

sequences from patients suspected of meningitis or encephalitis. A device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid is intended to aid in the diagnosis of meningitis or encephalitis when used in conjunction with clinical signs and symptoms and other clinical and laboratory findings.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Premarket notification submissions must include detailed device description documentation, including the device components, ancillary reagents required but not provided, and a detailed explanation of the methodology, including primer/probe sequence, design, and rationale for sequence selection.

(2) Premarket notification submissions must include detailed documentation from the following analytical studies: Analytical sensitivity (limit of detection), inclusivity, reproducibility, interference, cross reactivity, and specimen stability.

(3) Premarket notification submissions must include detailed documentation from a clinical study. The study, performed on a study population consistent with the intended use population, must compare the device performance to results obtained from well-accepted comparator methods.

(4) Premarket notification submissions must include detailed documentation for device software, including, but not limited to, software applications and hardware-based devices that incorporate software.

(5) The Intended Use statement in the device labeling must include a statement that the device is intended to be used in conjunction with standard of care culture.

(6) A detailed explanation of the interpretation of results and acceptance criteria must be included in the device's 21 CFR 809.10(b)(9) compliant labeling.

(7) The device labeling must include a limitation stating that the negative results do not preclude the possibility of central nervous system infection.

(8) The device labeling must include a limitation stating that device results are not intended to be used as the sole basis for diagnosis, treatment, or other patient management decisions.

(9) The device labeling must include a limitation stating that positive results do not mean that the organism detected is infectious or is the causative agent for clinical symptoms.

(10) As part of the risk management activities performed as part of your 21 CFR 820.30 design controls, you must

document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

Dated: October 13, 2017.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF DEFENSE

### Department of the Navy

#### 32 CFR Part 706

#### Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

**AGENCY:** Department of the Navy, DoD.

**ACTION:** Final rule.

**SUMMARY:** The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that certain vessels of the VIRGINIA SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with their special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

**DATES:** This rule is effective October 20, 2017 and is applicable beginning September 30, 2017.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Kyle Fralick, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374-5066, telephone 202-685-5040.

**SUPPLEMENTARY INFORMATION:** Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that certain vessels of the SSN Class are vessels of the Navy which, due to their special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with their special function as a naval ship: Rule 23(a) and Annex I, paragraph 2(a)(i), pertaining to the vertical placement of the masthead,

light and Annex I, paragraph 2(f)(i), pertaining to the masthead light being above and clear of all other lights and obstructions; Rule 30 (a), Rule 21(e), and Annex I, paragraph 2(k), pertaining to the vertical separation of the anchor lights, vertical placement of the forward anchor light above the hull, and the arc of visibility of all around lights; Rule 23 (a) and Annex I, paragraph 3(b), pertaining to the location of the sidelights; and Rule 21(c), pertaining to the location and arc of visibility of the sternlight. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on these vessels in a manner differently from that prescribed herein will adversely affect these vessels' ability to perform their military functions.

#### List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

#### PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

**Authority:** 33 U.S.C. 1605.

■ 2. Section 706.2 is amended by:

■ a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789);

■ b. In Table Three, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789); and

■ c. In Table Four:

■ i. In paragraph 25, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789); and

■ ii. In paragraph 26, adding, in alpha numerical order, by vessel number, an entry for USS INDIANA (SSN 789).

The additions read as follows:

**§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.**

\* \* \* \* \*

TABLE ONE

Vessel	Number	Distance in meters of forward masthead light below minimum required height §2(a)(i) Annex I
USS INDIANA	SSN 789	2.76

\* \* \* \* \*

TABLE THREE

Vessel	Number	Masthead lights arc of visibility; rule 21(a)	Side lights arc of visibility; rule 21(b)	Stern light arc of visibility; rule 21(c)	Side lights, distance inboard of ship's sides in meters 3(b) annex 1	Stern light, distance forward of stern in meters; rule 21(c)	Forward anchor light, height above hull in meters; 2(K) annex 1	Anchor lights relationship of aft light to forward light in meters 2(K) annex 1
USS INDIANA	SSN 789			206.0°	4.37	11.05	2.8	0.30

\* \* \* \* \* 25. \* \* \*

TABLE FOUR

Vessel	Number	Distance in meters of masthead light below the submarine identification lights
USS INDIANA	SSN 789	0.81

26. \* \* \*

Vessel	Number	Obstruction angle relative to ship's headings	
		Forward anchor light	Aft anchor light
USS INDIANA	SSN 789	172° to 188°	359° to 1°

\* \* \* \* \*

Approved: September 30, 2017.

**A.S. Janin,**

*Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law Division).*

Dated: October 10, 2017.

**A.M. Nichols,**

*Lieutenant Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 52**

[EPA-R05-OAR-2017-0157; FRL-9969-87-Region 5]

**Air Plan Approval; Wisconsin; Regional Haze Progress Report**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is approving the regional haze progress report under the Clean Air Act as a revision to the Wisconsin State Implementation Plan (SIP). Wisconsin has satisfied the progress report requirements of the Regional Haze Rule. Wisconsin has also met the requirements for a determination of the adequacy of its regional haze plan with its negative declaration submitted with the progress report.

**DATES:** This direct final rule will be effective December 19, 2017, unless EPA receives adverse comments by November 20, 2017. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-R05-OAR-2017-0157 at <http://www.regulations.gov> or via email to [aburano.douglas@epa.gov](mailto:aburano.douglas@epa.gov). For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be

accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit <http://www2.epa.gov/dockets/commenting-epa-dockets>.

**FOR FURTHER INFORMATION CONTACT:**

Gilberto Alvarez, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR-18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6143, [alvarez.gilberto@epa.gov](mailto:alvarez.gilberto@epa.gov).

**SUPPLEMENTARY INFORMATION:**

Throughout this document whenever “we,” “us,” or “our” is used, we mean EPA. This supplementary information section is arranged as follows:

- I. Background
- II. Requirements for the Regional Haze Progress Report SIPs and Adequacy of Determinations
- III. What is EPA's analysis?
- IV. What action is EPA taking?
- V. Statutory and Executive Order Reviews

**I. Background**

States are required to submit a progress report every five years that evaluates progress towards the Reasonable Progress Goals (RPGs) for each mandatory Class I Federal area within the State and in each mandatory Class I Federal area outside the State which may be affected by emissions from within the State. *See* 40 CFR 51.308(g). States are also required to submit, at the same time as the progress report, a determination of the adequacy of the State's existing regional haze SIP. *See* 40 CFR 51.308(h). The first progress report is due five years after the submittal of the initial regional haze SIP.

Wisconsin submitted its regional haze plan on January 18, 2012. EPA approved Wisconsin's regional haze plan into its SIP on August 7, 2012, 77 FR 46952. Wisconsin submitted its five-year progress report on March 17, 2017. This is a report on progress made in the first implementation period towards RPGs for Class I areas outside of Wisconsin. Wisconsin does not have any Class I

areas within its borders. This progress report SIP included a determination that Wisconsin's existing regional haze SIP requires no substantive revision to achieve the established regional haze visibility improvement and emissions reduction goals for 2018. EPA is proposing to approve Wisconsin's progress report on the basis that it satisfies the applicable requirements of the rule at 40 CFR 51.308.

**II. Requirements for the Regional Haze Progress Report SIPs and Adequacy of Determinations**

Under 40 CFR 51.308(g), states must periodically (every five years) submit a regional haze progress report that address the seven elements found in 40 CFR 51.308(g).

Under 40 CFR 51.308(h), states are required to submit, at the same time as the progress report, a determination of the adequacy of their existing regional haze SIP and to take one of four possible listed actions based on information in the progress report.

**III. What is EPA's analysis?**

The Regional Haze Rule provides the required elements for five-year progress reports in 40 CFR 51.308(g). EPA finds that Wisconsin satisfied the 40 CFR 51.308(g) requirements with its progress report. EPA finds that, with its negative declaration, Wisconsin also satisfied the requirements for the determination of adequacy provided in 40 CFR 51.308(h).

The following sections discuss the information provided by Wisconsin in the progress report submission, along with EPA's analysis and determination of whether the submission met the applicable requirements of § 51.308.

**1. Status of Implementation of all Measures Included in the Regional Haze SIP**

In its progress report, Wisconsin summarizes the status of the emissions reduction measures that were included in its 2012 regional haze SIP. Specifically, the report addresses the status of the on-the-books emissions reduction measures. The measures include applicable Federal programs (*e.g.*, Clean Air Interstate Rule—CAIR, Cross State Pollution Rule—CSAPR, on- and off-highway mobile source rules, area source rules, point sources, Title IV programs, nitrogen oxides (NO<sub>x</sub>) SIP Call, Maximum Achievable Control Technology (MACT) standards, Federal and State consent agreements, and Federal and State control strategies for electric generating units (EGUs)). This summary includes a discussion of the benefits associated with each measure.