

exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain federal requirements applicable to devices. 21 U.S.C. 360k; *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 128 S. Ct. 999 (2008). The special controls established by this final rule create “requirements” for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements. (*Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997)).

V. How Does This Rule Comply With the Paperwork Reduction Act of 1995?

This final rule establishes as special controls three guidance documents 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 no. 0910–0120. The collections of information in 21 CFR part 801 and 21 CFR 809.10, regarding labeling, have been approved under OMB control no. 0910–0485.

VI. What References Are on Display?

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Luminex Molecular Diagnostics, Inc., dated December 1, 2007.

List of Subjects in 21 CFR Part 866

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 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Section 866.3980 is added to subpart D to read as follows:

§ 866.3980 Respiratory viral panel multiplex nucleic acid assay.

(a) *Identification.* A respiratory viral panel multiplex nucleic acid assay is a qualitative in vitro diagnostic device intended to simultaneously detect and identify multiple viral nucleic acids extracted from human respiratory specimens or viral culture. The detection and identification of a specific viral nucleic acid from individuals exhibiting signs and symptoms of respiratory infection aids in the diagnosis of respiratory viral infection when used in conjunction with other clinical and laboratory findings. The device is intended for detection and identification of a combination of the following viruses:

- (1) Influenza A and Influenza B;
- (2) Influenza A subtype H1 and Influenza A subtype H3;
- (3) Respiratory Syncytial Virus subtype A and Respiratory Syncytial Virus subtype B;
- (4) Parainfluenza 1, Parainfluenza 2, and Parainfluenza 3 virus;
- (5) Human Metapneumovirus;
- (6) Rhinovirus; and
- (7) Adenovirus.

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

- (1) FDA’s guidance document entitled “Class II Special Controls Guidance Document: Respiratory Viral Panel Multiplex Nucleic Acid Assay;”
- (2) For a device that detects and identifies Human Metapneumovirus, FDA’s guidance document entitled “Class II Special Controls Guidance Document: Testing for Human Metapneumovirus (hMPV) Using Nucleic Acid Assays;” and
- (3) For a device that detects and differentiates Influenza A subtype H1 and subtype H3, FDA’s guidance document entitled “Class II Special Controls Guidance Document: Testing for Detection and Differentiation of Influenza A Virus Subtypes Using Multiplex Nucleic Acid Assays.” See § 866.1(e) for the availability of these guidance documents.

Dated: October 1, 2009.

Jeffrey Shuren,

Acting Director, Center for Devices and Radiological Health.

[FR Doc. E9–24432 Filed 10–8–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

National Indian Gaming Commission

25 CFR Parts 542 and 543

RIN 3141–AA–37

Minimum Internal Control Standards for Class II Gaming

AGENCY: National Indian Gaming Commission.

ACTION: Final rule; delay of effective date.

SUMMARY: The National Indian Gaming Commission (“NIGC”) announces the extension of the effective date on the final rule for Minimum Internal Control Standards for Class II Gaming. The final rule was published in the **Federal Register** on October 10, 2008. The Commission has changed the effective date for the amendments to §§ 542.7 and 542.16 as well as the date for operations to implement tribal internal controls found in 543.3(c)(3) to October 13, 2010, in order to extend the transition time.

DATES: Effective Date: The effective date for the amendments to §§ 542.7 and 542.16 for the final rule published October 10, 2008, at 73 FR 60492, is delayed from October 13, 2009, until October 13, 2010. The effective date for the amendment to § 543.3(c)(3) is October 9, 2009.

FOR FURTHER INFORMATION CONTACT: John R. Hay, Attorney, Office of General Counsel, at (202) 632–7003; fax (202) 632–7066 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: Congress established the National Indian Gaming Commission under the Indian Gaming Regulatory Act of 1988 (25 U.S.C. 2701–21) (“IGRA”) to regulate gaming on Indian lands. The NIGC issued a final rule that superseded specified sections of established Minimum Internal Control Standards and replaced them with a new part titled Minimum Internal Control Standards Class II Gaming, that was published in the **Federal Register** on October 10, 2008 (73 FR 60492). The final rule provided an effective date for amendments to §§ 542.7 and 542.16 of October 13, 2009. The NIGC is extending the effective date for these amendments to October 13, 2010. The rule at § 543.3(c)(3) also set a deadline of within six months of the date the tribal gaming regulatory authorities’ enactment of tribal internal controls for tribal operators to come into compliance with tribal internal controls. This deadline has likewise been extended to October 13, 2010.

List of Subjects in 25 CFR Part 543

Administrative practice and procedure, Gambling, Indians—lands, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, under the authority at 25 U.S.C. 2701, 2702, 2706, *et seq.*, the effective date for the amendments to §§ 542.7 and 542.16 for the final rule published October 10, 2008, at 73 FR 60492, is delayed from October 13, 2009, until October 13, 2010 and 25 CFR Part 543.3 is amended as set forth below:

PART 543—MINIMUM INTERNAL CONTROL STANDARDS FOR CLASS II GAMING

■ 1. The authority citation for Part 543 continues to read as follows:

Authority: 25 U.S.C. 2701 *et seq.*

■ 2. Section 543.3 is amended by revising paragraph (c)(3) to read as follows:

§ 543.3 How do tribal governments comply with this part?

* * * * *

(c) * * *

(3) Establish a deadline, no later than October 13, 2010, by which a gaming operation must come into compliance with the tribal internal control standards. However, the tribal gaming regulatory authority may extend the deadline by six months if written notice citing justification is provided to the Commission no later than two weeks before the deadline.

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Dated: October 5, 2009.

George T. Skibine,

Acting Chairman.

Norman H. DesRosiers,

Vice Chairman.

[FR Doc. E9-24434 Filed 10-8-09; 8:45 am]

BILLING CODE 7565-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Parts 100, 117, 147, and 165**

[USCG-2009-0909]

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

AGENCY: Coast Guard, DHS.

ACTION: Notice of expired temporary rules issued.

SUMMARY: This document provides required notice of substantive rules issued by the Coast Guard and temporarily effective between February 2006 and January 2008, that expired before they could be published in the **Federal Register**. This notice lists temporary safety zones, security zones, special local regulations, regulated navigation areas and drawbridge operation regulations, all of limited duration and for which timely publication in the **Federal Register** was not possible.

DATES: This document lists temporary Coast Guard rules between February 9, 2006 and January 12, 2008 that became effective and were terminated before they could be published in the **Federal Register**.

ADDRESSES: The Docket Management Facility maintains the public docket for this notice. Documents indicated in this notice will be available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building ground floor, room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590 between 9 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: For questions on this notice contact Yeoman First Class Denise Johnson, Office of Regulations and Administrative Law, telephone (202) 372-3862. For questions on viewing, or on submitting material to the docket, contact Ms. Angie Ames, Docket Operations, telephone 202-366-5115.

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 and may also describe a zone around a vessel in motion. *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** is often precluded when a rule responds to an emergency, or when an event occurs without sufficient advance notice. The affected public is, however, 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 beginning 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 temporary rules listed in this notice have been exempted from review under Executive Order 12666, Regulatory Planning and Review, because of their emergency nature, or limited scope and temporary effectiveness.

The following unpublished rules were placed in effect temporarily during the period between February 2006 and January 2008, unless otherwise indicated.

Dated: September 30, 2009.

S.G. Venckus,

Chief, Office of Regulations and Administrative Law.