

FDA has determined that special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of safety and effectiveness. In order for a device to fall within this classification, and thus avoid automatic classification in class III, it would have to comply with the special controls named in this final order. The necessary special controls appear in the regulation codified by this order. This device is subject to premarket notification requirements under section 510(k).

### III. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These 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. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120.

#### List of Subjects in 21 CFR Part 862

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 862 is amended as follows:

#### PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

- 1. The authority citation for part 862 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

- 2. Add § 862.3652 to subpart D to read as follows:

#### § 862.3652 Organophosphate test system.

(a) *Identification.* An organophosphate test system is a device intended to measure organophosphate metabolites quantitatively in human urine from individuals who have signs and symptoms consistent with cholinesterase poisoning. The data obtained by this device is intended to aid in the confirmation and

investigation of organophosphate exposure.

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

(1) The distribution of these devices is limited to laboratories with experienced personnel who are trained to measure and evaluate organophosphate exposure and guide public health response.

(2) Analytical testing must demonstrate the device has appropriate performance characteristics, including adequate precision and accuracy across the measuring range and near medical decision points.

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, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG)(Admiralty and Maritime Law) has determined that USS MICHAEL MONSOOR (DDG 1001) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its 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 18, 2017 and is applicable beginning October 3, 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 USS MICHAEL MONSOOR (DDG 1001) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the location of the forward masthead light at a height not less than 6 meters above the hull; Annex I, paragraph 2(g) pertaining to the placement of sidelights above the hull of the vessel; Rule 30(a)(i) and Annex I, paragraph 2(k) pertaining to the vertical separation between anchor lights, and the location of the forward anchor light at a height of not less than 6 meters above the hull; Annex I, paragraph 3(a), pertaining to the horizontal separation between the forward and after masthead lights; Annex I, paragraph 2(i)(iii), pertaining to the vertical spacing of task lights; and Annex I, paragraph 3(c), pertaining to the task lights placed at a horizontal distance of not less than 2 meters from the fore and aft centerline of the vessel. 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 this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its 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 alphanumeric order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001);

■ b. In Table Three, adding in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001);

■ c. In Table Four, under paragraph 15, adding in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001);

■ d. In Table Four, under paragraph 19, adding in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001);

■ e. In Table Four, under paragraph 22 adding, in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001); and

■ f. In Table Five, adding, in alphanumerical order by vessel number, an entry for USS MICHAEL MONSOOR (DDG 1001).  
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 1
USS MICHAEL MONSOOR .....	DDG	2.33

\* \* \* \* \*

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 MICHAEL MONSOOR .....	DDG 1001						5.3	2.99 below.

15. \* \* \* \*

\* \* \* \* \*

TABLE FOUR

Vessel	Number	Horizontal distance from the fore and aft centerline of the vessel in the athwartship direction
USS MICHAEL MONSOOR .....	DDG 1001	FWD Lower: 10.33 meters. FWD Middle: 10.31 meters. FWD Upper: 10.30 meters. AFT Lower: 11.05 meters. AFT Middle: 11.05 meters. AFT Upper: 11.05 meters.

<sup>1</sup> On DDG 1000, the ship does not have a traditional mast. To achieve the effect of a "single, all-around light," multiple sets of task lights are embedded into each of the four faces of the ship's superstructure. Except when viewing the ship from dead ahead, dead astern or broadside, two deckhouse surfaces are visible; consequently, two sets of task lights are visible simultaneously. Because the deckhouse surfaces are sloped, unless the lights are viewed dead-on, the three task lights do not present as being in a vertical line.

19. \* \* \* \*

Vessel	Number	Distance in meters of sidelights above maximum allowed height
USS MICHAEL MONSOOR .....	DDG 1001	2.23 PORT. 2.52 STBD.
* * * * *		

\* \* \* \* \* 22. \* \* \*

Vessel	Number	Vertical Separation of the task light array is not equally spaced, the separation between the middle and lower task light exceed the separation between the upper and middle light by
USS MICHAEL MONSOOR .....	DDG 1001	FWD: 0.01 meter. AFT: 0.00 meter. PORT: 0.17 meter. STBD: 0.24 meter.
* * * * *		

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstructions; annex 1, sec. 2(f)	Forward masthead light not in forward quarter of ship; annex 1, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light; annex 1, sec.3(a)	Percentage horizontal separation attained
USS MICHAEL MONSOOR .....	DDG 1001	X	X	X	77.2
* * * * *					

Approved: October 3, 2017.  
**A.S. Janin,**  
*Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).*  
 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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**DEPARTMENT OF HOMELAND SECURITY**  
**Coast Guard**  
**33 CFR Part 100**  
**[Docket Number USCG-2017-0858]**  
**RIN 1625-AA08**  
**Special Local Regulation; Clinch River, Oak Ridge, TN**  
**AGENCY:** Coast Guard, DHS.  
**ACTION:** Temporary final rule.  
**SUMMARY:** The Coast Guard is establishing a special local regulation for all navigable waters of the Clinch River from mile marker (MM) 49.5 to MM 54.0. This action is necessary to provide for the safety of life on these navigable waters near Oak Ridge, TN during the Secret City Head Race. Entry

into, transiting through, or anchoring within this regulated area is prohibited unless authorized by the Captain of the Port Sector Ohio Valley (COTP) or a designated representative.  
**DATES:** This rule is effective from 6 a.m. through 6 p.m. on October 21, 2017.  
**ADDRESSES:** To view documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type USCG-2017-0858 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.  
**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call Petty Officer Vera Max, Marine Safety Detachment Nashville, U.S. Coast Guard; telephone 615-736-5421, email [MSDNashville@uscg.mil](mailto:MSDNashville@uscg.mil).  
**SUPPLEMENTARY INFORMATION:**