



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: 048

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: 048" (Recognition List Number: 048), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: These modifications to the list of recognized standards are applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit electronic or written comments concerning this document at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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: 048." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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: 048.

- 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 048 is available on the internet at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>. See section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 048 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: 048" to Scott 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. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8144.

FOR FURTHER INFORMATION CONTACT: Scott 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, [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov).

SUPPLEMENTARY INFORMATION:

#### I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (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 the *Federal Register* notice 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. The guidance was updated in September 2007 and is available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf>.

Modifications to the initial list of recognized standards, as published in the *Federal Register*, can be accessed at <https://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. Additional information on the Agency's standards program is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>.

## II. Listing of New Entries, Recognition List Number: 048

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: 048. FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

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

Recognition No.	Title of Standard <sup>1</sup>	Reference No. and Date
A. Radiology		
12-307	Radiation therapy readiness check	AAMI RT2:2017
B. Software/Informatics		
13-98	Information technology--ISO 7-bit coded character set for information interchange	ISO/IEC 646 Third edition 1991-12-15
13-99	Information technology--Automatic identification and data capture techniques--Unique identification--Part 2: Registration procedures	ISO/IEC 15459-2 Third edition 2015-03-01

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

Recognition No.	Title of Standard <sup>1</sup>	Reference No. and Date
13-100	Information technology--Automatic identification and data capture techniques--Unique identification--Part 4: Individual products and product packages	ISO/IEC 15459-4 Third edition 2014-11-15 Corrected version 2016-09-01
13-101	Information technology--Automatic identification and data capture techniques--Unique identification--Part 6: Groupings	ISO/IEC 15459-6 Second edition 2014-11-15 Corrected version 2016-09-01
13-102	Application of risk management for IT-networks incorporating medical devices--Part 2-8: Application guidance--Guidance on standards for establishing the security capabilities identified in IEC TR 80001-2-2	IEC TR 80001-2-8 Edition 1.0 2016-05
13-103	Application of risk management for IT-networks incorporating medical devices--Part 2-9: Application guidance--Guidance for use of security assurance cases to demonstrate confidence in IEC TR 80001-2-2 security capabilities	IEC TR 80001-2-9 Edition 1.0 2017-01

<sup>1</sup> All standard titles in this table conform to the style requirements of the respective organizations.

### III. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>. FDA will be incorporating the modifications described in this notice into the database and, upon publication in the *Federal Register*, this recognition of consensus standards will be effective. FDA will be announcing 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.

### IV. 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 [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov). To be 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 electronic or mailing address of the requestor, (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.

Dated: November 29, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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