

21 CFR 211.110.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.³

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). The collections of information in parts 210 and 211 relating to CGMP have been approved under OMB control number 0910–0139.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics>, <https://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: December 23, 2024.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2024–31356 Filed 1–3–25; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2024–1099]

Security Zone; Potomac River and Anacostia River, and Adjacent Waters, Washington, DC

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

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce a security zone along the Potomac River, Anacostia River, and adjacent waters at Washington, DC, for the State Funeral for former President James Carter. This action is necessary to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after this activity. During the enforcement period, entry into or remaining within the zone is prohibited unless authorized by the Captain of the Port or their designated representative.

DATES: The regulations in 33 CFR 165.508 will be enforced from 8 a.m., January 7, 2025, through 4 p.m., January 9, 2025, for the security zone location identified in 33 CFR 16.508(a)(6).

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email LCDR Kate Newkirk, U.S. Coast Guard Sector Maryland-National Capital Region, Waterways Management Division; telephone 410–576–2596, email Kate.M.Newkirk@uscg.mil.

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce regulations in 33 CFR 165.508 for the locations identified in paragraph (a)(6) from 8 a.m., January 7, 2025, through 4 p.m., January 9, 2025. This action is being taken to protect government officials, mitigate potential terrorist acts and incidents, and enhance public and maritime safety and security immediately before, during, and after this event. Our regulations for the Security Zone; Potomac River and Anacostia River, and adjacent waters at Washington, DC. The regulation at 33 CFR 165.508(a)(6) specifies the location for this security zone as an area that includes all navigable waters described in paragraphs (a)(1) through (3), which includes Zones 1, 2, and 3.

- Security Zone 1, paragraph (a)(1); all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by the Francis Scott Key (US–29) Bridge, at mile 113, and bounded to the south by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, including the waters of the Boundary Channel, Pentagon Lagoon, Georgetown Channel Tidal Basin, and Roaches Run.

- Security Zone 2, paragraph (a)(2); all navigable waters of the Anacostia River, from shoreline to shoreline, bounded to the north by the John Philip Sousa (Pennsylvania Avenue) Bridge, at

mile 2.9, and bounded to the south by a line drawn from the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50′52.4″ N, 077°01′10.9″ W, including the waters of the Washington Channel.

- Security Zone 3 paragraph (a)(3); all navigable waters of the Potomac River, from shoreline to shoreline, bounded to the north by a line drawn from the Virginia shoreline at Ronald Reagan Washington National Airport, at 38°51′21.3″ N, 077°02′00.0″ W, eastward across the Potomac River to the District of Columbia shoreline at Hains Point at position 38°51′24.3″ N, 077°01′19.8″ W, thence southward across the Anacostia River to the District of Columbia shoreline at Giesboro Point at position 38°50′52.4″ N, 077°01′10.9″ W, and bounded to the south by the Woodrow Wilson Memorial (I–95/I–495) Bridge, at mile 103.8.

During the enforcement period, as specified in § 165.508(b), entry into or remaining in these zones is prohibited unless authorized by the Coast Guard Captain of the Port Maryland-National Capital Region. Public vessels and vessels already at berth at the time of the security zone is implemented do not have to depart the security zone. All vessels underway within the security zone at the time the security zone is implemented are to depart the zone. To seek permission to transit the zone, the Captain of the Port Maryland-National Capital Region can be contacted at telephone number (410) 576–2525 or on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). Coast Guard vessels enforcing this zone can be contacted on Marine Band Radio, VHF–FM channel 16 (156.8 MHz). The Coast Guard may be assisted by other Federal, state, or local law enforcement agencies in enforcing this regulation. If the Captain of the Port or his designated on-scene patrol personnel determines the security zone need not be enforced for the full duration stated in this notification, a Broadcast Notice to Mariners may be used to suspend enforcement and grant general permission to enter the security zone.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification to this enforcement period via the Local Notice to Mariners, and marine information broadcasts.

³ The Office of the Federal Register has published this document under the category “Rules and Regulations” pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

Dated: December 30, 2024.
Patrick C. Burkett,
Captain, U.S. Coast Guard, Captain of the Port Maryland-National Capital Region.
[FR Doc. 2024–31636 Filed 1–3–25; 8:45 am]
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DEPARTMENT OF TRANSPORTATION

Great Lakes St. Lawrence Seaway Development Corporation

33 CFR Part 402

RIN 2135–AA58

Tariff of Tolls

AGENCY: Great Lakes St. Lawrence Seaway Development Corporation, Department of Transportation (DOT).
ACTION: Final rule.

SUMMARY: The Great Lakes St. Lawrence Seaway Development Corporation (GLS) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls in their respective jurisdictions. The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the facilities operated by the GLS and the SLSMC. The GLS is revising its regulations to reflect the fees and charges levied by the SLSMC in Canada starting in the 2025 navigation season, which are effective only in Canada.

DATES: This rule is effective on January 6, 2025

ADDRESSES: *Docket:* For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>; or in person at the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Carrie Mann Lavigne, Chief Counsel,

Great Lakes St. Lawrence Seaway Development Corporation, 180 Andrews Street, Massena, New York 13662; (315) 764–3200.

SUPPLEMENTARY INFORMATION: The GLS and SLSMC of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Tariff of Tolls (Schedule of Fees and Charges in Canada) in their respective jurisdictions.

The Tariff sets forth the level of tolls assessed on all commodities and vessels transiting the facilities operated by the GLS and the SLSMC. The GLS is revising 33 CFR 402.12, “Schedule of tolls”, to reflect the fees and charges levied by the SLSMC in Canada beginning in the 2025 navigation season. The GLS finds there is good cause to make the Tariff of Tolls effective on the date of publication to harmonize the effective dates on both sides of the border.

Regulatory Notices: Privacy Act: Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT’s complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78) or you may visit <https://www.regulations.gov>.

Regulatory Evaluation

This regulation involves a foreign affairs function of the United States and therefore, Executive Order 12866 does not apply and evaluation under the Department of Transportation’s Regulatory Policies and Procedures is not required.

Regulatory Flexibility Act Determination

The GLS certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The St. Lawrence Seaway Regulations and Rules primarily relate to commercial users of the Seaway, the vast majority of whom are foreign vessel

operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

Environmental Impact

This regulation does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, *et seq.*) because it is not a major Federal action significantly affecting the quality of the human environment.

Federalism

The Corporation has analyzed this rule under the principles and criteria in Executive Order 13132, dated August 4, 1999, and has determined that this rule does not have sufficient federalism implications to warrant a Federalism Assessment.

Unfunded Mandates

The Corporation has analyzed this rule under title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48) and determined that it does not impose unfunded mandates on State, local, and Tribal governments and the private sector requiring a written statement of economic and regulatory alternatives.

Paperwork Reduction Act

This regulation has been analyzed under the Paperwork Reduction Act of 1995 and does not contain new or modified information collection requirements subject to the Office of Management and Budget review.

List of Subjects in 33 CFR Part 402

Vessels, Waterways.
Accordingly, the Great Lakes St. Lawrence Seaway Development Corporation is amending 33 CFR part 402 as follows:

PART 402—TARIFF OF TOLLS

■ 1. The authority citation for part 402 continues to read as follows:

Authority: 33 U.S.C. 983(a), 984(a)(4), and 988, as amended; 49 CFR 1.101.

■ 2. Revise § 402.12 to read as follows:

§ 402.12 Schedule of tolls.

TABLE 1 TO § 402.12

Item	Column 1	Column 2	Column 3
	Description of charges	Rate (\$) Montreal to or from Lake Ontario (5 locks)	Rate (\$) Welland Canal—Lake Ontario to or from Lake Erie (8 locks)
1.	Subject to item 3, for complete transit of the Seaway, a composite toll, comprising:		