4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 033

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews ("FDA Recognized Consensus Standards"). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 033" ("Recognition List Number: 033"), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 033" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149.

Submit electronic comments concerning this document, or recommendations for additional standards for recognition, by email to standards@cdrh.fda.gov. Submit written comments to the contact person (see FOR FURTHER INFORMATION CONTACT). This document may also be accessed on FDA's Internet site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 033 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993-0002, 301-796-6287.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the Federal Register of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the Federal Register, can be accessed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 033

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database, using the term "Recognition List Number: 033" to identify these current modifications.

In table 1 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable; (2) the correction of errors made by FDA in listing previously recognized standards; and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Anesthesia			
1-60		IEC 60601-2-12 (2001-10) Medical electrical equipment--Part 2-12: Particular requirements for the safety of lung ventilators--Critical care ventilators	Withdrawn. Transition period expired. See 1-88
1-61		IEC 60601-2-13 (2003-05) Medical electrical equipment--Part 2-13: Particular requirements for the safety and essential performance of anesthetic systems	Withdrawn. Transition period expired. See 1-82
1-66		ISO 9919:2005 Medical electrical equipment--Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use	Withdrawn. Transition period expired. See 1-85
B. Cardiovascular			
3-38		IEC 60601-2-34 (2000-10) Medical electrical equipment--Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	Withdrawn. Transition period expired. See 3-115
C. Dental/ENT			
4-122		IEC 60601-2-18:1996 Amendment 1 2000 Medical electrical equipment--Part 2-18: Particular requirements for the safety of endoscopic equipment	Withdrawn. Transition period expired. See 4-187
D. General			
5-4		IEC 60601-1 1988; Amendment 1, 1991-11, Amendment 2, 1995 Medical electrical equipment--Part 1: General requirements for safety and essential performance	Withdrawn. Transition period expired. See 5-77
5-27		IEC 60601-1-1:2000 Medical electrical equipment--Part 1-1: General requirements for safety--Collateral standard: Safety requirements for medical electrical systems	Withdrawn.
5-34		IEC 60601-1-2 Medical electrical equipment--Part 1-2: General requirements for safety--Collateral standard: Electromagnetic compatibility--Requirements and tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1) (Edition 2:2001 consolidated with Amendment 1:2004)	Withdrawn. Transition period expired. See 5-53
5-35		ANSI/AAMI/IEC 60601-1-2:2001 Medical electrical equipment--Part 1-2: General requirements for safety--Collateral standard: Electromagnetic compatibility--Requirements and tests	Withdrawn. Transition period expired. See 5-54
5-41		IEC 60601-1-4 Edition 1.1 2000-04 Medical electrical equipment--Part 1-4: General requirements for safety--Collateral standard: Programmable electrical medical systems	Withdrawn.
5-49		IEC 60601-1-8 First edition 2003-08 Medical electrical equipment--Part 1-8: General requirements for safety--Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems	Withdrawn. Transition period expired. See 5-76
5-60		IEC 60601-1-2 Int. 1 Third edition/I-SH 01:2007 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic compatibility--Requirements and tests, interpretation sheet	Withdrawn. See 5-53

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
5-77		ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Transition period extended.
E. General Hospital/General Plastic Surgery			
6-9		IEC 60601-2-21 First edition 1994-02 Medical electrical equipment--Part 2: Particular requirements for the safety of infant radiant warmers	Withdrawn. Transition period expired. See 6-300
6-29		IEC 60601-2-19 First edition 1990-12 Medical electrical equipment--Part 2: Particular requirements for safety of baby incubators	Withdrawn. Transition period expired. See 6-298
6-32		IEC 60601-2-20 First edition 1990-12 Medical electrical equipment--Part 2: Particular requirements for safety of transport incubators	Withdrawn. Transition period expired. See 6-299
6-146		ANSI/AAMI/IEC 60601-2-21 First edition 1994-02 and Amendment 1:2000 Medical electrical equipment--Part 2: Particular requirements for safety of infant radiant warmers	Withdrawn. Transition period expired. See 6-227
6-182		IEC 60601-2-38 First edition 1996-10 and Amendment 1:1999 Medical electrical equipment--Part 2-38: Particular requirements for the safety of electrically operated hospital beds	Withdrawn. Transition period expired. See 6-233
6-197		IEC 60601-2-2 Ed. 1.0 Medical electrical equipment--Part 2-2: Particular requirements for the safety of high-frequency surgical equipment	Withdrawn. Transition period expired. See 6-228
F. Neurology			
17-5		IEC 60601-2-10 First edition 1987, Amendment 1 2001-09 Medical electrical equipment--Part 2-10: Particular requirements for the safety of nerve and muscle stimulators	Withdrawn. Transition period expired. See 17-11
G. OB-GYN/Gastroenterology			
9-4		IEC 60601-2-16 Second edition 1998-02 Medical electrical equipment--Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration, and haemofiltration equipment	Withdrawn. Transition period expired. See 9-80
9-42		IEC 60601-2-18 Second edition 1996-08, Amendment 1 2000-07 Medical electrical equipment--Part 2-18: Particular requirements for the safety of endoscopic equipment	Withdrawn. Transition period expired. See 9-61
9-46		IEC 60601-2-2 Fourth edition 2006-07 Medical electrical equipment--Part 2-2: Particular requirements for the safety of high frequency surgical equipment	Withdrawn. Transition period expired. See 9-62
H. Radiology			
12-34		IEC 60601-2-7 Second edition 1998-02 Medical electrical equipment--Part 2-7: Particular requirements for the safety of high-voltage generators of diagnostic x ray generators	Withdrawn. Transition period expired. See 12-251
12-54		IEC 60601-2-8 Edition 1.1 1999-04 Medical electrical equipment--Part 2-8: Particular requirements for the safety of therapeutic x ray equipment operating in the range 10 kilovolt (kV) to 1 millivolt (mV)	Withdrawn. Transition period expired. See 12-254
12-63		IEC 60601-2-43 Edition 1.0 2000-06 Medical electrical equipment--Part 2-43: Particular requirements for the safety of x ray equipment for interventional procedures	Withdrawn. Transition period expired. See 12-202

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-120		IEC 60601-2-44 Edition 2.1 2002-11 Medical electrical equipment--Part 2-44: Particular requirements for the safety of x ray equipment for computed tomography	Withdrawn. Transition period expired. See 12-256
12-126		IEC 60601-2-28 First Edition 1.0 1993-03 Medical electrical equipment--Part 2-28: Particular requirements for the safety of x ray source assemblies and x ray tube assemblies for medical diagnosis	Withdrawn. Transition period expired. See 12-204
12-127		60601-2-32 First edition 1994-03 Medical electrical equipment--Part 2-32: Particular requirements for the safety of associated equipment of x ray equipment	Withdrawn. Transition period expired. See 12-201
12-133		IEC 60601-2-11 Second edition 1997-08, Amendment 1, 2004-07 Medical electrical equipment--Part 2-11: Particular requirements for the safety of gamma beam therapy equipment	Withdrawn. Transition period expired. See 12-255
12-147		IEC 60601-2-5 Edition 2.0 2000-07 Medical electrical equipment--Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment	Withdrawn. Transition period expired. See 12-205
12-152		IEC 60601-2-1 Second edition 1998-06, Amendment 1 2002-05 Medical electrical equipment--Part 2-1: Particular requirements for the safety of electron accelerators in the range 1 megaelectronvolts (MeV) to 50 MeV	Withdrawn. Transition period expired. See 12-206
12-178		IEC 60601-2-45 Edition 2.0 2001-05 Medical electrical equipment--Part 2-45: Particular requirements for the safety of mammographic x ray equipment and mammographic stereotactic devices	Withdrawn. Transition period expired. See 12-236
12-189		IEC 60601-2-33 Edition 2.2 2008-04 Medical electrical equipment--Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis	Withdrawn. Transition period expired. See 12-207
12-197		IEC 60601-2-22 Second edition 1995-11 Medical electrical equipment--Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment	Withdrawn. Transition period expired. See 12-208
12-198		IEC 60601-2-37 First edition 2007-01, Amendment 1 2004-08, Amendment 2 2005-11 Medical electrical equipment--Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Withdrawn. Transition period expired. See 12-209
12-199		IEC 60601-1-3 First edition 1994-07 Medical electrical equipment--Part 1-3: General requirements for safety--3. Collateral standard: General requirements for radiation protection in diagnostic x ray equipment	Withdrawn. Transition period expired. See 12-210
12-200		IEC 60601-2-29 Second edition 1999-01 Medical electrical equipment--Part 2-29: Particular requirements for the safety of radiotherapy simulators	Withdrawn. Transition period expired. See 12-211
12-207		IEC 60601-2-33 Edition 3.0 2010-03, Medical electrical equipment--Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic	Transition period extended.
12-208		IEC 60601-2-22 Third edition 2007-05 Medical electrical equipment--Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic, and diagnostic laser equipment	Transition period extended

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-210		IEC 60601-1-3 Edition 2.0 2008-01 Medical electrical equipment--Part 1-3: General requirements for basic safety and essential performance--Collateral standard: Radiation protection in diagnostic x ray equipment	Transition period extended

[1]All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 2 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 033.

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
A. General		
5-78	Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text)
B. Radiology		
12-257	Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of x ray equipment for computed tomography	IEC 60601-2-44 Edition 3.0 2009-02
12-268	Medical electrical equipment--Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	IEC 60601-2-22 Edition 3.1 2012-10
12-269	Medical electrical equipment--Part 1-3: General requirements for basic safety and essential performance--Collateral standard: radiation protection in diagnostic x ray equipment	IEC 60601-1-3 Edition 2.1 2013-04
12-271	Medical electrical equipment--Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	IEC 60601-2-33 Edition 3.1 2013-04

[1] All standard titles in this table conform to the style requirements of the respective organizations.

IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at our Internet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. We will incorporate the modifications and revisions described in this notice into the database and, upon publication in

the Federal Register, this recognition of consensus standards will be effective. We will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the Federal Register once a year, or more often if necessary. Beginning with Recognition List Number: 033, we will no longer be announcing minor revisions to the list of recognized consensus standards such as technical contact person, relevant guidance, processes affected, Code of Federal Regulations citations, and product codes.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to the contact person (see FOR FURTHER INFORMATION CONTACT). To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the Federal Register, this

notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 033" will be available on the CDRH home page. You may access the CDRH home page at http://www.fda.gov/MedicalDevices.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.

This Federal Register document on modifications in FDA's recognition of consensus standards is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments concerning this document, or recommendations for additional standards for recognition, by email to standards@cdrh.fda.gov or written comments to the contact person (see FOR FURTHER INFORMATION CONTACT). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 033. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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