



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: 053

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: 053” (Recognition List Number: 053), 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 on the notice at any time. These modifications to the list of recognized standards are applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time 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

<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: 053." 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: 053.

- 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.govinfo.gov/content/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: 053 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: 053 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: 053” to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, 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. 5606, 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 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act 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* of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.” The guidance describes how FDA has implemented its standards recognition program and is available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>. Modifications to the initial list of recognized standards, as published in the *Federal Register*, can be accessed at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents>.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains a portable document format (PDF) version of the list of FDA Recognized Consensus Standards. Additional information on the Agency’s Standards and Conformity Assessment Program is available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program>.

## II. Modifications to the List of Recognized Standards, Recognition List Number: 053

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency’s searchable database. FDA is using the term “Recognition List Number: 053” to identify the 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 new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 053.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard <sup>1</sup>	Change
<b>A. Anesthesiology</b>			
1-47	-	AS 4259-1995 Ancillary devices for expired air resuscitation.	Withdrawn.
1-102	-	ISO 80601-2-69 First edition 2014-07-15 Medical electrical equipment--Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.	Extent of Recognition.
<b>B. Biocompatibility</b>			
2-259	2-269	USP 42-NF37:2019 <87> Biological Reactivity Test, In Vitro - Direct Contact Test.	Withdrawn and replaced with newer version.
2-260	2-270	USP 42-NF37:2019 <87> Biological Reactivity Test, In Vitro-Elution Test.	Withdrawn and replaced with newer version.
2-261	2-271	USP 42-NF37:2019 <88> Biological Reactivity Tests, In Vivo.	Withdrawn and replaced with newer version.
2-262	2-272	USP 42-NF37:2019 <151> Pyrogen Test (USP Rabbit Test).	Withdrawn and replaced with newer version.
<b>C. Cardiovascular</b>			
3-139	3-161	ISO 14117 Second edition 2019-09 Active implantable medical devices--Electromagnetic compatibility--EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices.	Withdrawn and replaced with newer version.
<b>D. Dental/Ear, Nose, and Throat (ENT)</b>			
4-186	4-260	ANSI/ASA S12.2-2019 American National Standard Criteria for Evaluating Room Noise.	Withdrawn and replaced with newer version.
4-212	4-261	ISO 7405 Third edition 2018-10 Corrected version 2018-12 Dentistry--Evaluation of biocompatibility of medical devices used in dentistry.	Withdrawn and replaced with newer version.
4-229	4-262	IEC 80601-2-60 Edition 2.0 2019-06 Medical electrical equipment--Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment.	Withdrawn and replaced with newer version.
<b>E. General I (Quality Systems/Risk Management) (QS/RM)</b>			
5-103	5-124	ISO 7000 Sixth edition 2019-07 Graphical symbols for use on equipment--Registered symbols.	Withdrawn and replaced with newer version.
5-40	5-125	ISO 14971 Third edition 2019-12 Medical devices--Application of risk management to medical devices	Withdrawn and replaced with newer version.
<b>F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)</b>			
19-13	-	IEC 62133 Edition 2.0 2012-12 Secondary cells and batteries containing alkaline or other non-acid electrolytes--Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including CORRIGENDUM 1 (2013)].	Transition removed. Recognition restored.

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19-32	-	IEC 62133-1 Edition 1.0 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes--Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications--Part 1: Nickel systems.	Transition removed.
19-33	-	IEC 62133-2 Edition 2017-02 Secondary cells and batteries containing alkaline or other non-acid electrolytes--Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications--Part 2: Lithium systems.	Transition removed.
<b>G. General Hospital/General Plastic Surgery (GH/GPS)</b>			
6-175	6-424	ASTM D5151-19 Standard Test Method for Detection of Holes in Medical Gloves.	Withdrawn and replaced with newer version.
6-254	6-425	ASTM F2100-19 Standard Specification for Performance of Materials Used in Medical Face Masks.	Withdrawn and replaced with newer version.
6-293	6-426	ISO 23907-1 First edition 2019-01 Sharps injury protection--Requirements and test methods--Part 1: Single-use sharps containers.	Withdrawn and replaced with newer version.
6-335	6-427	ASTM F2101-19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.	Withdrawn and replaced with newer version.
6-412	6-428	USP 42-NF37:2019 Sodium Chloride Irrigation.	Withdrawn and replaced with newer version.
6-413	6-429	USP 42-NF37:2019 Sodium Chloride Injection.	Withdrawn and replaced with newer version.
6-414	6-430	USP 42-NF37:2019 Nonabsorbable Surgical Suture.	Withdrawn and replaced with newer version.
6-415	6-431	USP 42-NF37:2019 <881> Tensile Strength.	Withdrawn and replaced with newer version.
6-416	6-432	USP 42-NF37:2019 <861> Sutures--Diameter.	Withdrawn and replaced with newer version.
6-417	6-433	USP 42-NF37:2019 <871> Sutures--Needle Attachment.	Withdrawn and replaced with newer version.
6-418	6-434	USP 42-NF37:2019 Sterile Water for Irrigation.	Withdrawn and replaced with newer version.
6-419	6-435	USP 42-NF37:2019 Heparin Lock Flush Solution.	Withdrawn and replaced with newer version.
6-420	6-436	USP 42-NF37:2019 Absorbable Surgical Suture.	Withdrawn and replaced with newer version.
<b>H. In Vitro Diagnostics (IVD)</b>			
7-226	7-293	CLSI QMS01, 5 <sup>th</sup> ed. June 2019 (Replaces QMS01-A4) A Quality Management System Model for Laboratory Services.	Withdrawn and replaced with newer version.
7-281	7-294	CLSI M100, 29th ed. January 2019 (Replaces M100 28th ed.) Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
<b>I. Materials</b>			
8-68	8-519	ISO 13782 Second edition 2019-04 Implants for surgery--Metallic materials--Unalloyed tantalum for surgical implant applications.	Withdrawn and replaced with newer version.

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Old Recognition No.	Replacement Recognition No.	Title of Standard <sup>1</sup>	Change
8-218	8-520	F799-19 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539).	Withdrawn and replaced with newer version.
8-391	8-521	F2313-18 Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70 % Glycolide.	Withdrawn and replaced with newer version.
8-477	8-522	F2129-19a Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Withdrawn and replaced with newer version.
8-480	-	ASTM F2063-18 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.	Transition period extended.
8-481	-	ASTM F1314-18 Standard Specification for Wrought Nitrogen Strengthened 22 Chromium-13 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910).	Transition period extended.
8-484	-	ASTM F2066-18 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150).	Transition period extended.
8-491	-	ASTM F1088-18 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Transition period extended.
8-492	-	ISO 5832-9 Third edition 2019-02 Implants for surgery--Metallic materials--Part 9: Wrought high nitrogen stainless steel.	Transition period extended.
8-494	-	ISO 6474-1 Second edition 2019-03 Implants for surgery--Ceramic materials--Part 1: Ceramic materials based on high purity alumina.	Transition period extended.
8-498	-	ASTM F75-18 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Transition period extended.
8-499	-	ASTM F1580-18 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Transition period extended.
8-500	-	ISO 5832-12 Third edition 2019-02 Implants for surgery--Metallic materials--Part 12: Wrought cobalt-chromium-molybdenum alloy.	Transition period extended.
8-501	-	ISO 5834-1 Fourth edition 2019-02 Implants for surgery--Ultra-high-molecular-weight polyethylene--Part 1: Powder form.	Transition period extended.
8-502	-	ASTM F2038-18 Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I--Formulations and Uncured Materials.	Transition period extended.
8-505	-	ISO 6474-2 Second edition 2019-03 Implants for surgery--Ceramic materials--Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement.	Transition period extended.
8-507	-	ASTM F688-19 Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Transition period extended.

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Old Recognition No.	Replacement Recognition No.	Title of Standard <sup>1</sup>	Change
8-508	-	ASTM F2579-18 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants.	Transition period extended.
8-511	-	ASTM F1925-17 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.	Withdrawn. Duplicate recognition. See 8-471.
8-512	-	ASTM F2026-17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Withdrawn. Duplicate recognition. See 8-475.
J. Nanotechnology			
		No new entries at this time.	
K. Neurology			
		No new entries at this time.	
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9-84	9-123	ISO 8600-3 Second edition 2019-08 Endoscopes-- Medical endoscopes and endotherapy devices--Part 3: Determination of field of view and direction of view of endoscopes with optics.	Withdrawn and replaced with newer version.
M. Ophthalmic			
		No new entries at this time.	
N. Orthopedic			
11-328	11-360	ASTM F1378-18 $\epsilon$ 1 Standard Specification for Shoulder Prostheses.	Withdrawn and replaced with newer version.
O. Physical Medicine			
16-168	16-207	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability.	Withdrawn and replaced with a newer version.
16-169	16-208	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16-170	16-209	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 3: determination of effectiveness of brakes.	Withdrawn and replaced with a newer version.
16-171	16-210	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 4 Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range.	Withdrawn and replaced with a newer version.
16-172	16-211	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space.	Withdrawn and replaced with a newer version.

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16-173	16-212	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16-174	16-213	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of measurement of seating and wheel dimensions.	Withdrawn and replaced with a newer version.
16-175	16-214	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths.	Withdrawn and replaced with a newer version.
16-176	16-215	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16-177	16-216	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16-178	16-217	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test mannequins.	Withdrawn and replaced with a newer version.
16-179	16-218	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces.	Withdrawn and replaced with a newer version.
16-180	16-219	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs, scooters and add-on devices--Requirements and test methods.	Withdrawn and replaced with a newer version.
16-181	16-220	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling.	Withdrawn and replaced with a newer version.
16-182	16-221	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of postural support devices.	Withdrawn and replaced with a newer version.

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16-183	16-222	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 20: Determination of the performance of stand-up type wheelchairs.	Withdrawn and replaced with a newer version.
16-184	16-223	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 22: Set-up procedures.	Withdrawn and replaced with a newer version.
16-185	16-224	ANSI/RESNA WC-2:2019 American National Standard for Wheelchairs--Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers	Withdrawn and replaced with a newer version.
16-187	16-225	ANSI/RESNA WC-1:2019 American National Standard for Wheelchairs--Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary.	Withdrawn and replaced with a newer version.
16-205	-	ANSI/RESNA W-4:2017 American National Standard for Wheelchairs--Volume 4: Wheelchairs and Transportation.	Withdrawn. See 16-226, 16-227, 16-228, and 16-229.
P. Radiology			
12-110	12-327	ISO 11551 Third edition 2019-10 Optics and optical instruments--Lasers and laser-related equipment--Test method for absorptance of optical laser components.	Withdrawn and replaced with newer version.
12-270	12-328	IEC 61223-3-5 Edition 2.0 2019-09 Evaluation and routine testing in medical imaging departments--Part 3-5: Acceptance tests--Imaging performance of computed tomography X-ray equipment.	Withdrawn and replaced with newer version.
12-308	12-329	IEC 60601-2-43 Edition 2.2 2019-10 CONSOLIDATED VERSION Medical electrical equipment--Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.	Withdrawn and replaced with newer version.
12-309	-	IEC 60601-2-28 Edition 3.0 2017-06 Medical electrical equipment--Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.	Transition period extended.
12-317	-	IEC 60601-2-54 Edition 1.1 2015-04 CONSOLIDATED VERSION Medical electrical equipment--Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including AMENDMENT 2 (2018)].	Transition period extended.

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Old Recognition No.	Replacement Recognition No.	Title of Standard <sup>1</sup>	Change
Q. Software/Informatics			
13-47	13-110	ISO/IEEE 11073-10101 First edition 2004- 12- 15 Health informatics--Point-of-care medical device communication--Part 10101: Nomenclature [Including AMENDMENT 1 (2017)].	Withdrawn and replaced with newer version including amendment.
13-48	13-111	IEEE Std 11073-10201-2018 Health informatics--Point-of-care medical device communication Part 10201: Domain Information Model.	Withdrawn and replaced with newer version.
R. Sterility			
14-325	14-528	ISO 11139 First edition 2018-08 Sterilization of health care products--Vocabulary of terms used in sterilization and related equipment and process standards.	Withdrawn and replaced with newer version.
14-354	14-529	ISO 18472 Second edition 2018-08 Sterilization of health care products--Biological and chemical indicators--Test equipment.	Withdrawn and replaced with newer version.
14-382	14-530	ISO/ASTM 51276 Fourth edition 2019-08 Practice for use of a polymethylmethacrylate dosimetry system.	Withdrawn and replaced with newer version.
14-520	14-531	USP 42-NF37:2019 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14-521	14-532	USP 42-NF37:2019 <71> Sterility Tests.	Withdrawn and replaced with newer version.
14-522	14-533	USP 42-NF37:2019 <85> Bacterial Endotoxins Test.	Withdrawn and replaced with newer version.
14-523	14-534	USP 42-NF37:2019 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14-524	14-535	USP 42-NF37:2019 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14-525	14-536	USP 42-NF37:2019 <55> Biological Indicators--Resistance Performance Tests.	Withdrawn and replaced with newer version.
14-526	14-537	USP 42-NF37:2019 <1229.5> Biological Indicators for Sterilization.	Withdrawn and replaced with newer version.
S. Tissue Engineering			
		No new entries at this time.	

<sup>1</sup> 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: 053. These entries are of standards not previously recognized by FDA.

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

Recognition No.	Title of Standard <sup>1</sup>	Reference No. and Date
<b>A. Anesthesiology</b>		
1-145	Lung ventilators and related equipment--Vocabulary and semantics.	ISO 19223 First edition 2019-07.
<b>B. Biocompatibility</b>		
	No new entries at this time.	
<b>C. Cardiovascular</b>		
3-162	Standard Guide for Active Fixation Durability of Endovascular Prostheses.	ASTM F3374-19.
3-163	Cardiovascular implants and extracorporeal systems--Centrifugal blood pumps.	ISO 18242 First edition 2016-09-01.
<b>D. Dental/Ear, Nose, and Throat (ENT)</b>		
	No new entries at this time.	
<b>E. General I (Quality Systems/Risk Management) (QS/RM)</b>		
	No new entries at this time.	
<b>F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)</b>		
	No new entries at this time.	
<b>G. General Hospital/General Plastic Surgery (GH/GPS)</b>		
6-437	Sharps injury protection--Requirements and test methods--Part 2: Reusable sharps containers.	ISO 23907-2 First edition 2019-11.
6-438	Medical electrical equipment--Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT.	IEC 80601-2-77 Edition 1.0 2019-07.
<b>H. In Vitro Diagnostics (IVD)</b>		
7-295	Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems.	CLSI M52, 1 <sup>st</sup> ed. August 2015.
<b>I. Materials</b>		
8-523	Standard Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device.	ASTM F3275-19.
8-524	Standard Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device.	ASTM F3276-19.
<b>J. Nanotechnology</b>		
	No new entries at this time.	
<b>K. Neurology</b>		
	No new entries at this time.	
<b>L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)</b>		
	No new entries at this time.	
<b>M. Ophthalmic</b>		
	No new entries at this time.	
<b>N. Orthopedic</b>		
11-361	Implants for surgery--Wear of total knee prostheses--Part 5: Durability performance of the patellofemoral joint.	ISO 14243-5 First edition 2019-05.
11-362	Implants for surgery--Wear of total ankle-joint prostheses--Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test.	ISO 22622 First edition 2019-07.

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

Recognition No.	Title of Standard <sup>1</sup>	Reference No. and Date
O. Physical Medicine		
16-226	American National Standard for Wheelchairs--Volume 4: Wheelchairs and Transportation Section 10 Wheelchair containment and occupant retention systems for use in large accessible transit vehicles: systems for rearward-facing passengers.	ANSI/RESNA WC-4:2017 Section 10.
16-227	American National Standard for Wheelchairs--Volume 4: Wheelchairs and Transportation Section 18: Wheelchair tiedown and occupant restraint systems for use in motor vehicles.	ANSI/RESNA WC-4:2017 Section 18.
16-228	ANSI/RESNA W-4:2017 American National Standard for Wheelchairs--Volume 4: Wheelchairs and Transportation Section 19: Wheelchairs used as seats in motor vehicles.	ANSI/RESNA WC-4:2017 Section 19.
16-229	American National Standard for Wheelchairs--Volume 4: Wheelchairs and Transportation Section 20: Wheelchair seating systems for use in motor vehicles.	ANSI/RESNA WC-4:2017 Section 20.
P. Radiology		
	No new entries at this time.	
Q. Software/Informatics		
13-112	Principles for medical device security--Postmarket risk management for device manufacturers.	AAMI TIR97:2019.
R. Sterility		
14-538	Standard Guide for Designing Reusable Medical Devices for Cleanability.	ASTM F3357-19.
S. Tissue Engineering		
	No new entries at this time.	

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

#### IV. 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>. Such standards are those that FDA has recognized by notice published in the *Federal Register* or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the *Federal Register*). 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.

#### 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 [CDRHStandardsStaff@fda.hhs.gov](mailto:CDRHStandardsStaff@fda.hhs.gov). To be considered, such recommendations should contain, at a minimum, the information listed on FDA's website, which is specifically available at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/recognition-standard>.

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Principal Associate Commissioner for Policy.

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