https://www.regulations.gov. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 19, 2018.

Leslie Kux.

Associate Commissioner for Policy. [FR Doc. 2018-05843 Filed 3-21-18; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF TRANSPORTATION

Saint Lawrence Seaway Development Corporation

33 CFR Part 401

[Docket No. SLSDC-2016-0006]

RIN 2135-AA43

Seaway Regulations and Rules: Periodic Update, Various Categories

AGENCY: Saint Lawrence Seaway Development Corporation, DOT.

ACTION: Final rule.

SUMMARY: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the SLSDC is amending the joint regulations by updating the Seaway Regulations and Rules in various categories. The changes update the following sections of the Regulations and Rules: Condition of Vessels; and, Dangerous Cargo. These amendments are merely editorial or for clarification of existing requirements. The joint regulations will become effective in Canada on March 29, 2018. For consistency, because these are joint regulations under international agreement, and to avoid confusion among users of the Seaway, the SLSDC finds that there is good cause to make the U.S. version of the amendments effective on the same date.

DATES: This rule is effective on March 29, 2018.

ADDRESSES: Docket: For access to the docket to read background documents or comments received, go to http:// 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, Saint Lawrence Seaway Development Corporation, 180 Andrews Street, Massena, New York 13662; 315/764-3200.

SUPPLEMENTARY INFORMATION: The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the SLSDC is amending the joint regulations by updating the Regulations and Rules in various categories. The changes update the following sections of the Regulations and Rules: Condition of Vessels; and, Dangerous Cargo. These changes are to clarify existing requirements in the regulations.

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 (Volume 65, Number 70; Pages 19477-78) or you may visit http:// www.Regulations.gov.

The joint regulations will become effective in Canada on March 29, 2018.

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**

I certify 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 who 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 have 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 401

Hazardous materials transportation, Navigation (water), Penalties, Radio, Reporting and recordkeeping requirements, Vessels, Waterways.

Accordingly, the Saint Lawrence Seaway Development Corporation amends 33 CFR part 401 as follows:

PART 401—SEAWAY REGULATIONS AND RULES

Subpart A—Regulations

■ 1. The authority citation for subpart A of part 401 is revised to read as follows:

Authority: 33 U.S.C. 983(a) and 984(a)(4), as amended; 49 CFR 1.52, unless otherwise noted.

■ 2. In § 401.12, revise paragraph (a)(3)(iii) to read as follows:

§ 401.12 Minimum requirements—mooring lines and fairleads.

(a) * * *

(3) * * *

(iii) All lines shall be led through closed chocks or fairleads acceptable to the Manager and the Corporation.

■ 3. In § 401.66, revise paragraph (a) to read as follows:

§ 401.66 Applicable laws.

(a) Where a vessel on the seaway is involved in an accident or a dangerous occurrence, the master of the vessel shall report the accident or occurrence, pursuant to the requirements of the Transportation Safety Board Regulations, to the nearest Seaway station and Transport Canada Marine Safety and Security or U.S. Coast Guard office as soon as possible and prior to departing the Seaway system.

Issued at Washington, DC, on March 16, 2018.

Saint Lawrence Seaway Development Corporation.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2018–05781 Filed 3–21–18; 8:45 am]

BILLING CODE 4910-61-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R07-OAR-2017-0267; FRL-9975-78-Region 7]

Approval of Implementation Plans; State of Iowa; Elements of the Infrastructure SIP Requirements for the 2010 Sulfur Dioxide National Ambient Air Quality Standard (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve certain elements of a 2013 State Implementation Plan (SIP) submission from the State of Iowa for the 2010 Sulfur Dioxide (SO₂) National Ambient Air Quality Standard (NAAQS). States are required to have a SIP that provides for the implementation, maintenance, and enforcement of the NAAQS. Whenever EPA promulgates a new or revised NAAQS, states are required to make a SIP submission establishing that the existing approved SIP has provisions necessary to address various requirements to address the new or revised NAAQS or to add such provisions. These SIPs submissions are commonly referred to as "infrastructure" SIPs. The infrastructure

"infrastructure" SIPs. The infrastructure SIP requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

DATES: This final rule is effective on April 23, 2018.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA-R07-OAR-2017-0267. All documents in the docket are listed on the https://www.regulations.gov website. Although listed in the index,

some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through https://www.regulations.gov or please contact the person identified in the FOR FURTHER INFORMATION CONTACT section for additional information.

FOR FURTHER INFORMATION CONTACT:

Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219 at 913–551–7039, or by email at hamilton.heather@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document "we," "us," and "our" refer to EPA. This section provides additional information by addressing the following:

I. Background

II. What is being addressed in this document?

III. Have the requirements for approval of the SIP submission been met?

IV. EPA's Response to Comments V. What action is EPA taking?

VI. Statutory and Executive Order Reviews

I. Background

EPA received Iowa's 2010 SO₂ NAAOS infrastructure SIP submission on July 29, 2013. On September 29, 2017, EPA proposed to approve elements of this submission. See 82 FR 45550. In conjunction with the September 29, 2017 notice of proposed rulemaking (NPR), EPA issued a direct final rule (DFR) approving the same elements of the 2010 SO₂ NAAQS infrastructure SIP. See 82 FR 45497. However, in the DFR, EPA stated that if EPA received adverse comments by October 30, 2017, the action would be withdrawn and not take effect. EPA received three comments prior to the close of the comment period which were adverse. EPA withdrew the DFR on November 14,2017. See 82 FR 54300. This action is a final rule based on the NPR. A detailed discussion of Iowa's SIP submission and EPA's rationale for approving the SIP submission were provided in the DFR and the associated Technical Support Document in the docket for this rulemaking and will not be restated here, except to the extent relevant to our response to the public comment we received.

II. What is being addressed in this document?

EPA is approving certain elements of the 2010 SO_2 NAAQS infrastructure SIP

submission from the State of Iowa received on July 29, 2013. Specifically, EPA is approving Iowa's submission with regard to the following elements of section 110(a)(2): (A), (B), (C), (D)(i)(II)—prevent of significant deterioration of air quality (prong 3), (D)(ii), (E) through (H), and (J) through (M).

EPA is not taking action at this time on the following elements for the 2010 SO₂ NAAQS: Section 110(a)(2)(D)(i)(I)—significant contribution to nonattainment (prong 1) and interfering with maintenance of the NAAQS (prong 2), and section 110(a)(2)(D)(i)(II)—protection of visibility (prong 4).

III. Have the requirements for approval of the SIP submission been met?

The state met the public notice requirements for SIP submission in accordance with 40 CFR 51.102. The state initiated public comment from April 6, 2013, to May 8, 2013. One comment was received and adequately addressed in the final SIP submission. This submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. In addition, as explained above and in more detail in the technical support document which is part of the docket for this rulemaking, the submission meets the applicable substantive SIP requirements of the CAA, including section 110 and implementing regulations.

IV. EPA's Response to Comments

The public comment period on EPA's proposed rule opened September 29, 2017, the date of its publication in the Federal Register, and closed on October 30, 2017. During this period, EPA received three public comments on the proposal to approve certain elements of Īowa's 2010 ŠŌ₂ infrastructure SIP submission, one of which is addressed below. The other two comments were not specific to this action, which is concerned with evaluating whether Iowa has the required elements in place to implement, maintain, and enforce the NAAQS, and thus no further response is required.

Comment: The commenter stated that EPA must act on 110(a)(2)(D)(I) prong 1 (significant contribution to nonattainment), prong 2 (interference with maintenance), and 110(a)(2)(D)(II), prong 4 (interference with visibility protection.) The commenter asserted that EPA had stated in the Technical Support Document (TSD) for the proposed action that "EPA WILL NOT ACT on [prongs 1, 2 and 4]" (emphasis added in comment). The commenter went on to state that EPA was therefore stating that it "will never act and does not need to act on these elements." The