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: 043

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: 043" (Recognition List Number: 043), 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: 043." 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: 043.

- 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: 043 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: 043 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: 043" to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, 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 (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 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: 043

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: 043" 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. Anesthesia			
1-91	1-116	ISO 5360 Fourth edition 2016-02-15 Anaesthetic vaporizers -- Agent specific filling systems	Withdrawn and replaced with newer version
B. Cardiovascular			
3-135	--	ISO/TS 12417-1:2011 Cardiovascular implants and extracorporeal systems -- Vascular device-drug combination products	Withdrawn
3-136	--	AAMI/ANSI/ISO TIR 12417:2011 Cardiovascular implants and extracorporeal systems -- Vascular device-drug combination products	Withdrawn
C. Dental/Ear, Nose, and Throat (ENT)			
4-86	--	ANSI/ADA 38-2000 (R2015) Metal-Ceramic Systems	Reaffirmation
4-139	--	ANSI/ADA 48-2004 (R2015) Visible Light Curing Units	Reaffirmation
4-146	4-227	ISO 22674 Second edition. 2016-01-15 Dentistry -- Metallic materials for fixed and removable restorations and appliances	Withdrawn and replaced with newer version
4-166	4-228	ANSI/ASA S3.20-2015 (Revision of ANSI S3.20-1995) AMERICAN NATIONAL STANDARD: Bioacoustical Terminology	Withdrawn and replaced with newer version
4-196	--	ANSI/ADA 69-2010 (R2015) Dental Ceramics	Reaffirmation
4-202	--	ANSI/ADA 58-2010 (R2015) Root Canal Files, Type H (Hedstrom)	Reaffirmation
D. General I (Quality Systems/Risk Management) (QS/RM)			
5-36	--	ISO TR 16142 Second edition. 2006-1-15, Technical information report: Medical devices - Guidances on the selection of standards in support of recognized essential principles of safety and performance of medical devices	Withdrawn. See 5-105
5-40	--	ISO 14971 Second edition. 2007-03-01 Medical devices - Application of risk management to medical devices	Relevant guidance
5-57	--	AAMI/ANSI HE75:2009/(R)2013 Human factors engineering - Design of medical devices	Relevant guidance
5-67	--	AAMI/ANSI/IEC 62366:2007/(R) 2013 Medical devices - Application of usability engineering to medical devices	Transition period
5-70	--	AAMI/ANSI/ISO 14971:2007/(R) 2010 (Corrected 4 October 2007) Medical devices - Application of risk management to medical devices	Relevant guidance
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	Relevant guidance
5-87	--	IEC 62366 Edition 1.1 2014-01 Medical devices - Application of usability engineering to medical devices	Transition period

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
5-89	--	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Relevant guidance
5-92	--	AAMI/ANSI/IEC 60601-1-8:2006 & A1:2012 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	Relevant guidance
5-93	--	AAMI CN3:2014 Small-bore connectors for liquids and gases in healthcare applications -- Part 3: Connectors for enteral applications	Withdrawn. See 5-106
5-95	--	IEC 62366-1 Edition 1.0 2015-02 Medical devices - Part 1: Application of usability engineering to medical devices	Transition period, Relevant guidance
5-96	--	AAMI/ANSI/IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices	Transition period, Relevant guidance
5-101	--	AAMI CN6:2015 Small-bore connectors for liquids and gases in healthcare applications -- Part 6: Connectors for neuraxial applications	Withdrawn. See 5-108
E. General II (Electrical Safety/Electromagnetic Compatibility)(ES/EMC)			
19-1		IEC 60601-1-2 Edition 3. 2007-03, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Transition period
19-2		AAMI/ANSI/ IEC 60601-1-2:2007/(R)2012 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	Transition period
19-6	--	IEC 60601-1-11 Edition 1.0. 2010-04 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [including: Technical Corrigendum 1 (2011)]	Relevant guidance
19-7	--	AAMI/ANSI HA 60601-1-11:2011 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010 Mod)	Relevant guidance
19-8		IEC 60601-1-2 Edition 4.0. 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	Transition period

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
19-12		AAMI/ANSI/IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests	Transition period
19-14	--	IEC 60601-1-11 Edition 2.0. 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	Relevant guidance
19-15	--	IEC 60601-1-12 Edition 1.0. 2014-06 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	Relevant guidance
F. General Hospital/General Plastic Surgery (GH/GPS)			
6-15	6-362	ISO/FDIS 7864 Fourth edition 2016-XX-XX Sterile hypodermic needles for single use -- Requirements and test methods	Withdrawn and replaced with newer version
6-132	6-363	ISO 11810 Second edition 2015-12-15 Lasers and laser-related equipment -- Test method and classification for the laser resistance of surgical drapes and/or patient protective covers -- Primary ignition, penetration, flame spread and secondary ignition	Withdrawn and replaced with newer version
6-145	--	ASTM D3578--05 (Reapproved 2015) Standard Specification for Rubber Examination Gloves	Reaffirmation
6-168	--	ASTM D3577--09 (Reapproved 2015) Standard Specification for Rubber Surgical Gloves	Reaffirmation
6-175	--	ASTM D5151--06 (Reapproved 2015) Standard Test Method for Detection of Holes in Medical Gloves	Reaffirmation
6-183	--	ASTM D5250--06 (Reapproved 2015) Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	Reaffirmation
6-202	--	ISO 11810-2 First edition. 2007-05-01, Lasers and laser-related equipment -- Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers -- Part 2: Secondary ignition	Withdrawn. See 6-362
6-204	6-364	ISO 8537 Third edition. 2016-03-15 Sterile single-use syringes, with or without needle, for insulin	Withdrawn and replaced with newer version
6-244	--	ASTM D6319 -- 10 (Reapproved 2015) Standard Specification for Nitrile Examination Gloves for Medical Application	Reaffirmation
6-277	6-365	ISO 11040-4 Third edition. 2015-04-01 Prefilled syringes -- Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling	Withdrawn and replaced with newer version
6-302	6-366	ISO/FDIS 9626 Second edition 2016-XX-XX Stainless steel needle tubing for the manufacture of medical devices -- Requirements and test methods	Withdrawn and replaced with newer version
6-343	6-367	USP 39-NF 34:2016, Sodium Chloride Irrigation	Withdrawn and replaced with newer version

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-344	6-368	USP 39-NF 34:2016, Sodium Chloride Injection	Withdrawn and replaced with newer version
6-345	6-369	USP 39-NF 34:2016, Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version
6-346	6-370	USP 39-NF 34:2016, <881> Tensile Strength	Withdrawn and replaced with newer version
6-347	6-371	USP 39-NF 34:2016, <861> Sutures -- Diameter	Withdrawn and replaced with newer version
6-348	6-372	USP 39-NF 34:2016, <871> Sutures -- Needle Attachment	Withdrawn and replaced with newer version
6-349	6-373	USP 39-NF 34:2016, Sterile Water for Irrigation	Withdrawn and replaced with newer version
6-350	6-374	USP 39-NF 34:2016, Heparin Lock Flush Solution	Withdrawn and replaced with newer version
6-351	6-375	USP 39-NF 34:2016, Absorbable Surgical Suture	Withdrawn and replaced with newer version
G. In Vitro Diagnostics (IVD)			
7-198	7-261	CLSI M23 Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters, 4th edition	Withdrawn and replaced with newer version
7-218	7-262	CLSI M45 Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline, 3rd edition	Withdrawn and replaced with newer version
7-256	7-263	CLSI M100-S26 Performance Standards for Antimicrobial Susceptibility Testing, 26th edition	Withdrawn and replaced with newer version
H. Materials			
8-217	--	ASTM F620-11(Reapproved 2015) Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition	Reaffirmation
8-220	8-421	ASTM F629-11 Standard Practice for Radiography of Cast Metallic Surgical Implants	Withdrawn and replaced with newer version
8-381	8-422	ASTM F2052-15 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Withdrawn and replaced with newer version
I. Orthopedic			
11-168	11-305	ASTM F1781-15 Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Withdrawn and replaced with newer version
11-171	11-306	ASTM F1814-15 Standard Guide for Evaluating Modular Hip and Knee Joint Components	Withdrawn and replaced with newer version
11-203	--	ASTM F1541-02 (Reapproved 2015) Standard Specification and Test Methods for External Skeletal Fixation Devices	Reaffirmation
11-271	--	ASTM F2180-02(Reapproved 2015) Standard Specification for Metallic Implantable Strands and Cables	Reaffirmation
J. Radiology			
12-153	12-297	ANSI/IESNA RP-27.1-15 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - General requirements	Withdrawn and replaced with newer version

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-158	12-298	NEMA MS 10-2010 Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging	Withdrawn and replaced with newer version
12-207	--	IEC 60601-2-33 Ed. 3.0 2010 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	Transition period extended
12-209	--	IEC 60601-2-37 Ed. 2.0:2007 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Recognition restored with transition period
12-216	12-299	IEC 62563-1 Ed.1.1 2016 Medical electrical equipment - Medical image display systems -- Part 1: Evaluation methods	Withdrawn and replaced with newer version with transition
12-236	--	IEC 60601-2-45 Ed. 3.0: 2011 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	Recognition restored with transition period
12-238	12-300	NEMA Digital Imaging and Communications in Medicine (DICOM) set PS3.1-3.20 (2016)	Withdrawn and replaced with newer
12-254	12-301	IEC 60601-2-8 Ed. 2.1 b:2015 Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	Withdrawn and replaced with newer version
12-256	--	IEC 60601-2-44 Ed. 3.1 2012 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Transition extended
12-257	--	IEC 60601-2-44 Ed. 3.0 2009 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Transition extended
12-271	--	IEC 60601-2-33 Ed. 3.1:2013 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	Recognition restored with transition period
12-274	--	IEC 60601-2-54 Ed. 1.0:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including: Technical Corrigendum 1: 2010 and Technical Corrigendum 2:2011]	Recognition restored with transition
12-293	--	IEC 60601-2-37 Ed. 2.1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Transition period.
12-294	--	IEC 60601-2-45 Ed. 3.1: 2015 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	Transition period.

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-295	--	IEC 60601-2-33 Ed. 3.2 b:2015 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	Transition period extended
12-296	--	IEC 60601-2-54 Ed. 1.1:2015 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Transition period
K. Sterility			
14-139	14-479	ISO 14644-1 Second edition 2015-12-15 Cleanrooms and associated controlled environments -- Part 1: Classification of air cleanliness by particle concentration	Withdrawn and replaced with newer version
14-140	14-481	ISO 14644-2 Second edition 2015-12-15 Cleanrooms and associated controlled environments -- Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	Withdrawn and replaced with newer version
14-283	14-482	ASTM F88/F88M--15 Standard Test Method for Seal Strength of Flexible Barrier Materials	Withdrawn and replaced with newer version
14-341	14-483	ISO/ASTM 52303 First edition 2015-07-15 Guide for absorbed-dose mapping in radiation processing facilities	Withdrawn and replaced with newer version
14-344	--	ASTM F2825--10 (Reapproved 2015) Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	Reaffirmation
14-378	14-484	ASTM F1929--15 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Withdrawn and replaced with newer version
14-466	14-485	USP 39-NF34:2016 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	Withdrawn and replaced with newer version
14-467	14-486	USP 39-NF34:2016 <71> Sterility Tests	Withdrawn and replaced with newer version
14-468	14-487	USP 39-NF34:2016 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version
14-469	14-488	USP 39-NF34:2016 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests	Withdrawn and replaced with newer version
14-470	14-489	USP 39-NF34:2016 Biological Indicator for Steam Sterilization, Self Contained	Withdrawn and replaced with newer version
14-471	14-490	USP 39-NF34:2016 Biological Indicator for Dry-Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14-472	14-491	USP 39-NF34:2016 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14-473	14-492	USP 39-NF34:2016 Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14-474	14-493	USP 39-NF34:2016 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	Withdrawn and replaced with newer version
14-475	14-494	USP 39-NF34:2016 <55> Biological Indicators--Resistance Performance Tests	Withdrawn and replaced with newer version
14-476	14-495	USP 39-NF34:2016 <1035> Biological Indicators for Sterilization	Withdrawn and replaced with newer version

[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: 043.

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

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Cardiovascular		
3-142	Cardiovascular implants and extracorporeal systems -- Cardiovascular absorbable implants	ISO/TS 17137:2014
3-143	Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products	ISO 12417 First edition 2015-10-01
B. General I (Quality Systems/Risk Management) (QS/RM)		
5-105	Medical devices -- Recognized essential principles of safety and performance of medical devices -- Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	ISO 16142-1 First edition 2016-03-01
5-106	Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	ISO/FDIS 80369-3 First edition 2016-02-04
5-107	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications	IEC 80369-5: Edition 1.0 2016-03
5-108	Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	ISO 80369-6 First edition. 2016-03-15
C. General Hospital/General Plastic Surgery (GH/GPS)		
6-376	Hypodermic needles for single use -- Colour coding for identification	ISO/FDIS 6009 Fourth edition 2016-01-18
6-377	Needle-based injection systems for medical use -- Requirements and test methods -- Part 5: Automated functions	ISO 11608-5 First edition 2012-10-01
6-378	Needle-based injection systems for medical use -- Requirements and test methods -- Part 7: Accessibility for persons with visual impairment	ISO/FDIS 11608-7 First edition 2016-06-16
D. In Vitro Diagnostic		
7-264	Genomic Copy Number Microarrays for Constitutional Genetic and Oncology Applications, 1st edition	MM21- Ed. 1
E. Materials		
8-423	Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications	ASTM F2565 -- 13
8-424	Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications	ASTM F2695 -- 12
8-425	Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications	ASTM F2820 -- 12
8-426	Standard Specification for Acrylic Molding Resins for Medical Implant Applications	ASTM F3087 -- 15
8-427	Standard Specification for Composition of Hydroxylapatite for Surgical Implants	ASTM F1185-03 (Reapproved 2014)
8-428	Standard Specification for Composition of Anorganic Bone for Surgical Implants	ASTM F1581-08 (Reapproved 2012)

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

Recognition No.	Title of Standard[1]	Reference No. and Date
8-429	Standard Specification for High Purity Calcium Sulfate Hemihydrate or Dihydrate for Surgical Implants	ASTM F2224-09 (Reapproved 2014)
8-430	Implants for surgery -- Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP)	ISO 13356:2015 Third edition. 2015-09-15
8-431	Standard Practice for Reporting Data for Test Specimens Prepared by Additive Manufacturing	ASTM F2971 -- 13
8-432	Standard Terminology for Additive Manufacturing-Coordinate Systems and Test Methodologies	ISO/ASTM 52921 -- 13 First edition 2013-06-01
8-434	Additive manufacturing -- General principles -- Terminology	ISO/ASTM 52900 First edition 2015-12-15
F. Orthopedic		
11-307	Standard Practice for Determining Femoral Head Penetration into Acetabular Components of Total Hip Replacement Using Clinical Radiographs	ASTM F2385-15
11-308	Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions	ASTM F3161-16
11-309	Standard Specification for Medical Screwdriver Bits	ASTM F116-12
11-310	Standard Specification for Intramedullary Reamers	ASTM F1611-00 (Reapproved 2013)
G. Radiology		
12-302	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 Ed. 3.2:2016
H. Software/Informatics		
13-82	Application of risk management for IT networks incorporating medical -- Application guidance -- Part 2-6: Guidance for responsibility agreements	AAMI/ISO TIR 80001-2-6:2014
13-83	Principles for medical device security -- Risk management	AAMI TIR 57:2016.
13-84	Health informatics -- Point-of-care medical device communication -- Part 10103: Nomenclature -- Implantable device, cardiac	ISO/IEEE 11073-10103 First edition 2014-03-01
I. Tissue Engineering		
15-45	Medical devices utilizing animal tissues and their derivatives -- Part 1: Application of risk management	ISO 22442-1 Second edition 2015-11-1
15-46	Medical devices utilizing animal tissues and their derivatives -- Part 2: Controls on sourcing, collection and handling	ISO 22442-2 Second edition 2015-11-1
15-47	Medical devices utilizing animal tissues and their derivatives -- Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents	ISO 22442-3 First edition 2007-12-15

[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: 043" 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: June 21, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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