

investigator shall obtain the informed consent of each human subject to whom the drug is administered, in accordance with part 50 of this chapter. Additional specific responsibilities of clinical investigators are set forth in this part and in parts 50 and 56 of this chapter.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 6. The authority citation for part 812 is revised to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360hh–360pp, 360rr–360ss, 360bbb–8b, 371, 372, 374, 379e, 381, 382; 42 U.S.C. 216, 241, 262.

■ 7. Revise § 812.2 (b)(1)(iii) to read as follows:

§ 812.2 Applicability.

* * * * *

(b) * * *

(1) * * *

(iii) Ensures that each investigator participating in an investigation of the device obtains from each subject under the investigator's care, informed consent in accordance with part 50 of this chapter.

* * * * *

Dated: December 1, 2023.

Robert M. Califf,

Commissioner of Food and Drugs.

[FR Doc. 2023–27935 Filed 12–20–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 3, 100, 165

[Docket Number USCG–2023–0970]

RIN 1625–AA00

Coast Guard Sector Sault Sainte Marie; Sector Name Conforming Amendment

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The rule makes non-substantive changes to Coast Guard regulations in association with a change in the Coast Guard's internal organization. The purpose of this rule is to reflect that U.S. Coast Guard Sector Sault Sainte Marie has been renamed U.S. Coast Guard Sector Northern Great Lakes. This rule will have no substantive effect on the regulated public.

DATES: This rule is effective without actual notice December 21, 2023. For the purposes of enforcement, actual

notice will be used from December 1, 2023, until December 21, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2023–0970 in the search box and click “Search.” Next, in the Document Type column, select “Supporting & Related Material.”

FOR FURTHER INFORMATION CONTACT: If you have questions about this rule, call or email Chief Warrant Officer Charles Palmer, U.S. Coast Guard; telephone 906–253–2462, email Charles.b.palmer@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

AOR Area of responsibility
CFR Code of Federal Regulations
COTP Captain of the Port
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of Proposed Rulemaking
OCMI Officer in Charge of Marine Inspections
OFCO Operating Facility Change Order
SAR Search and Rescue
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

For the last several years, the Coast Guard has sought to better align the names of its assets to correspond to the area of responsibility which they serve. Review of the missions and engagements within the northern Great Lakes region highlighted that “Sector Sault Sainte Marie” alone did not adequately capture the breadth and range of Coast Guard operations and relationships throughout the region. The Coast Guard has approved the name change to U.S. Coast Guard Sector Northern Great Lakes to acknowledge the long-standing commitment to all communities of the region and to reaffirm the multi-mission support that the Coast Guard provides to ensure safety at sea and enhanced maritime governance. The geographic boundaries of Sector Northern Great Lakes are not changing, and its office is not moving from Sault Sainte Marie, MI.

We did not publish a notice of proposed rulemaking (NPRM) before this final rule. The Coast Guard finds that this rule is exempt from notice and comment rulemaking requirements under 5 U.S.C. 553(b)(A) because the changes it makes are conforming amendments involving agency organization. The Coast Guard also finds good cause exists under 5 U.S.C. 553(b)(B) for not publishing an NPRM because the changes will have no

substantive effect on the public and notice and comment are therefore unnecessary. For the same reasons, the Coast Guard finds good cause exists under 5 U.S.C. 553(d)(3) to make the rule effective fewer than 30 days after publication in the **Federal Register**.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 14 U.S.C. 504(a)(2), as delegated at 33 CFR 1.05–1(h), to issue regulations necessary to implement technical, organizational, and conforming amendments and corrections to rules, regulations, and notices.

On November 06, 2023, the Coast Guard issued Operating Facility Change Order (OFCO) No. 037–23 which changed the official unit name of U.S. Coast Guard Sector Sault Sainte Marie to U.S. Coast Guard Sector Northern Great Lakes. The previous name of Sector Sault Sainte Marie is described and reflected in regulations, which also contain contact details and other references to Sector Sault Sainte Marie. These conforming amendments update those regulations so that they contain current information.

Under 14 U.S.C. 504(a)(2), the Commandant of the Coast Guard has the authority to establish and prescribe the purpose of Coast Guard Shore establishments. This authority has been delegated to the Chief of the Coast Guard's Office of Regulations and Administrative Law under 33 CFR 1.05–1(h).

IV. Discussion of the Rule

OFCO No. 037–23, issued November 06, 2023, changed the official unit name of U.S. Coast Guard Sector Sault Sainte Marie to U.S. Coast Guard Sector Northern Great Lakes. The November 2023 OFCO did not change the area of responsibility (AOR). The AOR of U.S. Coast Guard Sector Northern Great Lakes is identical to that of what was U.S. Coast Guard Sector Sault Sainte Marie. All authorities and responsibilities previously assigned to Commander, U.S. Coast Guard Sector Sault Sainte Marie have been assigned to Commander, U.S. Coast Guard Sector Northern Great Lakes. Additionally, all authorities that were vested in the Commander, U.S. Coast Guard Sector Sault Sainte Marie as it pertains to the COTP, the OCMI, the Federal On Scene Coordinator, the Federal Maritime Security Coordinator, and the Search and Rescue Coordinator, have been assigned to Commander, U.S. Coast Guard Sector Northern Great Lakes. This rule does not change any sector, OCMI, or COTP zone boundary lines, nor does

it have any substantive impact on existing regulated navigation area, safety zone, or security zone regulation, or any naval vessel protection zones.

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

This regulatory action determination is based on the finding that the name change will have no substantive effect on the public.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 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.

For the reasons stated in section V.A. above, this rule will not have a significant economic impact on any member of the public, including “small entities.”

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 will not call for a 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 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 Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have 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 consists only of an organizational amendment. It is categorically excluded from further

review under paragraph L3 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1, Implementation of the National Environmental Policy Act.

List of Subjects

33 CFR Part 3

Organization and functions (Government agencies).

33 CFR Part 100

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR parts 3, 100, and 165 as follows:

PART 3—COAST GUARD AREAS, DISTRICTS, SECTORS, MARINE INSPECTION ZONES, AND CAPTAIN OF THE PORT ZONES

- 1. The authority citation for part 3 continues to read as follows:

Authority: 14 U.S.C. 501, 504; Pub. L. 107–296, 116 Stat. 2135; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

§ 3.45–45 [Amended]

- 2. Amend § 3.45–45 by removing the words “Sector Sault Ste. Marie” and adding in their place the words “Sector Northern Great Lakes” in the section heading and removing the words “Sector Sault Ste. Marie’s” and adding in their place the words “Sector Northern Great Lakes’” in the introductory text and paragraph (a).

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

- 3. The authority citation for part 100 continues to read as follows:

Authority: 46 U.S.C. 70041; 33 CFR 1.05–1.

§ 100.901 [Amended]

- 4. Amend § 100.901 in table 1 by removing the words “Sector Sault Ste. Marie” and adding in their place the words “Sector Northern Great Lakes” in the center heading above the entry “(1) Bridgefest Regatta Sponsor: Bridgefest Committee”.

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 5. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

§ 165.918 [Amended]

■ 6. Amend § 165.918 by removing the words “Port Sault Sainte Marie” and adding in their place the words “Port Northern Great Lakes” in the section heading and wherever they appear in paragraphs (a)(1) through (3), (b), (d), and (e).

§ 165.928 [Amended]

■ 7. Amend § 165.928 in paragraph (g) by removing the words “Sault Ste. Marie” and adding in their place the words “Northern Great Lakes”.

§ 165.944 [Amended]

■ 8. Amend § 165.944 in paragraphs (d)(1) and (e) by removing the words “Sault Sainte Marie” and adding in their place the words “Northern Great Lakes”.

Dated: December 18, 2023.

Michael T. Cunningham,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2023–28103 Filed 12–20–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[Docket No. USCG–2023–0934]

RIN 1625–AA09

Drawbridge Operation Regulation; Turner Cut, Near Stockton, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule and request for comments

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the draw of the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, across Turner Cut, near Stockton, CA. This action is necessary to allow the bridge owner, Reclamation District 2030 (RD2030), to complete design plans and conduct repairs to the bridge to bring it back to its normal operating status.

DATES: This temporary interim rule is effective from December 21, 2023 through 5 p.m. on September 30, 2024.

Comments and related material must reach the Coast Guard on or before January 22, 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–2023–0934) 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 temporary interim rule, call or email Carl Hausner, Chief, Bridge Section, Eleventh Coast Guard District; telephone 510–437–3516, email Carl.T.Hausner@uscg.mil.

SUPPLEMENTARY INFORMATION:**I. Table of Abbreviations**

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
NOTD Notice of Temporary Deviation
PG&E Pacific Gas and Electric
Pub. L. Public Law
RD2030 Reclamation District 2030
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

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. This bridge is secured closed and will be secured closed until design plans are finalized, coordination of construction schedule can be made with landowners and PG&E, contractor hired, and repairs completed.

On June 21, 2023, RD2030 notified the Coast Guard that the Zuckerman Brothers (McDonald Island) retractable span bridge should not open for the passage of vessels. The cause was the gradual movement which squeezed the abutments towards the center movable steel section. The span cannot be opened without the risk of it being stuck in the open-to-navigation position. The Zuckerman Brothers (McDonald Island)

bridge is the only road in and out of McDonald Island, which includes farms and a PG&E station and wells. The Coast Guard granted a Notice of Temporary Deviation (NOTD) from the operating schedule of the bridge, allowing the span to be secured in the closed position until repairs can be made. The NOTD will expire at 7 a.m. on December 18, 2023. The design, coordination of work with affected parties, and repair is delayed. The retractable span will not be operational at the expiration of the NOTD. The Coast Guard received the report of these delays on November 17, 2023. Therefore, there is insufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**. For reasons presented above, delaying the effective date of this rule would be impracticable and contrary to the public interest because the retractable span of the bridge is currently secured closed and cannot be operated until repairs are completed.

We are soliciting comments on this rulemaking. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this temporary interim rule under authority in 33 U.S.C. 499. The Coast Guard is modifying the operating schedule that governs the Zuckerman Brothers (McDonald Island) bridge, mile 2.3, across Turner Cut, near Stockton, CA. The Zuckerman Brothers (McDonald Island) bridge has a vertical clearance, in the closed position, of 16 feet at mean high water and unlimited vertical clearance when opened.

The existing drawbridge regulation, 33 CFR 117.5, states that the draw of the Zuckerman Brothers (McDonald Island) bridge must open for vessels if a signal is given to do so. RD2030, the bridge owner, has requested this modification as additional time is required to complete bridge repairs.

Drawtender logs from January 2022 through June 2023 indicate the span opened on average, 2 times in January; 1 time in February; 1 time in March; 3 times in April; 11 times in May; 8 times in June; 18 times in July; 6 times in August; 7 times in September; 4 times in October; 2 times in November; and 3 times in December. No complaints have been received from mariners since the