

(H) Specimen stability data, including stability under various storage times, temperatures, freeze-thaw, and transport conditions where appropriate;

(I) Method comparison data generated by comparison of the results obtained with the device to those obtained with a legally marketed predicate device with similar indication of use. Patient samples from the intended use population covering the device measuring range must be used;

(J) Specimen matrix comparison data if more than one specimen type or anticoagulant can be tested with the device. Samples used for comparison must be from patient samples covering the device measuring range;

(K) A description of how the assay cut-off (the medical decision point between positive and negative) was established and validated as well as supporting data;

(L) Clinical performance must be established by comparing data generated by testing samples from the intended use population and the differential diagnosis groups with the device to the clinical diagnostic standard. The diagnosis of Type 1 diabetes mellitus must be based on clinical history, physical examination, and laboratory tests, such as one or more pancreatic or insulin autoantibody test. Because the intended use population for Type 1 diabetes mellitus includes subjects less than 18 years old, samples from representative numbers of these subjects must be included. Representative numbers of samples from all age strata must also be included. The differential diagnosis groups must include, but not be limited to the following: Type 2 diabetes mellitus; metabolic syndrome; latent autoimmune diabetes in adults; other autoimmune diseases such as celiac disease (without a concomitant diagnosis of Type 1 diabetes mellitus), systemic lupus erythematosus, rheumatoid arthritis, and Hashimoto's thyroiditis; infection; renal disease; and testicular cancer. Diseases for the differential groups must be based on established diagnostic criteria and clinical evaluation. For all samples, the diagnostic clinical criteria and the demographic information must be collected and provided. The clinical validation results must demonstrate clinical sensitivity and clinical specificity for the test values based on the presence or absence of Type 1 diabetes mellitus. The data must be summarized in tabular format comparing the interpretation of results to the disease status; and

(M) Expected/reference values generated by testing an adequate

number of samples from apparently healthy normal individuals.

(iii) Identification of risk mitigation elements used by the device, including description of all additional procedures, methods, and practices incorporated into the directions for use that mitigate risks associated with testing.

(2) Your 21 CFR 809.10(a) compliant label and 21 CFR 809.10(b) compliant labeling must include warnings relevant to the assay including:

(i) A warning statement that reads, "The device is for use by laboratory professionals in a clinical laboratory setting";

(ii) A warning statement that reads, "The test is not a stand-alone test but an adjunct to other clinical information. A diagnosis of Type 1 diabetes mellitus should not be made on a single test result. The clinical symptoms, results on physical examination, and laboratory tests (e.g., serological tests), when appropriate, should always be taken into account when considering the diagnosis of Type 1 diabetes mellitus and Type 2 diabetes mellitus";

(iii) A warning statement that reads, "Absence of Zinc T8 autoantibody does not rule out a diagnosis of Type 1 diabetes mellitus"; and

(iv) A warning statement that reads, "The assay has not been demonstrated to be effective for monitoring the stage of disease or its response to treatment."

(3) Your 21 CFR 809.10(b) compliant labeling must include a description of the protocol and performance studies performed in accordance with paragraph (b)(1)(ii) of this section and a summary of the results.

Dated: October 18, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2017-22995 Filed 10-23-17; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2017-0048]

RIN 1625-AA09

#### Drawbridge Operation Regulation; Reynolds Channel, Lawrence, NY

**AGENCY:** Coast Guard, DHS.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is modifying the operating schedule that governs the Atlantic Beach Bridge across Reynolds

Channel, mile 0.4 at Lawrence, New York. This action is necessary to allow for an unexpected delay in the reconstruction and painting of the bascule leaves. A temporary deviation was previously granted for a length of 180 days. As the Coast Guard may not approve extensions beyond that allotted timeframe nor approve back-to-back or sequential deviations, it is necessary to issue this rule in order to allow the bridge owner to complete the remaining work items.

**DATES:** This rule is effective without actual notice from October 24, 2017 until 11:59 p.m. on November 13, 2017. For the purposes of enforcement, actual notice will be used from 12:01 on October 14, 2017 until October 24, 2017.

**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-0048 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rulemaking.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this interim rule, call or email James M. Moore, Bridge Management Specialist, U.S. Coast Guard; telephone 202-372-1518, email [James.M.Moore2@uscg.mil](mailto:James.M.Moore2@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  
§ Section  
U.S.C. United States Code

##### **II. Background Information and Regulatory History**

On April 6, 2017, we published a temporary deviation entitled, "Drawbridge Operation Regulation; Atlantic Beach Bridge, Reynolds Channel, Lawrence, NY" in the **Federal Register** (see 82 FR 06735). Although we did not request public comments, outreach conducted with mariners utilizing the waterway indicated no objections to the temporary deviation. No complaints have been submitted during the current temporary deviation.

The Coast Guard is issuing this temporary interim rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary

to the public interest.” Under 5 U.S.C. 553(b), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. Due to unanticipated difficulties and delays impacting the schedule and pace of bascule leaf reconstruction and painting, additional time is required to finalize and complete the work necessary to restore the bridge to full operational capacity. We must modify the operation schedule of the bridge by October 15, 2017 to allow the completion of bascule leaf reconstruction and painting. Due to the circumstances of this repair project, we lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

We are issuing this rule and under 5 U.S.C. 553(d)(3), and for the reasons stated above, the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**.

### III. Legal Authority and Need for the Rule

The Coast Guard is issuing this rule under authority 33 U.S.C. 499. The Coast Guard is modifying the operating schedule that governs the Atlantic Beach Bridge across Reynolds Channel, mile 0.4, at Lawrence, New York. The Atlantic Beach Bridge is a double-leaf bascule bridge offering mariners a vertical clearance of 25 feet at mean high water and 30 feet at mean low water in the closed position. Work platforms installed underneath the bascule spans have reduced the available vertical clearance to 21.5 feet at mean high water in the closed position and to 26.5 feet at mean low water in the closed position.

The existing drawbridge regulations are listed at 33 CFR 117.799(e). The Nassau County Bridge Authority, the bridge owner, has requested this modification as additional time is required to complete the final reconstruction and painting of the bascule leaves.

The Nassau County Bridge Authority has also requested that the Atlantic Beach Bridge be allowed to open on signal only one of two bascule spans for bridge openings with the understanding that dual lift-span operations will occur for vessels requiring such an opening provided a 48 hour advance notice, and receipt of 24 hour advance confirmation, from 7 a.m. Monday through 6 p.m. Friday. The bridge will operate normally and open fully upon signal on weekends from 6 p.m. Friday through 7 a.m. Monday.

The bridge generally opens four times per week for routine passage of towing vessels with tank barges or dry cargo barges. The bulk of remaining vessel traffic is recreational not requiring an opening in order to proceed through the draw. Vessels that can pass under the bridge without an opening may do so at all times. The bridge will be able to open for emergencies and there is an alternate route for vessels unable to pass through the bridge when in the closed position.

### IV. Discussion of the Rule

The Coast Guard is issuing this rule, which permits a temporary deviation from the operating schedule that governs the Atlantic Beach Bridge across Reynolds Channel, mile 0.4, at Lawrence, New York. The rule is necessary to accommodate the completion of bascule leaf reconstruction and painting. This rule allows for single-leaf operations upon signal during the week, Monday through Friday. Dual lift-span operations will be provided for vessels requiring such an opening given 48 hours of advance notice and provided a 24 hour advance confirmation. The bridge will operate normally during weekends.

### V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive Orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive Orders, and we discuss First Amendment rights of protesters.

#### 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. Executive Order 13771 directs agencies to control regulatory costs through a budgeting process. This rule has not been designated a “significant regulatory action,” under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget (OMB) and pursuant to OMB guidance it is exempt from the requirements of Executive Order 13771. This regulatory action determination is based on the ability of the majority of vessels to successfully transit through the draw of the bridge without an opening or with a single-leaf opening. Vessels requiring dual lift-span operations during the week may continue to transit the draw provided submission of 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 rule will 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 V.A above, this interim rule will not have a significant economic impact on any vessel owner or operator. Commercial mariners requiring dual lift-span operations during the week have been able to transit the draw following provision of advance notice. Single-leaf operations will be furnished on signal for those vessels requiring such an opening.

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 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**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

#### C. Collection of Information

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

D. Federalism and Indian Tribal Government

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 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 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.

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

F. 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 made a determination 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 simply promulgates the operating regulations or procedures for drawbridges. This action is categorically excluded from further review, under figure 2–1, paragraph (32)(e), of the Instruction. A preliminary Record of Environmental Consideration and a Memorandum for the Record are not required for this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters.

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.

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. In § 117.799, effective from 12:01 a.m. on October 24, 2017, through 11:59 p.m. on November 13, 2017, suspend paragraph (e)(1) and add paragraph (e)(4) to read as follows:

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

\* \* \* \* \*

(e) \* \* \*

(4) The Atlantic Beach Bridge will open only one of two bascule spans on signal for bridge openings from 7 a.m. Monday through 6 p.m. Friday. Dual lift-span operations will occur for vessels requiring such an opening provided a 48 hour advance notice and 24 hour advance confirmation has been furnished from 7 a.m. Monday through 6 p.m. Friday. The bridge will open fully on signal on weekends from 6 p.m. Friday through 7 a.m. Monday.

\* \* \* \* \*

Dated: October 6, 2017.

S.D. Poulin,

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

[FR Doc. 2017–23053 Filed 10–23–17; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2017–0890]

RIN 1625–AA11

Regulated Navigation Area; Beals Island Bridge Replacement, Moosabec Reach, Jonesport, ME

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a temporary Regulated Navigation Area (RNA) for the navigable waters within 150-yards of the Beals Island Bridge between Jonesport, ME, and Beals Island, ME. The RNA is needed to protect personnel, vessels, and the marine environment from the potential hazards created by the demolition, subsequent removal, and replacement of the Beals Island Bridge. This RNA will establish speed and beam restrictions on vessels transiting the regulated area during bridge replacement operations. This rule will also allow the Coast Guard to prohibit vessel traffic through the RNA when necessary.

DATES: This rule is effective without actual notice from October 24, 2017 through January 31, 2021. For the purposes of enforcement, actual notice will be used from October 15, 2017, through October 24, 2017.

Comments and related material must be received by the Coast Guard on or before January 22, 2018.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to http://www.regulations.gov, type USCG–2017–0890 in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Mr. Craig Lapiejko, Waterways Management, First Coast Guard District; telephone (617) 223–8351, email Craig.D.Lapiejko@uscg.mil. You may also call or email Chief Petty Officer Chris Bains, Waterways Management Division, U.S. Coast Guard Sector Northern New England, telephone (207) 347–5003, email Chris.D.Bains@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

- CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code
RNA Regulated Navigation Area
MEDOT Maine Department of Transportation

II. Background Information and Regulatory History

On June 27, 2017, the U. S. Coast Guard District One Bridge Branch