

§ 864.1860 Immunohistochemistry reagents and kits.**(a) Identification.**

Immunohistochemistry test systems (IHC's) are in vitro diagnostic devices consisting of polyclonal or monoclonal antibodies labeled with directions for use and performance claims, which may be packaged with ancillary reagents in kits. Their intended use is to identify, by immunological techniques, antigens in tissues or cytologic specimens. Similar devices intended for use with flow cytometry devices are not considered IHC's.

(b) Classification of**immunohistochemistry devices—(1)**

Class I (general controls). Except as described in paragraphs (b)(2) and (b)(3) of this section, these devices are exempt from the premarket notification requirements in part 807, subpart E of this chapter. This exemption applies to IHC's that provide the pathologist with adjunctive diagnostic information that may be incorporated into the pathologist's report, but that is not ordinarily reported to the clinician as an independent finding. These IHC's are used after the primary diagnosis of tumor (neoplasm) has been made by conventional histopathology using nonimmunologic histochemical stains, such as hematoxylin and eosin. Examples of class I IHC's are differentiation markers that are used as adjunctive tests to subclassify tumors, such as keratin.

(2) Class II (special control, guidance document: "FDA Guidance for Submission of Immunohistochemistry Applications to the FDA," Center for Devices and Radiologic Health, 1998). These IHC's are intended for the detection and/or measurement of certain target analytes in order to provide prognostic or predictive data that are not directly confirmed by routine histopathologic internal and external control specimens. These IHC's provide the pathologist with information that is ordinarily reported as independent diagnostic information to the ordering clinician, and the claims associated with these data are widely accepted and supported by valid scientific evidence. Examples of class II IHC's are those intended for semiquantitative measurement of an analyte, such as hormone receptors in breast cancer.

(3) Class III (premarket approval). IHC's intended for any use not described in paragraphs (b)(1) or (b)(2) of this section.

(c) *Date of PMA or notice of completion of a PDP is required.* As of May 28, 1976, an approval under section 515 of the Federal Food, Drug, and Cosmetic Act is required for any

device described in paragraph (b)(3) of this section before this device may be commercially distributed. See § 864.3.

Dated: February 6, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 100**

[CGD 05-98-035]

RIN 2115-AE46

Special Local Regulations for Marine Events; The Great Chesapeake Bay Swim Event, Chesapeake Bay, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements 33 CFR 100.507 for the Great Chesapeake Bay Swim Event to be held on June 14, 1998. These special local regulations are needed to provide for the safety of participants and spectators on the navigable waters during this event. The effect will be to restrict general navigation in the regulated area for the safety of participants in the swim and their attending personnel.

EFFECTIVE DATE: 33 CFR 100.507 is effective from 10 a.m. until 4 p.m., on June 14, 1998.

FOR FURTHER INFORMATION CONTACT:

LT J. Driscoll, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Rd., Baltimore, MD 21226-1797, (410) 576-2676.

SUPPLEMENTARY INFORMATION: The March of Dimes will sponsor the Great Chesapeake Bay Swim Event on Chesapeake Bay in the vicinity of the William P. Lane Jr. Memorial Twin Bridges. Approximately 600 swimmers will start from Sandy Point State Park and swim between the William P. Lane Jr. Memorial Twin Bridges to the Eastern Shore. A large fleet of support vessels will be accompanying the swimmers. Therefore, to ensure the safety of the participants and support vessels, 33 CFR 100.507 will be in effect for the duration of the event. Under provisions of 33 CFR 100.507, no vessels may enter the regulated area without permission of the Coast Guard patrol commander. Vessel traffic will be permitted to transit the regulated area as the swim progresses. As a result,

maritime traffic should not be significantly disrupted.

Dated: May 20, 1998.

Roger T. Rufe, Jr.

Vice Admiral, U.S. Coast Guard Commander, Fifth Coast Guard District.

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DEPARTMENT OF TRANSPORTATION**Coast Guard****33 CFR Part 100**

[CGD01-98-057]

RIN 2115-AE46

Special Local Regulation: Fireworks Displays Within the First Coast Guard District

AGENCY: Coast Guard, DOT.

ACTION: Notice of Implementation.

SUMMARY: This document provides notice of the dates and times of the special local regulations contained in 33 CFR 100.114, Fireworks Displays Within the First Coast Guard District. All vessels will be restricted from entering the area of navigable water within a 500-yard radius of the fireworks launch platform for each event listed in the table below. Implementation of these regulations is necessary to control vessel traffic within the regulated area to ensure the safety of spectators.

EFFECTIVE DATE: The regulations in 33 CFR 100.114 are effective from one hour before the scheduled start of the event until thirty minutes after the last firework is exploded for each event listed in the table below. The events are listed chronologically by month with their corresponding number listed in the special local regulations, 33 CFR 100.114.

ADDRESSES: Comments should be mailed to Commander (osr), First Coast Guard District, Captain John Foster Williams Federal Building, 408 Atlantic Ave., Boston, MA 02110-3350, or may be hand delivered to Room 734 at the same address, between 8 a.m. and 4 p.m., Monday through Friday, except federal holidays. Comments will become part of this docket and will be available for inspection or copying at the above address.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Commander Mark A. Cawthorn, Office of Search and Rescue Branch, First Coast Guard District at (617) 223-8460.

SUPPLEMENTARY INFORMATION: This notice implements the special local