4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451] (formerly 2004N-0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 032

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). Specifically, this publication announces the addition of a list of recognized standards that are relevant to interoperability of medical devices. This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 032" (Recognition List Number: 032), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

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

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 032" 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, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149. Submit written comments concerning this document, or

recommendations for additional standards for recognition, to the contact person (see FOR FURTHER INFORMATION CONTACT). Submit electronic comments by email: standards@cdrh.fda.gov. This document may also be accessed on FDA's Internet site at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 032 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, 301-796-6287.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 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 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: 032

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: 032" to identify these current modifications.

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

III. Listing of New Entries

In table 1, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 032.

Table 1.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
Software/Informatics		
13-38	Application of risk management for IT networks incorporating medical devices--Part 1: Roles, responsibilities and activities	IEC 80001-1 Edition 1.0 2010-10
13-39	Application of risk management for IT networks incorporating medical devices--Part 1: Roles, responsibilities and activities	ANSI/AAMI/IEC 80001-1:2010
13-40	Application of risk management for IT networks incorporating medical devices--Part 2-1: Step-by-step risk management of medical IT networks--Practical applications and examples	IEC/TR 80001-2-1 Edition 1.0 2012-07
13-41	Application of risk management for IT networks incorporating medical devices--Part 2-1: Step by step risk management of medical IT networks; Practical applications and examples	ANSI/AAMI/IEC TIR80001-2-1:2012
13-42	Application of risk management for IT networks incorporating medical devices--Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	IEC/TR 80001-2-2 Edition 1.0 2012-07
13-43	Application of risk management for IT networks incorporating medical devices--Part 2-2: Guidance for the disclosure and communication of medical device security needs, risks and controls	ANSI/AAMI/IEC TIR80001-2-2:2012
13-44	Application of risk management for IT networks incorporating medical devices--Part 2-3: Guidance for wireless networks	IEC/TR 80001-2-3 Edition 1.0 2012-07
13-45	Application of risk management for IT networks incorporating medical devices--Part 2-3: Guidance for wireless networks	ANSI/AAMI/IEC TIR80001-2-3:2012
13-46	Medical Devices and Medical Systems--Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)--Part 1: General requirements and conceptual model	ASTM F2761-09
13-47	Health informatics--Point-of-care medical device communication--Part 10101: Nomenclature	ISO/IEEE 11073-10101 First edition 2004-12-15
13-48	Health informatics--Point-of-care medical device communication--Part 10201: Domain information model	ISO/IEEE 11073-10201 First edition 2004-12-15
13-49	Health informatics--Point-of-care medical device communication--Part 20101: Application Profiles--Base Standard	ISO/IEEE 11073-20101 First edition 2004-12-15
13-50	Health informatics--Personal health device communication--Part 20601: Application profile--Optimized exchange protocol	ISO/IEEE 11073-20601 First edition 2010-05-01
13-51	Health informatics--Personal health device communication--Part 20601: Application profile--Optimized Exchange Protocol Amendment 1	IEEE Std 11073-20601a-2010
13-52	Health informatics--Point-of-care medical device communication--Part 10408: Device specialization--Thermometer	ISO/IEEE 11073-10408 First edition 2010-05-01
13-53	Health informatics--Point-of-care medical device communication--Part 10415: Device specialization--Weighing scale	ISO/IEEE 11073-10415 First edition 2010-05-01
13-54	Health informatics--Personal health device communication--Part 10404: Device specialization--Pulse oximeter	ISO/IEEE 11073-10404 First edition 2010-05-01
13-55	Health informatics--Personal health device communication--Part 10421: Device specialization--Peak expiratory flow monitor (peak flow)	IEEE Std 11073-10421-2010
13-56	Health informatics--Personal health device communication--Part 10406: Device specialization--Basic electrocardiograph (ECG) (1- to 3-lead ECG)	IEEE Std 11073-10406-2011
13-57	Health informatics--Personal health device communication--Part 10407: Device specialization--Blood pressure monitor	ISO/IEEE 11073-10407 First edition 2010-05-01
13-58	Health informatics--Personal health device communication--Part 10417: Device specialization--Glucose meter	ISO/IEEE 11073-10417 First edition 2010-05-01

Table 1.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
Software/Informatics		
13-59	Systems and software engineering--Systems and software assurance--Part 4: Assurance in the life cycle	ISO/IEC 15026-4 First edition 2012-10-01
13-60	Industrial communication networks--Network and system security--Part 1-1: Terminology, concepts and models	IEC/TS 62443-1-1 Edition 1.0 2009-07
13-61	Industrial communication networks--Network and system security--Part 2-1: Establishing an industrial automation and control system security program	IEC 62443-2-1 Edition 1.0 2010-11
13-62	Industrial communication networks--Network and system security--Part 3-1: Security technologies for industrial automation and control systems	IEC/TR 62443-3-1 Edition 1.0 2009-07

[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 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 Number: 033, FDA will no longer be announcing minor revisions to the list of recognized consensus standards such as technical contact person, relevant guidance, processes affected, CFR 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: 032" 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 to the contact person (see FOR FURTHER INFORMATION CONTACT) either electronic or written comments regarding this document. It

is only necessary to send one set of comments. Comments are to be identified 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: 032. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: July 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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