

#### 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 the guidance document “De Novo Classification Process (Evaluation of Automatic Class III Designation)” have been approved under OMB control number 0910–0844; the collections of information in part 814, subparts A through E, regarding premarket approval, have been approved under OMB control number 0910–0231; the collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120; and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

#### List of Subjects in 21 CFR Part 868

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 868 is amended as follows:

#### PART 868—ANESTHESIOLOGY DEVICES

- 1. The authority citation for part 868 is revised to read as follows:

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

- 2. Add § 868.5105 to subpart F to read as follows:

#### § 868.5105 External negative pressure airway aid.

(a) *Identification.* An external negative pressure airway aid is a prescription device that applies negative pressure to a patient’s neck to aid in providing a patent airway during procedures requiring anesthesia.

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

(1) Clinical performance testing must document any adverse events observed during clinical use, including impaired blood flow, and demonstrate that the device performs as intended under anticipated conditions.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated patient positions, does not fail during use, and does not lose negative pressure

capability. The following testing should be performed:

- (i) Ability of the device to maintain a seal during various patient positions;
  - (ii) Device leakage testing to demonstrate the device maintains vacuum;
  - (iii) Drop testing to ensure the device does not incur functional damage after dropping the device; and
  - (iv) Functional testing after high and low storage temperature.
- (3) All patient contacting components must be demonstrated to be biocompatible.
- (4) Labeling must include:
- (i) A summary of clinical testing results, including any adverse events and evidence that effectiveness has been achieved.
  - (ii) Technical specifications of the device, including collar sizes, maximum duration of use, operating temperature, and storage temperature range.
  - (iii) Technical specifications of the vacuum source, including maximum vacuum level and operational vacuum level.
  - (iv) Instructions for use that includes how to place the device, determination of size, verification of suction, reference to training materials, and information on troubleshooting the device if it does not attach properly.

(v) A warning to screen patients for carotid artery disease due to the probable risk of the device to dislodge arterial plaques in the carotid artery.

(vi) A warning to exclude patients with anatomical abnormalities.

(vii) A warning not to use the device during medical procedures involving medications that contain propofol.

Dated: December 20, 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 USS TULSA (LCS 16) 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 December 26, 2017 and is applicable beginning December 7, 2017.

**FOR FURTHER INFORMATION CONTACT:** Lieutenant Commander Kyle Fralick, JAGC, U.S. Navy, Admiralty Attorney, (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 number: 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 TULSA (LCS 16) 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 height of the forward masthead light above the hull; Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions; Annex I, paragraph 2(f)(ii), pertaining to the vertical placement of task lights; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, and the horizontal distance between the forward and after masthead light; Rule 27(b)(i) and Annex I, paragraph 9(b)(i), pertaining to the arc of visibility of middle tasks lights. 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), and 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 TULSA (LCS 16);
    - b. In Table Four, under paragraph 15, adding, in alpha numerical order, by vessel number, an entry for USS TULSA (LCS 16);
    - c. In Table Four, under paragraph 16, adding, in alpha numerical order, by vessel number, an entry for USS TULSA (LCS 16);
    - d. In Table Four, under paragraph 27, adding, in alpha numerical order, by

vessel number, an entry for USS TULSA (LCS 16); and

■ e. In Table Five, adding, in alpha numerical order, by vessel number, an entry for USS TULSA (LCS 16).

**§ 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 TULSA .....	LCS 16	4.2

\* \* \* \* \* **Table Four** 15. \* \* \*

Vessel	Number	Horizontal distances from the fore and aft centerline of the vessel in the athwartship direction
USS TULSA .....	LCS 16	Upper—0.20 meters. Middle—1.32 meters. Lower—1.40 meters.

16. \* \* \*

Vessel	Number	Obstruction angle relative ship's headings
USS TULSA .....	LCS 16	72° thru 74°. 286° thru 288°.

27. \* \* \*

Vessel	Number	Obstruction angle relative ship heading
USS TULSA .....	LCS 16	47° thru 59°. 301° thru 313°.

Vessel					Number	Obstruction angle relative ship heading
*	*	*	*	*	*	

\* \* \* \* \*

TABLE FIVE

Vessel	Number	Mastheadlights not over all other lights and obstructions annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light annex I, sec. 3(a)	Percentage horizontal separation attained
USS TULSA .....	LCS 16	.....	X	X	15.0

Approved: December 7, 2017.  
**A.S. Janin,**  
*Captain, USN, JAGC, Deputy Assistant Judge Advocate General (Admiralty and Maritime Law).*

Dated: December 13, 2017.  
**E.K. Baldini,**  
*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 117**

[Docket No. USCG-2017-0967]

**Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Alligator River, Columbia, NC**

**AGENCY:** Coast Guard, DHS.  
**ACTION:** Notice of deviation from drawbridge regulation; modification.

**SUMMARY:** The Coast Guard has modified a temporary deviation from the operating schedule that governs the US 64/Alligator River Bridge which carries US 64 over the Atlantic Intracoastal Waterway (AICW), Alligator River, mile 84.2, near Columbia, NC. The deviation is necessary to facilitate bridge maintenance. This deviation allows the bridge to remain in the closed-to-navigation position.

**DATES:** This deviation is effective without actual notice from December 26, 2017 through 6 p.m. on March 29, 2018. For the purposes of enforcement, actual notice will be used from 7 a.m.

on November 6, 2017, until December 26, 2017.  
**ADDRESSES:** The docket for this deviation, USCG-2017-0967, is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Michael Thorogood, Bridge Administration Branch Fifth District, Coast Guard, telephone 757-398-6557, email [Michael.R.Thorogood@uscg.mil](mailto:Michael.R.Thorogood@uscg.mil).

**SUPPLEMENTARY INFORMATION:** On November 1, 2017, the Coast Guard published a temporary deviation entitled "Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Alligator River, Columbia, NC" in the **Federal Register** (82 FR 50577). That document resulted from North Carolina Department of Transportation's request for a temporary deviation, occurring from 7 a.m. on November 6, 2017, through 7 p.m. on November 17, 2017, from normal operation of the drawbridge to facilitate bridge maintenance. Subsequent to the approval of that request, North Carolina Department of Transportation requested a modification, extending the temporary deviation from 7:01 p.m. on November 17, 2017, through 6 p.m. on March 29, 2018, to allow more time to perform and complete additional bridge maintenance discovered during the previous temporary deviation. Therefore, through this document, the Coast Guard modifies the dates of the previously approved temporary deviation to allow the US 64/Alligator River Bridge that carries US 64 over the AICW, Alligator River, mile 84.2, at near Columbia, NC,

to remain in the closed-to-navigation position from 7 a.m. to 7 p.m., on Wednesday, December 27, 2017, through Saturday, December 30, 2017; Monday, January 1, 2018, through Saturday, January 5, 2018; and Monday, January 8, 2018, through Tuesday, January 9, 2018. During these closure periods the bridge will open on signal, if at least 2 hours notice is given. The bridge will also remain in the closed-to-navigation position 24 hours a day, 7 days a week, from 6 a.m. on Wednesday, January 10, 2018, through 6 p.m. on Wednesday, January 17, 2018; and from 6 a.m. on Wednesday, March 14, 2018, through 6 p.m. on Wednesday, March 21, 2018. Alternative work dates for these closure periods will be from noon on Thursday, January 18, 2018, through 6 p.m. on Wednesday, January 24, 2018; and from noon on Thursday, March 22, 2018, through 6 p.m. on Thursday, March 29, 2018. If the alternative work dates from noon on Thursday, January 18, 2018, through 6 p.m. on Wednesday, January 24, 2018 are used, the bridge will also remain in the closed-to-navigation position from 7 a.m. to 6 p.m., Monday through Saturday, from January 22, 2018, through March 14, 2018; except for scheduled daily openings at noon, if at least 2 hours notice is given. If the alternative work dates from noon on Thursday, January 18, 2018, through 6 p.m. on Wednesday, January 24, 2018 are not used, the bridge will also remain in the closed-to-navigation position from 7 a.m. to 6 p.m., Monday through Saturday, from January 17, 2018, through March 14, 2018; except for scheduled daily openings at noon, if at least 2 hours notice is given. The Coast Guard will inform the users of the waterway through our Broadcast Notices to Mariners, if the alternative work dates