and management of IFR operations at the airport. This action also notes the change in the airport name from Poplar Airport to Poplar Municipal Airport.

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. Therefore, this regulation: (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 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 U.S. Code. Subtitle 1, Section 106 discusses 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 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 establishes additional controlled airspace at Poplar Municipal Airport, Poplar, MT.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of 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(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 the Federal Aviation Administration Order 7400.9U, Airspace Designations and Reporting Points, dated August 18, 2010, and effective September 15, 2010 is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM MT E5 Poplar, MT [Modified]

Poplar Municipal Airport, MT
(Lat. 48°08'04" N., long. 105°09'44" W.)

That airspace extending upward from 700 feet above the surface within a 7.7-mile radius of the Poplar Municipal Airport, and within 4 miles each side of the 105° bearing extending from the airport to 10.3 miles southeast of the airport; and that airspace extending upward from 1,200 feet above the surface bounded by a line from lat. 47°53'25" N., long. 105°52'50" W.; to lat. 48°18'00" N., long. 105°52'50" W.; to lat. 48°18'00" N., long. 104°30'00" W.; to lat. 47°53'25" N., long. 104°30'00" W.; thence to point of beginning.

Issued in Seattle, Washington, on May 10, 2011.

John Warner,

Manager, Operations Support Group, Western Service Center.

[FR Doc. 2011-12001 Filed 5-16-11; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 800**

[Docket No. FDA-2011-D-0258]

Compliance Policy Guide: Surgeons' Gloves and Patient Examination Gloves; Defects—Criteria for Direct Reference Seizure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of Compliance Policy Guide Sec. 335.700, Surgeons' Gloves and Patient Examination Gloves; Defects—Criteria for Direct Reference Seizure (the CPG). The CPG, which was originally issued in 1991, provides guidance to FDA staff on the submission of seizure recommendations for medical gloves that exceed the defect levels in FDA regulations. The CPG has been revised to remove an appendix that became obsolete when the regulations were amended, and to make other minor changes for clarity and consistency with the amended regulation.

DATES: Submit either electronic or written comments on the CPG at any time.

ADDRESSES: Submit written requests for single copies of the CPG to the Division of Compliance Policy (HFC-230), Office of Enforcement, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the CPG.

Submit electronic comments on the CPG to <http://www.regulations.gov>. Submit written comments on the CPG to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David R. Kalins, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6612.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled "Compliance Policy Guide Sec. 335.700, Surgeons' Gloves and Patient Examination Gloves; Defects—Criteria for Direct Reference Seizure." The CPG provides guidance to FDA staff on the submission of seizure recommendations for medical gloves that exceed the defect levels in 21 CFR 800.20. The CPG was originally issued on May 31, 1991, and was previously revised in July 2005. It is currently being revised to remove an appendix that became obsolete when an amendment to 21 CFR 800.20 became effective December 19, 2008. The amended rule includes changes intended to improve the barrier quality of medical gloves marketed in the United States by reducing the

acceptable quality levels (AQLs) for leaks and visual defects observed during FDA testing of medical gloves. The CPG was revised for consistency with the AQLs in the amended regulation. The text of the CPG also includes a number of minor edits made for clarity. This document supersedes Compliance Policy Guide Sec. 335.700, Surgeons' Gloves and Patient Examination Gloves; Defects—Criteria for Direct Reference Seizure dated July 2005.

FDA is issuing the CPG as Level 2 guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The CPG represents FDA's current thinking on the criteria for direct reference seizure of defective medical gloves. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding the CPG. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the CPG at either http://www.fda.gov/ora/compliance_ref/cpg/default.htm or at <http://www.regulations.gov>.

Dated: May 5, 2011.

Dara A. Corrigan,
Associate Commissioner for Regulatory Affairs.

[FR Doc. 2011-12037 Filed 5-16-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2011-0316]

Drawbridge Operation Regulation; Sturgeon Bay Ship Canal, Sturgeon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: Commander, Ninth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Michigan Street and Maple-Oregon Street Bridges across the Sturgeon Bay Ship Canal, at miles 4.3 and 4.17, respectively, both in Sturgeon Bay, Wisconsin. This deviation will test a change to the drawbridge operation schedules during the peak tourist and navigation seasons to provide for the efficient movement of vehicular traffic and the safety of navigation on the waterway. This deviation will allow scheduled openings for recreational vessels and openings on signal for commercial vessels.

DATES: This deviation is effective from noon on May 27, 2011 through noon on September 16, 2011. Comments and related material must be received by the Coast Guard by September 16, 2011.

ADDRESSES: You may submit comments identified by docket number USCG-2011-0316 using any one of the following methods:

(1) *Federal eRulemaking Portal:*
<http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(4) *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail Mr. Lee D. Soule, Bridge Management Specialist; telephone 216-902-6085, facsimile 216-902-6088, or e-mail lee.d.soule@uscg.mil. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related materials. All