4164-01-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: 045

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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: 045" (Recognition List Number: 045), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your

comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2004-N-0451 for "Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 045." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at

http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. 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: 045.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket

number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 045 is available on the Internet 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: 045 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 045" to Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5514, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5514, Silver Spring, MD 20993, 301-796-6287, standards@cdrh.fda.gov.

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 document 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 document 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 documents 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: 045

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. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term "Recognition List Number: 045" to identify these current modifications.

In table 1, 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, 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. General I (Quality Systems/Risk Management) (QS/RM)			
5-85	--	IEC 60601-1-6 Edition 3.0 2010-01 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.	Withdrawn. See Rec# 5-89.
5-86	--	IEC 60601-1-8 Edition 2.0 2006-10 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.	Withdrawn. See Rec# 5-76.
5-106	5-109	ISO 80369-3 First edition 2016-07-01 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications.	Withdrawn and replaced with newer version.
B. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19-3	--	IEC 60601-1-10 Edition 1.0 2007-11 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: requirements for the development of physiologic closed-loop controllers.	Withdrawn. See Rec# 19-9.
19-5	--	AAMI/ANSI ES60601-1:2005/(R) 2012 and 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).	Withdrawn. See Rec# 19-4.
C. General Hospital/General Plastic Surgery (GH/GPS)			
6-362	6-379	ISO 7864 Fourth edition 2016-08-01 Sterile hypodermic needles for single use - Requirements and test methods	Withdrawn and replaced with newer version.
6-366	6-380	ISO 9626 Second edition 2016-08-01 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods.	Withdrawn and replaced with newer version.
6-376	6-381	ISO 6009 Fourth edition 2016-08-01 Hypodermic needles for single use - Colour coding for identification	Withdrawn and replaced with a newer version.
6-378	6-382	ISO 11608-7 First edition 2016-08-01 Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment.	Withdrawn and replaced with a newer version.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
D. Obstetrics-Gynecology (OB-GYN)/Gastroenterology/Urology			
9-61	--	IEC 60601-2-18 Edition 3.0 2009-08 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Combined with 4-187.
E. Ophthalmic			
10-51	--	ISO 15004-2 First edition 2007-02-15 Ophthalmic Instruments - Fundamental requirements and test methods - Part 2: Light hazard protection.	Transition period.
F. Radiology			
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.	Withdrawn. See Rec# 12-268.
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.	Withdrawn. See Rec# 12-269.

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

III. Listing of New Entries

In table 2, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 045.

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

Recognition No.	Title of Standard[1]	Reference No. and Date
A. General I (Quality Systems/Risk Management) (QS/RM)		
5-110	Packaged-Products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.	ISTA 3A 2008
5-111	Packaged-Products for Less-Than-Truckload (LTL) Shipment.	ISTA 3B 2012
5-112	Unitized Loads of Same Product.	ISTA 3E 2009
B. In Vitro Diagnostics (IVD)		
7-265	Liquid Chromatography-Mass Spectrometry Methods; Approved Guideline.	C62-A: 2014.
7-266	A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures.	EP19 Second Edition: 2015.
C. Ophthalmic		
10-101	Ophthalmic optics - Contact lenses and contact lens care products - Cytotoxicity testing of contact lenses in combination with lens care solution to evaluate lens/solution interactions.	ISO 18189 First edition 2016-06-01
10-102	American National Standard for Ophthalmics - Light Hazard Protection for Ophthalmic Instruments.	ANSI Z80.36 - 2016

[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 FDA's Internet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. FDA 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. FDA 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 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, 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 standards@cdrh.fda.gov. 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, http://www.fda.gov/MedicalDevices, includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the Federal Register, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 045" will be available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. 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.

Dated: September 15, 2016.

Leslie Kux,
Associate Commissioner for Policy.
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