

(ix) Risk analysis and management strategies, such as Failure Modes Effects Analysis and/or Hazard Analysis and Critical Control Points summaries and their impact on test performance.

(x) Final release criteria to be used for manufactured device lots with an appropriate justification that lots released at the extremes of the specifications will meet the claimed analytical and clinical performance characteristics as well as the stability claims.

(xi) All stability protocols, including acceptance criteria.

(xii) Appropriate and acceptable procedure(s) for addressing complaints and other device information that determines when to submit a medical device report.

(xiii) Premarket notification submissions must include the information contained in paragraphs (b)(2)(i) through (xii) of this section.

Dated: November 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25372 Filed 11–23–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2021–0778]

RIN 1625–AA09

Drawbridge Operation Regulation; Willamette River, Portland, OR

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to modify the operating schedule that governs the Morrison Bridge across the Willamette River, mile 12.8, at Portland, OR. Multnomah County, Oregon, the bridge owner, is requesting to change the current regulation to allow painting and preservation of the Morrison Bridge including the double bascule span. The modified rule would change from a full span opening to a single leaf, half opening, and operation. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must reach the Coast Guard on or before December 27, 2021. The Coast Guard anticipates that this proposed rule will be effective from 7 p.m. on April 1, 2022, through 7 p.m. on May 31, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–

2021–0778 using Federal Decision Making Portal at <https://www.regulations.gov>. 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 email Steven Fischer, Thirteenth District Bridge Administrator, U.S. Coast Guard; telephone 206–220–7282, email d13-smb-d13-bridges@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
 DHS Department of Homeland Security
 FR Federal Register
 OMB Office of Management and Budget
 NPRM Notice of proposed rulemaking (Advance, Supplemental)
 § Section
 U.S.C. United States Code
 County Multnomah County

II. Background, Purpose and Legal Basis

Multnomah County, Oregon, owns and operates the Morrison Bridge across the Willamette River at mile 12.8. The County is requesting a temporary change to the existing operating regulation. The County is proposing to open the Morrison Bridge’s span in single leaf mode, half of the double bascule span, to marine vessels with a minimum of two-hour notice, or four-hour notice if a tug assist is needed. The County needs to maintain half of the draw closed to allow for preservation and paint efforts. The proposed regulation change would allow the Morrison Bridge to alternate operation of the east or west leaf span from April 1, 2022, through May 31, 2023. The west span will be operational at the beginning of construction and the east span will be closed to navigation. The dates to switch operational spans will be determined later and published in the Local and Broadcast Notice to Mariners. This proposal also allows a containment system under the bridge that reduces the non-opening half of the bridge’s vertical clearance by 5 feet from 69 feet center to 64 feet, and from 48 feet on the sides to 43 feet above the Columbia River Datum 0.0. Marine traffic on this section of the Willamette River consists of vessels ranging from small pleasure craft up to large commercial vessels and barges. The subject bridge currently operates in accordance with 33 CFR 117.897(c)(3)(iv).

III. Discussion of Proposed Rule

The Coast Guard proposes a temporary change to 33 CFR 117.897(c)(3)(iv) to be in effect from 7 p.m. on 1 April, 2022, through 7 p.m. on 31 May, 2023. This temporary rule will suspend the current regulatory cite regarding the Morrison Bridge, and add a temporary 33 CFR 117.897(c)(3)(vi) which will amend the operating schedule of the Morrison Bridge by requiring a two-hour notice, or four-hour notice with tug assist, for all draw openings, and alternate the operation of the double bascule spans to single span which will reduce the horizontal clearances of the bridge. The temporary rule is necessary to accommodate preservation and painting of the Morrison Bridge. This bridge provides a vertical clearance approximately 69 feet, at the center, above Columbia River Datum 0.0 when in the closed-to-navigation position. One half of the bascule bridge will have a containment system installed on the non-opening half of the span, which will reduce the vertical clearance by 5 feet to 64 feet center and 43 feet on the sides. A tug will be available for assists to mariners as needed when a request is given with a notice of four hours for an opening. The horizontal clearance with a full opening is 185 feet, therefore, in single leaf operations, a temporary rule change will reduce the horizontal clearance to approximately 90 feet. Vessels able to transit under the Morrison Bridge without an opening may do so at any time. Marine vessels are advised to be aware of fall hazards. This section of the Willamette River has no alternate routes. During the Portland Rose Festival, both leaves of the double bascule span will be fully operational. If any mariner submits a full opening request to the County prior to construction beginning, a full opening can be scheduled. All marine emergency vessels can navigate under the Morrison Bridge without an opening, and therefore do not need to contact the Hawthorne Bridge for an emergency opening.

This regulatory action determination is based on the ability of the Morrison Bridge to open on signal after the Hawthorne Bridge, at Willamette River mile 13.1, has received at least a two-hour notice, or four-hour notice for tug assist, by telephone at 503–988–3452 or VHF radio request. The Coast Guard has made this finding based on the fact that the proposed change allows any vessel needing a drawbridge opening to transit through the Morrison Bridge after providing adequate notice and being provided with tug assistance if required.

IV. Regulatory Analyses

We developed this proposed rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on these statutes and Executive orders and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This NPRM has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the ability that vessels can still transit the bridge given advance notice.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. 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 proposed rule would not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the bridge may be small entities, for the reasons stated in section IV.A above this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for

compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132 (Federalism), if it has 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. We have analyzed this proposed rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

E. 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 proposed rule will not result in such an expenditure, we do discuss the effects of this proposed rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning Policy

COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This proposed rule promulgates the operating regulations or procedures for drawbridges. Normally such actions are categorically excluded from further review, under paragraph L49, of Chapter 3, Table3–1 of the U.S. Coast Guard Environmental Planning Implementation Procedures.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are required for this rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protestors. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG–2021–0778 in the search box and click “Search.” Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Viewing material in docket. To view documents mentioned in this proposed rule as being available in the docket, find the docket as described in the

previous paragraph, and then select "Supporting & Related Material" in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the <https://www.regulations.gov> Frequently Asked Questions web page. We review all comments received, but we will only post comments that address the topic of the proposed rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

Personal information. We accept anonymous comments. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

List of Subjects in 33 CFR Part 117

Bridges.

For the reasons discussed in the preamble, the Coast Guard proposes to amend 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; and Department of Homeland Security Delegation No. 0170.1.

■ 2. In § 117.897, stay paragraph (c)(3)(iv) and add paragraph (c)(3)(vi) to read as follows.

§ 117.897 Willamette River.

* * * * *

(c) * * *

(3) * * *

(vi) Morrison Bridge, Portland, mile 12.8, will operate a single leaf opening, on signal after the Hawthorne Bridge, at Willamette River mile 13.1, has received, at least a two-hour advance notice, or four-hour advance notice for tug assist, to open by telephone at 503–988–3452 or VHF radio.

Dated: November 18, 2021.

M.W. Bouboulis,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2021–25638 Filed 11–23–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–R06–OAR–2021–0661; FRL–9262–01–R6]

National Emission Standards for Hazardous Air Pollutants; Delegation of Authority to Arkansas

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Arkansas Department of Energy and Environment, Division of Environmental Quality (DEQ) has submitted a request to update the delegation and approval of its program for the implementation and enforcement of certain National Emission Standards for Hazardous Air Pollutants (NESHAP) promulgated under the Clean Air Act (CAA), as provided for under the delegation mechanism previously approved by the Environmental Protection Agency (EPA). The EPA is proposing to approve DEQ's requested update of its NESHAP delegation. If finalized as proposed, the delegation will only encompass sources subject to one or more Federal section 112 standards which are also subject to the requirements of the Title V operating permits program.

DATES: Written comments on this proposed rule must be received on or before December 27, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R06–OAR–2021–0661, at <https://www.regulations.gov> or via email to barrett.richard@epa.gov. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact Rick Barrett, 214–665–7227, barrett.richard@epa.gov. For the full EPA public comment policy, information about CBI or multimedia

submissions, and general guidance on making effective comments, please visit <https://www.epa.gov/dockets/commenting-epa-dockets>.

Docket: The index to the docket for this action is available electronically at <https://www.regulations.gov>. While all documents in the docket are listed in the index, some information may not be publicly available due to docket file size restrictions or content (*e.g.*, CBI).

FOR FURTHER INFORMATION CONTACT: Rick Barrett, EPA Region 6 Office, ARPE, (214) 665–7227, barrett.richard@epa.gov. Out of an abundance of caution for members of the public and our staff, the EPA Region 6 office will be closed to the public to reduce the risk of transmitting COVID–19. We encourage the public to submit comments via <https://www.regulations.gov>, as there will be a delay in processing mail and no courier or hand deliveries will be accepted. Please call or email the contact listed above if you need alternative access to material indexed but not provided in the docket.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever "we," "us," or "our" is used, we mean the EPA.

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I. What does this action do?

The EPA is proposing to approve an update to the delegation of the implementation and enforcement of certain NESHAP to DEQ. If finalized, the delegation will provide DEQ with the primary responsibility to implement and enforce the delegated standards. See sections VI and VII, below, for a discussion of which standards are being delegated and which are not being delegated.