

**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](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.*

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**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](mailto: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



comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

### Submitting Comments

If you submit a comment, please include the docket number for this rulemaking (USCG–2011–0316), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online (<http://www.regulations.gov>), or by fax, mail or hand delivery, but please use only one of these means. If you submit a comment online via <http://www.regulations.gov>, it will be considered received by the Coast Guard when you successfully transmit the comment. If you fax, hand deliver, or mail your comment, it will be considered as having been received by the Coast Guard when it is received at the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the “submit a comment” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2011–0316,” click “Search,” and then click on the balloon shape in the “Actions” column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

### Viewing Comments and Documents

To view comments, as well as documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, click on the “read comments” box, which will then become highlighted in blue. In the “Keyword” box insert “USCG–2011–0316” and click “Search.” Click the “Open Docket Folder” in the “Actions” column. You may also visit the Docket Management Facility in Room W12–140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington,

DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

### Privacy Act

Anyone can search the electronic form of comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

### Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for one on or before September 1, 2011 by using one of the four methods specified under **ADDRESSES**. Please explain why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

### Basis and Purpose

The Sturgeon Bay Ship Canal is approximately 8.6 miles long and provides a navigable connection between Lake Michigan and Green Bay. The area experiences a significant increase in vehicular and vessel traffic during the peak tourist and navigation season, between approximately Memorial Day and Labor Day each year.

There are a total of three highway drawbridges across the waterway. The Michigan Street Bridge provides unlimited vertical clearance in the open position and 14 feet in the closed position. Maple-Oregon Bridge provides unlimited vertical clearance in the open position and 25 feet in the closed position. Bay View Bridge also provides unlimited vertical clearance in the open position and 42 feet in the closed position. Both Michigan Street and Maple-Oregon Bridges serve the downtown Sturgeon Bay area and are located approximately 750-feet apart on the canal.

A final rule, CGD9–05–080, was published in the October 24, 2005 edition of the **Federal Register** (70 FR 61380) to allow:

(1) The draw of the Michigan Street Bridge to open for recreational vessels on the hour 24 hours a day from March 15 through December 31 and on signal if at least 12 hours notice is given from January 1 through March 14. The final rule also included a requirement to open at any time if 20 or more vessels

gathered or vessels are seeking shelter from severe weather; and

(2) The draw of the Bayview (SR42/57) Bridge, mile 3.3 Sturgeon Bay to open on signal from March 15 through November 30; and on signal if at least 12 hours notice is given from December 31 through March 14.

A temporary final rule, USCG–2009–0385, was published in the June 5, 2009 edition of the **Federal Register** (74 FR 26954), effective from June 5, 2009 to November 15, 2010 that essentially shifted the March 15 through December 31 one bridge opening per hour at Michigan Street Bridge to the Maple-Oregon Bridge while the rehabilitation of Michigan Street was completed and the bridge was kept in the open-to-navigation position.

Both drawbridges are now operational for vehicular and vessel traffic and the one opening per hour schedule for Michigan Street Bridge is reinstated while Maple-Oregon Bridge opens at any time for vessels. With both Michigan Street and Maple-Oregon Bridges operational the one opening per hour schedule for Michigan Street is considered restrictive for vessels, and could potentially create an unsafe condition for vessel traffic that may be between the two closely located drawbridges while waiting for bridge openings. The Wisconsin Department of Transportation (WDOT) requested scheduled drawbridge openings for both Michigan Street and Maple-Oregon Bridges so vehicular traffic congestion would not develop on downtown Sturgeon Bay streets due to unscheduled bridge openings. Commander, Ninth Coast Guard District, evaluated that request, as well as the need to provide efficient and safe bridge openings for vessels, and along with WDOT and local stakeholders developed this temporary test drawbridge schedule for the 2011 peak tourist and navigation season. Throughout the temporary drawbridge schedule WDOT will post signs at both drawbridges and collect vehicular traffic and bridge opening data. Public comments will also be accepted throughout the test period.

### Temporary Drawbridge Schedule

From noon on May 27, 2011 through noon on September 16, 2011, 24-hours per day and 7-days per week, the Michigan Street Bridge at mile 4.3 over the Sturgeon Bay Ship Canal will open on the hour and half-hour for recreational vessels, if needed. The Maple-Oregon Bridge at mile 4.17 will open fifteen-minutes before the hour and fifteen minutes after the hour for recreational vessels, if needed. Both



bridges will open on signal for all commercial vessels, federal, state, and local government vessels used for public safety, vessels in distress, or seeking shelter from severe weather. If at any time more than 10 vessels accumulate at either bridge the bridge will open and allow all vessel traffic to clear the bridge. Vessels that may pass under the bridges without an opening may do so at anytime. In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedule immediately at the end of the designated time period. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: April 22, 2011.

**Scot M. Striffler,**

*Bridge Program Manager, Ninth Coast Guard District.*

[FR Doc. 2011-12011 Filed 5-16-11; 8:45 am]

BILLING CODE 9110-04-P

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2010-0972]

#### **Drawbridge Operation Regulations; Bayou Liberty, Mile 2.0, St. Tammany Parish, Slidell, LA**

**AGENCY:** Coast Guard, DHS.

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

**SUMMARY:** The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the S433 Bridge over Bayou Liberty, mile 2.0, St. Tammany Parish, Slidell, LA. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. It will allow the bridge to remain unmanned during most of the day by requiring a one-hour notice for an opening of the draw from 7 a.m. to 7 p.m., and a two-hour notice from 7 p.m. to 7 a.m. seven days a week. The Coast Guard may publish a Supplemental Notice of Proposed Rulemaking to make this deviation permanent.

**DATES:** This deviation is effective from June 1, 2011 through September 9, 2011.

Comments and related material must be received by the Coast Guard on or before July 15, 2011.

**ADDRESSES:** You may submit comments identified by docket number USCG-

2010-0972 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.

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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 Jim Wetherington; Bridge Administration Branch, Eighth Coast Guard District, telephone 504-671-2128, e-mail [james.r.wetherington@uscg.mil](mailto:james.r.wetherington@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 comments received will be posted, without change, to <http://www.regulations.gov> and will include any personal information you have provided.

##### *Submitting Comments*

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the Docket Management Facility. We recommend that you include your name and a mailing address, an e-mail address, or a phone number in the body of your document so that we can contact you if we have questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov>, click on the "submit a comment" box, which will then become highlighted in blue. In the "Keyword" box insert "USCG-2010-0972," click "Search," and then click on the balloon shape in the "Actions" column. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit them by mail and would like to know that they reached the Facility, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period and may change the rule based on your comments.

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