

direct final rule would be on March 30, 2011, 60 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA did not receive any significant adverse comments.

**Authority:** 21 U.S.C. 360ccc-1, 360ccc-2, 371. Accordingly, the amendments issued thereby are effective.

Dated: February 24, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011-4593 Filed 3-1-11; 8:45 am]

**BILLING CODE 4160-01-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**33 CFR Part 117**

[Docket No. USCG-2010-1030]

RIN 1625-AA09

**Drawbridge Operation Regulation; Duluth Ship Canal, Duluth-Superior Harbor, MN**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a drawbridge opening schedule for the Duluth Aerial Lift Bridge for vessels under 300 gross tons. Scheduled drawbridge openings will improve traffic congestion in the area and enhance safety for all modes of transportation.

**DATES:** This rule is effective April 1, 2011.

**ADDRESSES:** Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2010-1030 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-1030 in the "Keyword" box, and then clicking "Search." This material is also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail Mr. Lee Soule, Bridge Management Specialist, Ninth Coast Guard District; telephone (216) 902-6085, e-mail [lee.d.soule@uscg.mil](mailto:lee.d.soule@uscg.mil). If you have questions on viewing material in the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:**

**Regulatory Information**

Commander, Ninth Coast Guard District, published a temporary deviation from these regulations, with request for comments, on April 22, 2010, in the **Federal Register** (75 FR 20918). The temporary deviation was used to test a new bridge schedule during the 2010 navigation and tourist season. On December 8, 2010, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulation; Duluth Ship Canal, Duluth-Superior Harbor, MN, in the **Federal Register** (75 FR 76324). We received two comments in response to the proposed rule. No public meeting was requested, and none was held.

**Basis and Purpose**

The Duluth Aerial Bridge is located 0.25 miles from Duluth Harbor North Pier Light at the lakeward end of the Duluth Ship Canal. It is a vertical lift type bridge that provides 15 feet of vertical clearance in the down position and up to 141 feet in the open position. The bridge currently opens on signal for all vessel traffic that requires a bridge opening. Marine traffic on the waterway consists of both large and smaller commercial vessels, as well as both power and sail recreational vessels. Pursuant to 33 CFR 117.8 various entities in Duluth requested scheduled openings instead of opening on signal. The requesting entities included the City of Duluth, the Duluth Fire

Department-Emergency Management, the Duluth Police Department, the Park Point Community Association, and the Canal Park Business Association. The scheduled drawbridge openings were requested during the peak navigation and tourist season to improve the flow of vehicular traffic over the bridge, relieve vehicular traffic congestion near the bridge and on city streets on both sides of the bridge (Park Point and Canal Park), improve access and response times for emergency response entities, and enhance pedestrian safety in the vicinity of the bridge. The test schedule allowed for scheduled bridge openings on the hour and half-hour for all vessels under 300 gross tons between the hours of 6 a.m. and 9 p.m., seven days per week, and on signal between 9 p.m. and 6 a.m., from May 3 to October 29, 2010. The bridge continued to open on signal at all times for all vessels over 300 gross tons and Federal, state, and local government vessels, vessels in distress, commercial vessels engaged in rescue or emergency salvage operations, vessels engaged in pilot duties, and vessels seeking shelter from severe weather. The City of Duluth collected data throughout the test period related to vehicular and vessel traffic counts, and the number of bridge openings. In addition to the data collected, each stakeholder had the opportunity to amplify their written comments and provide additional direct input to the Coast Guard during the October 20, 2010 meeting. During the stakeholder meeting it was generally agreed by all parties that the scheduled bridge openings appeared to improve the general flow of vehicular traffic on both sides of the bridge and reduced vehicular traffic congestion. Regarding the time of year and hours each day that the scheduled openings would apply, it was generally agreed during the stakeholders meeting that the scheduled openings would be beneficial and effective between Memorial Day and Labor Day each year between the hours of 7 a.m. and 9 p.m. The data below collected by the City of Duluth illustrates support for the times and dates:

	May	June	July	Aug	Sep	Oct
<b>TOTAL VESSELS UNDER 300 GROSS TONS</b>						
2009	383	1287	2015	1974	1331	212
2010	528	1066	2088	1430	1016	380
<b>TOTAL BRIDGE OPENINGS</b>						
2009	320	841	1097	1184	800	350
2010	300	576	860	630	752	429

	May	June	July	Aug	Sep	Oct
<b>TOTAL VEHICLES (BOTH DIRECTIONS)</b> (Vehicular counts were not collected in 2009)						
2010	102,564	210,539	266,000	230,668	160,591	163,110
				6 a.m.–7 a.m.		7 a.m.–8 a.m.
<b>TOTAL AVERAGE VEHICLES FOR EACH HOUR</b>						
June .....				68.20		97.53
July .....				58.77		87.80
August .....				50.04		84.09

In addition to the two scheduled openings per hour, vessels will continue to have access to the harbor through the alternate Superior, Wisconsin, Entry Channel, as well as passage thru the Aerial Bridge during unscheduled openings for commercial vessels. This rule will provide for the reasonable balance of all modes of transportation and effectively accomplish the requested goal of improving traffic congestion and safety in the area of the Duluth Aerial Bridge. This final rule also adjusts the current required advance notice requirement for vessels from 24-hours to 12-hours vessels between January 1 and March 15.

#### Discussion of Comments and Changes

The Coast Guard received two comments regarding the NPRM, one that was successfully received by the Docket Management Facility, and the second by direct email. Both comments were from private citizens. The first comment cited that members of the Park Point Community Association were invited to the stakeholder meeting on October 20, 2010 described in the NPRM, however no representative from Park Point Community Association attended, that there was no provision in the proposed rule providing priority for emergency vehicles to cross the bridge, and that the proposed schedule should be extended to twelve months instead of providing only for the peak tourist season.

The October 20, 2010 stakeholders meeting was attended by a Duluth City Councilwoman, who stated at the meeting she was representing Park Point residents. Additionally, all Park Point residents had the opportunity to provide comments during the test deviation as well as during the comment period for the NPRM. Regarding priority for emergency vehicles, 33 CFR 117.31(a) states that upon receiving notification that an emergency vehicle is responding to an emergency situation, a drawtender must make all reasonable efforts to have the drawspan closed at the time the emergency vehicle arrives.

As described in the Basis and Purpose section above, all data, and all other comments, indicate that the dates and times in this final rule are the appropriate dates and times for scheduled drawbridge openings, and not throughout the whole year.

The second comment, received by direct email, was from a local recreational vessel operator. The comment stated no general objection to the schedule, but he also stated the schedule did not appear to improve general vehicular and pedestrian traffic congestion. All other accounts of the scheduled openings indicate that the schedule has helped reduce traffic congestion and improved safety for all modes of transportation.

The Coast Guard decided not to make any changes to the proposed rule.

#### Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

#### Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. The rule will establish permanent scheduled openings and revise the advance notice time during winter seasons from twenty-four hours to twelve hours. The scheduled bridge openings are expected to improve vehicular traffic congestion and safety near the bridge while still providing for reasonable openings for vessel traffic.

#### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a

substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities. This rule continues to provide at least two drawbridge openings per hour between 7:00 a.m. and 9 p.m. each day, and openings at any time during all other hours, as well as during unscheduled transits of commercial vessels. The test schedule implemented this year resulted in only minor adjustments in schedules or operations for all entities. Additionally, all vessels that do not require bridge openings may transit the drawbridge at any time, and the alternate Superior, Wisconsin, Entry Channel may be used by all vessels at any time.

#### Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

#### Collection of Information

This rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

#### Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed

this rule under that Order and have determined that it does not have implications for federalism.

#### Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

#### Taking of Private Property

This rule would not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

#### Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

#### Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

#### Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

#### Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a “significant energy action” under that order because it is not a “significant regulatory action” under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of

energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

#### Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

#### Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, and Commandant Instruction M16475.ID, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded under figure 2–1, paragraph (32)(e), of the Instruction.

Under figure 2–1, paragraph (32)(e), of the instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

#### List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

#### PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for part 117 continues to read as follows:

**Authority:** 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.661 to read as follow:

#### § 117.661 Duluth Ship Canal (Duluth-Superior Harbor).

The draw of the Duluth Ship Canal Aerial bridge, mile 0.25 at Duluth, shall open on signal; except that, from the Friday before Memorial Day through the Tuesday after Labor Day each year, between the hours of 7 a.m. and 9 p.m., seven days a week, the drawbridge shall open on the hour and half-hour for vessels under 300 gross tons, if needed; and the bridge will open on signal for all vessels from 9 p.m. to 7 a.m., seven days a week, and at all times for Federal, state, and local government vessels, vessels in distress, commercial vessels engaged in rescue or emergency salvage operations, commercial-assist towing vessels engaged in towing or port operations, vessels engaged in pilot duties, vessels seeking shelter from severe weather, and all commercial vessels 300 gross tons or greater. From January 1 through March 15, the draw shall open on signal if at least 12 hours notice is given. The opening signal is one prolonged blast, one short blast, one prolonged blast, one short blast. If the drawbridge is disabled, the bridge authorities shall give incoming and outgoing vessels timely and dependable notice, by tug service if necessary, so that the vessels do not attempt to enter the canal.

Dated: February 7, 2011.

#### M.N. Parks,

*Rear Admiral, U. S. Coast Guard,  
Commander, Ninth Coast Guard District.*

[FR Doc. 2011–4591 Filed 3–1–11; 8:45 am]

BILLING CODE 9110–04–P

#### DEPARTMENT OF HOMELAND SECURITY

#### Coast Guard

#### 33 CFR part 165

[Docket No. USCG–2011–0086]

RIN 1625–AA00

#### Safety Zone; Soil Sampling; Chicago River, Chicago, IL

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the North Branch of the Chicago River near Chicago, Illinois. This zone is intended to restrict vessels from a portion of the North Branch of the Chicago River due to soil sampling in this area. This temporary safety zone is necessary to protect the surrounding public and vessels from the hazards