

62. Kaplan, S., “Trump Administration Says Some Coronavirus Tests Can Bypass F.D.A. Scrutiny,” *New York Times*, August 24, 2020. Available at <https://www.nytimes.com/2020/08/21/health/coronavirus-tests-fda.html>.

63. Baumann, J., “Virus Testing Push Leaves FDA Lab Oversight in ‘a Bizarre Limbo,’” *Bloomberg Law*, August 26, 2020. Available at <https://news.bloomberglaw.com/pharma-and-life-sciences/virus-testing-push-leaves-fda-lab-oversight-in-a-bizarre-limbo>.

64. Howard, J., “HHS Withdraws Trump Administration Policy That Limited FDA Review of Certain Covid-19 Tests,” *CNN*, November 15, 2021. Available at <https://www.cnn.com/2021/11/15/health/covid-lab-tests-hhs-withdraws-policy-bn/index.html>.

65. Fortune, “Fortune 500—The Largest Companies in the U.S. by Revenue,” 2023. Available at <https://fortune.com/ranking/fortune500/>.

* 66. FDA, “Compliance Program Guidance Manual 7341.002; Inspection of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).” Available at <https://www.fda.gov/media/73949/download>.

* 67. FDA, “Compliance Program Guidance Manual 7342.002; Inspection of Source Plasma Establishments, Brokers, Testing Laboratories, and Contractors,” January 31, 2019. Available at <https://www.fda.gov/media/80179/download>.

* 68. Government Accountability Office, “COVID—19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed,” May 2022. Available at <https://www.gao.gov/assets/gao-22-104266.pdf>.

* 69. “It Has Come to Our Attention” Letter to MD Biosciences re: the Zika Virus RNA by RT—PCR Assay (March 4, 2016). Available at <https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/96214/download>.

* 70. “It Has Come to Our Attention” Letter to First Diagnostic Corp. re: ATFirst One Step Zika Antibody Test (March 10, 2016). Available at <https://public4.pagefreezer.com/content/FDA/04-10-2022T10:19/https://www.fda.gov/media/96739/download>.

* 71. FDA, “Direct-to-Consumer Tests,” December 20, 2019, available at <https://www.fda.gov/medical-devices/in-vitro-diagnostics/direct-consumer-tests> (last accessed on March 9, 2023).

* 72. Untitled Letter to Interleukin Genetics, Inc. (November 4, 2015). Available at <https://public4.pagefreezer.com/browse/FDA/22-02-2023T10:21/https://www.fda.gov/media/94365/download>.

* 73. Untitled Letter to Pathway Genomics, Inc. (September 21, 2015). Available at <https://public4.pagefreezer.com/browse/FDA/30-12-2022T07:46/https://www.fda.gov/media/93493/download>.

* 74. Transcript of the Molecular and Clinical Genetics Panel meeting, March 8, 2011. Available at <https://wayback.archive-it.org/7993/20170404140959/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249857.pdf>.

* 75. Transcript of the Molecular and Clinical Genetics Panel meeting, March 9,

2011. Available at <https://wayback.archive-it.org/7993/20170404141000/https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/MolecularandClinicalGeneticsPanel/UCM249858.pdf>.

76. Bradley, P.L., J.S. Dickey, J.D. Levin, et al., “Complex Clinical Laboratory Tests Can Benefit From Design Controls,” *Health Affairs Forefront*, June 3, 2022. Available at <https://www.healthaffairs.org/doi/10.1377/forefront.20220601.318288>.

* 77. FDA, “510(k) Third Party Review Program,” August 19, 2022. Available at [https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/510k-third-party-review-program\(lastaccessedonSeptember22,2023\)](https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/510k-third-party-review-program(lastaccessedonSeptember22,2023)).

List of Subjects in 21 CFR Part 809

Labeling, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes to amend 21 CFR part 809 as follows:

PART 809—IN VITRO DIAGNOSTIC PRODUCTS FOR HUMAN USE

■ 1. The authority citation for part 809 is revised to read as follows:

Authority: 21 U.S.C. 321(h)(1), 331, 351, 352, 360, 360c, 360d, 360e, 360h, 360i, 360j, 371, 372, 374, 381.

■ 2. In § 809.3, revise the last sentence of paragraph (a) to read as follows:

§ 809.3 Definitions.

(a) * * * These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory.

* * * * *

Dated: September 27, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–21662 Filed 9–29–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0530]

RIN 1625–AA09

Drawbridge Operation Regulation; Long Creek, Nassau County, NY

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily modify the operating schedule that governs the Loop Parkway Bridge across Long Creek, mile 0.7, Nassau County, NY. The bridge owner, New York State Department of Transportation (NYSDOT), submitted a request to operate the bridge under single leaf openings to perform bridge deck replacement. We invite your comments on this proposed rulemaking. **DATES:** Comments and related material must reach the Coast Guard on or before November 2, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0530 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 Ms. Stephanie E. Lopez, First Coast Guard District, Project Officer, telephone 212–514–4335, email Stephanie.E.Lopez@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
NYSDOT New York State Department of Transportation

II. Background, Purpose, and Legal Basis

The Loop Parkway Bridge across Long Creek, mile 0.7, Nassau County, NY, has a vertical clearance of 21 feet at mean high water and a horizontal clearance of 75.5 feet at mean high water. Waterway

users include recreational and commercial vessels, including fishing vessels.

The existing drawbridge operating regulations are listed at 33 CFR 117.799(f). NYSDOT is requesting a temporary rulemaking to operate under single leaf openings while they perform bridge deck replacements. NYSDOT has reached out to local mariners and notified them of the proposed temporary rulemaking as well as outlined an alternate route for larger vessels that may not be able to make passage under the bridge with single leaf openings.

III. Discussion of Proposed Rule

The Loop Parkway Bridge will continue to operate under its regular operating schedule found in 33 CFR 117.799(f). However, this proposed rule will allow the bridge to operate under single leaf openings from September 15, 2023, through May 15, 2024. For vessels that are too large for single leaf openings, NYSDOT has set an alternate route. Vessels that can pass without requesting a bridge opening may do so. NYSDOT has reached phase 2 of the project which requires replacing the bridge deck. The reason for this request is to allow the project to progress while minimizing impact on mariners.

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.

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 proposed rule has not been designated a “significant regulatory action,” under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). 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 of vessels to still transit the bridge under single leaf openings or may transit through an alternate route.

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 proposed 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 rulemaking 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 proposed 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, Table 3–1 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 proposed rule. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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–2023–0530 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. Also, if you click on the “Dockets” tab and then the proposed rule, you should see a “Subscribe” option for email alerts. Selecting this option will enable notifications when comments are posted, or if/when a final rule is published.

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 DHS Delegation No. 00170.1, Revision No. 01.3.

■ 2. Section 117.799 is amended as follows:

■ a. Stay paragraph (f).

■ b. Add paragraph (j).

The addition reads as follows:

§ 117.799 Long Island, New York Inland Waterway from East Rockaway Inlet to Shinnecock Canal.

* * * * *

(j) The draw of the Loop Parkway Bridge across Long Creek, mile 0.7, shall operate on single leaf openings until May 15, 2024. The draw will open for commercial vessels engaged in commerce and shall open Monday thru Friday from 6:20 a.m. to 9:50 a.m. and 3:20 p.m. to 7:20 p.m. on signal at 20 and 50 minutes after the hour, and on signal at all other times. For all other vessels, the draw shall open on Monday through Friday from 6:20 a.m. to 7:20 p.m. on signal at 20 and 50 minutes after the hour, and the draw shall open on Saturday, Sunday, and Federal holidays from 7:20 a.m. to 8:20 p.m. on signal at 20 and 50 minutes after the hour, and on signal at all other times.

Dated: August 21, 2023.

J.W. Mauger,

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

[FR Doc. 2023–21753 Filed 9–28–23; 4:15 pm]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0532]

RIN 1625–AA09

Drawbridge Operation Regulation; Sloop Channel, Nassau County, NY

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily modify the operating schedule that governs the Meadowbrook State Parkway Bridge, mile 12.8, across Sloop Channel, Nassau County, NY. The bridge owner, New York State Department of Transportation (NYSDOT), submitted a request to

operate the bridge under single leaf openings to perform bridge deck replacement. We invite your comments on this proposed rulemaking.

DATES: Comments and relate material must reach the Coast Guard on or before November 2, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0532 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 Ms. Stephanie E. Lopez, First Coast Guard District, Project Officer, telephone 212–514–4335, email Stephanie.E.Lopez@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations [Delete/Add Any Abbreviations Not Used/Used in This Document]

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
NYSDOT New York State Department of Transportation

II. Background, Purpose and Legal Basis

The Meadowbrook State Parkway Bridge across Sloop Channel, mile 12.8, Nassau County, NY, has a vertical clearance of 21 feet at mean high water and a horizontal clearance of 75.5 feet at mean high water. Waterway users include recreational and commercial vessels, including fishing vessels.

The existing drawbridge operating regulations are listed at 33 CFR 117.799(h). NYSDOT is requesting a temporary rulemaking to operate under single leaf openings while they perform bridge deck replacements. NYSDOT has reached out to local mariners and notified them of the proposed temporary rulemaking as well as outlined an alternate route for larger vessels that may not be able to make passage under the bridge with single leaf openings.

III. Discussion of Proposed Rule

The Meadowbrook State Parkway Bridge will continue to operate under its regular operating schedule found in 33 CFR 117.799(f). However, this proposed rule when made final would allow the