

(iii) Statistical performance of the device within clinical risk strata (*e.g.*, age, relevant comorbidities, disease stability) must be reported;

(iv) The dataset must be adequately representative of the intended use population for the device (*e.g.*, patients, range of vessel sizes, imaging device models). Any selection criteria or limitations of the samples must be fully described and justified;

(v) Statistical methods must consider the predefined endpoints:

(A) Estimates of probabilities of incorrect results must be provided for each endpoint,

(B) Where multiple samples from the same patient are used, statistical analysis must not assume statistical independence without adequate justification, and

(C) The report must provide appropriate confidence intervals for each performance metric;

(vi) Sensitivity and specificity must be characterized across the range of available measurements;

(vii) Agreement of the simulated measure(s) with clinically acceptable measure(s) must be assessed across the full range of measurements;

(viii) Comparison of the measurement performance must be provided across the range of intended image acquisition hardware; and

(ix) If the device uses a cutoff threshold or operates across a spectrum of disease, it must be established prior to validation, and it must be justified as to how it was determined and clinically validated;

(4) Adequate validation must be performed and controls implemented to characterize and ensure consistency (*i.e.*, repeatability and reproducibility) of measurement outputs:

(i) Acceptable incoming image quality control measures and the resulting image rejection rate for the clinical data must be specified, and

(ii) Data must be provided within the clinical validation study or using equivalent datasets demonstrating the consistency (*i.e.*, repeatability and reproducibility) of the output that is representative of the range of data quality likely to be encountered in the intended use population and relevant use conditions in the intended use environment;

(A) Testing must be performed using multiple operators meeting planned qualification criteria and using the procedure that will be implemented in the production use of the device, and

(B) The factors (*e.g.*, medical imaging dataset, operator) must be identified regarding which were held constant and which were varied during the

evaluation, and a description must be provided for the computations and statistical analyses used to evaluate the data;

(5) Human factors evaluation and validation must be provided to demonstrate adequate performance of the user interface to allow for users to accurately measure intended parameters, particularly where parameter settings that have impact on measurements require significant user intervention; and

(6) Device labeling must be provided that adequately describes the following:

(i) The device's intended use, including the type of imaging data used, what the device measures and outputs to the user, whether the measure is qualitative or quantitative, the clinical indications for which it is to be used, and the specific population for which the device use is intended;

(ii) Appropriate warnings specifying the intended patient population, identifying anatomy and image acquisition factors that may impact measurement results, and providing cautionary guidance for interpretation of the provided measurements;

(iii) Key assumptions made in the calculation and determination of simulated measurements;

(iv) The measurement performance of the device for all presented parameters, with appropriate confidence intervals, and the supporting evidence for this performance. Per-vessel clinical performance, including where applicable localized performance according to vessel and segment, must be included as well as a characterization of the measurement error across the expected range of measurement for key parameters based on the clinical data;

(v) A detailed description of the patients studied in the clinical validation (*e.g.*, age, gender, race or ethnicity, clinical stability, current treatment regimen) as well as procedural details of the clinical study (*e.g.*, scanner representation, calcium scores, use of beta-blockers or nitrates); and

(vi) Where significant human interface is necessary for accurate analysis, adequately detailed description of the analysis procedure using the device and any data features that could affect accuracy of results.

Dated: October 14, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-26658 Filed 10-20-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Parts 100, 117, 147, and 165 [USCG-2015-0242]

#### Quarterly Listings; Safety Zones, Security Zones, Special Local Regulations, Drawbridge Operation Regulations and Regulated Navigation Areas

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of expired temporary rules issued.

**SUMMARY:** This document provides notice of substantive rules issued by the Coast Guard that were made temporarily effective between January 2015 and March 2015 but expired before they could be published in the **Federal Register**. This notice lists temporary safety zones, security zones, special local regulations, drawbridge operation regulations and regulated navigation areas, all of limited duration and for which timely publication in the **Federal Register** was not possible.

**DATES:** This document lists temporary Coast Guard rules that became effective between January 2015 and March 2015 and were terminated before they could be published in the **Federal Register**.

**ADDRESSES:** Temporary rules listed in this document may be viewed online, under their respective docket numbers, using the Federal eRulemaking Portal at <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** For questions on this notice contact Yeoman First Class Maria Fiorella Villanueva, Office of Regulations and Administrative Law, telephone (202) 372-3862.

**SUPPLEMENTARY INFORMATION:** Coast Guard District Commanders and Captains of the Port (COTP) must be immediately responsive to the safety and security needs within their jurisdiction; therefore, District Commanders and COTPs have been delegated the authority to issue certain local regulations. *Safety zones* may be established for safety or environmental purposes. A safety zone may be stationary and described by fixed limits or it may be described as a zone around a vessel in motion. *Security zones* limit access to prevent injury or damage to vessels, ports, or waterfront facilities. *Special local regulations* are issued to enhance the safety of participants and spectators at regattas and other marine events. *Drawbridge operation regulations* authorize changes to

drawbridge schedules to accommodate bridge repairs, seasonal vessel traffic, and local public events. *Regulated Navigation Areas* are water areas within a defined boundary for which regulations for vessels navigating within the area have been established by the regional Coast Guard District Commander.

Timely publication of these rules in the **Federal Register** may be precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, often informed of these rules through Local Notices to Mariners, press releases, and other means. Moreover, actual notification is provided by Coast Guard patrol vessels

enforcing the restrictions imposed by the rule. Because **Federal Register** publication was not possible before the end of the effective period, mariners were personally notified of the contents of these safety zones, security zones, special local regulations, regulated navigation areas or drawbridge operation regulations by Coast Guard officials on-scene prior to any enforcement action. However, the Coast Guard, by law, must publish in the **Federal Register** notice of substantive rules adopted. To meet this obligation without imposing undue expense on the public, the Coast Guard periodically publishes a list of these temporary safety zones, security zones, special

local regulations, regulated navigation areas and drawbridge operation regulations. Permanent rules are not included in this list because they are published in their entirety in the **Federal Register**. Temporary rules are also published in their entirety if sufficient time is available to do so before they are placed in effect or terminated.

The following unpublished rules were placed in effect temporarily during the period between January 2015 and March 2015 unless otherwise indicated. To view copies of these rules, visit [www.regulations.gov](http://www.regulations.gov) and search by the docket number indicated in the list below.

Docket No.	Location	Type	Effective date
USCG-2014-1035	Clearwater Beach, FL	Safety Zones (Parts 147 and 165)	12/21/2014
USCG-2014-1033	Wilmington, DE	Safety Zones (Parts 147 and 165)	12/9/2014
USCG-2014-1046	Miami, FL	Safety Zones (Parts 147 and 165)	12/31/2014
USCG-2014-1010	Oahu, HI	Security Zones (Part 165)	12/18/2014
USCG-2014-0957	Owensboro, KY	Security Zones (Part 165)	10/21/2014
USCG-2014-1014	St. Petersburg, FL	Safety Zones (Parts 147 and 165)	12/25/2014
USCG-2014-1067	Wilmington, NC	Safety Zones (Parts 147 and 165)	1/8/2015
USCG-2014-0826	Chicago, IL	Safety Zones (Parts 147 and 165)	9/5/2014
USCG-2014-0081	Buffalo, NY	Safety Zones (Parts 147 and 165)	9/6/2014
USCG-2014-1058	Tampa, FL	Safety Zones (Parts 147 and 165)	1/11/2015
USCG-2014-0817	Township, MI	Safety Zones (Parts 147 and 165)	9/4/2014
USCG-2014-0810	St. Clair Shores, MI	Safety Zones (Parts 147 and 165)	9/6/2014
USCG-2014-0815	Ecorse, MI	Safety Zones (Parts 147 and 165)	9/2/2014
USCG-2014-0779	Toledo, OH	Safety Zones (Parts 147 and 165)	8/29/2014
USCG-2014-0682	Cincinnati, OH	Safety Zones (Parts 147 and 165)	8/31/2014
USCG-2014-0615	Orange Beach, AL	Special Local Regulations (Part 100)	8/22/2014
USCG-2014-0595	Cleveland, OH	Safety Zones (Parts 147 and 165)	7/27/2014
USCG-2014-0346	Ledbetter, KY	Safety Zones (Parts 147 and 165)	4/27/2014
USCG-2014-1072	Oak Island, NC	Safety Zones (Parts 147 and 165)	1/4/2015
USCG-2015-0009	Washington, DC	Security Zones (Part 165)	1/20/2015
USCG-2015-0080	Tracy, CA	Drawbridges (Part 117)	2/11/2015
USCG-2015-0043	Wilmington, NC	Safety Zones (Parts 147 and 165)	1/23/2015
USCG-2015-0081	Walnut Grove, CA	Drawbridges (Part 117)	2/17/2015
USCG-2015-0091	Queen Ann County, MD	Safety Zones (Parts 147 and 165)	2/16/2015
USCG-2014-0989	Mt. Vernon, IN	Safety Zones (Parts 147 and 165)	12/1/2014
USCG-2014-1022	Rockport, KY	Safety Zones (Parts 147 and 165)	12/1/2014
USCG-2015-0124	Fort Pierce, FL	Safety Zones (Parts 147 and 165)	2/26/2015
USCG-2015-0015	Port NY Zone, NY	Safety Zones (Parts 147 and 165)	2/17/2015
USCG-2015-0106	Pacific Ocean, CA	Safety Zones (Parts 147 and 165)	2/17/2015
USCG-2015-0147	Wilmington, NC	Safety Zones (Parts 147 and 165)	3/8/2015
USCG-2015-0026	Los Angeles, CA	Safety Zones (Parts 147 and 165)	1/20/2015
USCG-2015-0089	Naples, FL	Safety Zones (Parts 147 and 165)	3/7/2015
USCG-2015-0033	Alameda, CA	Safety Zones (Parts 147 and 165)	2/9/2015
USCG-2015-0032	Tacoma, WA	Safety Zones (Parts 147 and 165)	1/22/2015
USCG-2015-0077	Miami, FL	Security Zones (Part 165)	2/13/2015
USCG-2015-0047	Fort Myers, FL	Security Zones (Part 165)	1/30/2015
USCG-2014-0139	Marcus Hook, PA	Anchorage	3/20/2015
USCG-2015-0116	San Francisco, CA	Safety Zones (Parts 147 and 165)	3/21/2015
USCG-2015-0153	Boston, MA	Security Zones (Part 165)	3/29/2015
USCG-2015-0044	Biloxi, MS	Safety Zones (Parts 147 and 165)	3/27/2015
USCG-2015-0143	New Orleans, LA	Safety Zones (Parts 147 and 165)	3/26/2015
USCG-2015-0160	Pensacola, FL	Safety Zones (Parts 147 and 165)	3/24/2015
USCG-2015-0173	Fort Walton Beach, FL	Safety Zones (Parts 147 and 165)	3/11/2015

#### K. Kroutil,

Chief, Office of Regulations and Administrative Law.

[FR Doc. 2015-26623 Filed 10-20-15; 8:45 am]

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