

7400.11J is publicly available online at www.faa.gov/air_traffic/publications/. You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 600 Independence Avenue SW, Washington, DC 20597; telephone: (202) 267-8783.

FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Good Cause for No Notice and Comment

Section 553(b)(3)(B) of Title 5, United States Code, (the Administrative Procedure Act) authorizes agencies to dispense with notice and comment procedures for rules when the agency for “good cause” finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under this section, an agency, upon finding good cause, may issue a final rule without seeking comment prior to the rulemaking. The FAA finds that prior notice and public comment to this final rule is unnecessary due to the brief length of the extension of the effective date and the fact that there is no substantive change to the rule.

Delay of Effective Date

■ Accordingly, pursuant to the authority delegated to me, the effective date of the final rule for Airspace Docket 23-AGL-26, as published in the **Federal Register** on August 19, 2024 (89 FR 66987), FR Doc. 2024-18431, and corrected on September 30, 2024 (89 FR 79429), FR Doc. 2024-22253, is hereby delayed until December 26, 2024.

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., P. 389.

Issued in Washington, DC, on October 8, 2024.

Brian Eric Konie,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2024-23612 Filed 10-11-24; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. FDA-2021-N-0507]

RIN 0910-AH99

Medical Devices; Quality System Regulation Amendments; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA or Agency) is correcting a final rule that appeared in the **Federal Register** on February 2, 2024. In that final rule, FDA amended the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) regulation to harmonize and modernize the device CGMP. FDA is correcting an editorial error that inadvertently omitted a definition in the codified of the final rule. This action is editorial in nature and is intended to ensure the accuracy and clarity of the Agency’s regulations.

DATES: Effective February 2, 2026.

FOR FURTHER INFORMATION CONTACT: Laurie Sternberg, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5517, Silver Spring, MD 20993-0002, 240-402-0425.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 2, 2024 (89 FR 7496), FDA published a final rule that amended the device CGMPs requirements in 21 CFR part 820. The preamble indicated that the definition for “batch” or “lot” was set forth at § 820.3 (21 CFR 820.3) but the definition for “batch” or “lot” was inadvertently omitted from the codified portion of § 820.3 in the final rule. FDA is, therefore, correcting the codified for § 820.3 to include the definition of “batch” or “lot” as was intended and to be consistent with the preamble of the final rule.

In FR Doc. 2024-01709 appearing on page 7524 in the **Federal Register** of Friday, February 2, 2024 (89 FR 7496), the following correction is made:

§ 820.3 [Corrected]

■ 1. On page 7524, in amendment number 4, in the first column, in paragraph (a) of § 820.3, the definition for “Batch or lot” is added in alphabetical order to read as follows:

“*Batch or lot* means one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits.”

Dated: October 7, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024-23701 Filed 10-11-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2024-0845]

RIN 1625-AA09

Drawbridge Operation Regulation; Wappinger Creek, New Hamburg, New York

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is removing the existing drawbridge operation regulation for the Metro-North Commuter Railroad Bridge, mile 0.0 across the Wappinger Creek at New Hamburg, New York. In 1991, the Metro-North Railroad Bridge was allowed to no longer be maintained as a movable structure and in 2004, the bridge was converted to a fixed bridge. The operating regulation is no longer applicable or necessary.

DATES: This rule is effective October 15, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type the docket number (USCG-2024-0845) in the “SEARCH” box and click “SEARCH”. In the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Ms. Judy Leung-Yee, Project Officer, First Coast Guard District, telephone 212-514-4336, email Judy.K.Leung-Yee@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
Pub. L. Public Law
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this final 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 unnecessary. The Metro-North Railroad Bridge at mile 0.0 across the Wappinger Creek was converted to a fixed bridge in 2004. Therefore, the regulation in § 117.823 is no longer applicable and will be removed.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. The bridge has been a fixed bridge for 20 years and this rule merely removes a regulatory requirement that is no longer applicable or necessary. The modification of the bridge has already taken place and the removal of the regulation will not affect mariners currently operating on this waterway. Therefore, a delayed effective date is unnecessary.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under the authority in Public Law 102–241 and 33 U.S.C. 499.

Section 36 of the Coast Guard Authorization Act of 1991 (Pub. L. 102–241) determined that the Metro-North Railroad Bridge at mile 0.0 across the Wappinger Creek provided for the reasonable needs of navigation in the closed to navigation position. As such, Public Law 102–241 declared that the bridge need not be maintained as a movable structure and in 2004 was converted to a fixed bridge. The governing regulation for this drawbridge was never removed subsequent to the completion of the fixed bridge that replaced it. The elimination of this drawbridge necessitates the removal of the drawbridge operation regulation in § 117.813 that pertains to the former drawbridge.

IV. Discussion of Final Rule

The Coast Guard is removing and reserving the regulation in § 117.813 related to the draw operations for this bridge because it is no longer a drawbridge. The Metro-North Railroad Bridge has been replaced with a fixed bridge. This change does not affect waterway or land traffic.

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.

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 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). Accordingly, it has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the fact that under Public Law 102–241 SEC 36 the vertical clearance of the bridge in the closed to navigation position was sufficient for waterway traffic. Since the bridge no longer needed to open, it does not be maintained as a movable structure. The bridge owner converted the bridge to a fixed bridge and no longer operates as a drawbridge. The removal of the operating schedule from 33 CFR part 117, subpart B will have no effect on the movement of waterway or land traffic.

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 final rule would not have a significant economic impact on any vessel owner or operator.

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** section.

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, 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 rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of

Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

Neither a Record of Environmental Consideration nor a Memorandum for the Record are 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. 00170.1. Revision No. 01.3

§ 117.813 [Removed and Reserved]

■ 2. Remove and reserve § 117.813.

M.E. Platt,

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

[FR Doc. 2024–23769 Filed 10–11–24; 8:45 am]

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