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: 059

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: 059" (Recognition List Number: 059), 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: 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: 059." 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, 240-402-7500. 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: 059.

- 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, 240-402-7500.

An electronic copy of Recognition List Number: 059 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: 059 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: 059" to Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301-796-6580. 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: Jianchao Zeng, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5572, Silver Spring, MD 20993, 301-796-6580, 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 on its website HTML and PDF versions of the list of FDA Recognized Consensus Standards, available at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents. 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: 059

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: 059" 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: 059.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Anesthesiology			
1-67	1-153	NFPA 99:2021 Health Care Facilities Code	Withdrawn and replaced with newer version.
1-78	1-154	ASME PVHO-1-2019 Safety Standard for Pressure Vessels for Human Occupancy	Withdrawn and replaced with newer version.
1-132	1-155	ISO 10079-2 Fourth edition 2022-03 Medical suction equipment--Part 2: Manually powered suction equipment	Withdrawn and replaced with newer version.
1-133	1-156	ISO 10079-3 Fourth edition 2022-03 Medical suction equipment--Part 3: Suction equipment powered from a vacuum or positive pressure gas source	Withdrawn and replaced with newer version.
1-142	1-157	ISO 10079-1 Fourth edition 2022-03 Medical suction equipment--Part 1: Electrically powered suction equipment	Withdrawn and replaced with newer version.
B. Biocompatibility			
2-93	2-297	ASTM F763-22 Standard Practice for Short-Term Intramuscular Screening of Implantable Medical Device Materials	Withdrawn and replaced with newer version.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2-276	2-298	ISO 10993-18 Second edition 2020-01 Amendment 1:2022-05 Biological evaluation of medical devices--Part 18: Chemical characterization of medical device materials within a risk management process [Including Amendment 1 (2022)]	Withdrawn and replaced with newer version, including amendment.
2-289		ISO 10993-12 Fifth edition 2021-01 Biological evaluation of medical devices--Part 12: Sample preparation and reference materials	Transition period extended.
2-296		ISO 10993-10 Fourth edition 2021-11 Biological evaluation of medical devices--Part 10: Tests for skin sensitization	Transition period extended.
C. Cardiovascular			
No new entries at this time.			
D. Dental/Ear, Nose, and Throat (ENT)			
4-234	4-294	ANSI/ADA Standard No. 139-2020 Dental Base Polymers	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
15-135	5-135	ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices--Information to be supplied by the manufacturer	New recognition number.
5-99	5-136	ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing	Withdrawn and replaced with newer version.
5-104	5-137	IEC TR 60878 Edition 4.0 2022-11 Graphical symbols for electrical equipment in medical practice	Withdrawn and replaced with newer version.
5-118	5-138	AAMI TIR66:2017/(R)2020 Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms	New recognition number.
5-119	5-139	ISO 18250-3 First edition 2018-06 Medical devices--Connectors for reservoir delivery systems for healthcare applications--Part 3: Enteral application	New recognition number.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19-29	19-48	IEEE ANSI/USEMCSC C63.27 American National Standard for Evaluation of Wireless Coexistence	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6-390		IEC 80601-2-35 Edition 2.1 2016-04 CONSOLIDATED VERSION Medical electrical equipment-Part--2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use [Including Amendment 1 (2016)]	Withdrawn. See 6-483.
6-460	6-484	ASTM F3502-22a Standard Specification for Barrier Face Coverings	Extent of recognition. Withdrawn and replaced with a newer version.
H. In Vitro Diagnostics (IVD)			
7-291	7-313	CLSI EP27 2nd Edition Constructing and Interpreting an Error Grid for Quantitative Measurement Procedures	Extent of recognition. Withdrawn and replaced with newer version.
7-303		CLSI M60 2nd Edition Performance Standards for Antifungal Susceptibility Testing of Yeast	Withdrawn. See 7-314.

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
I. Materials			
8-61	8-594	ISO 5832-6 Third Edition 2022-03 Implants for surgery--Metallic materials--Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	Withdrawn and replaced with newer version.
8-123	8-595	ISO 5832-5 Fourth Edition 2022-03 Implants for surgery--Metallic materials--Part 5: Wrought cobalt-chromium-tungsten-nickel	Withdrawn and replaced with newer version.
8-559	8-596	ASTM D412-16(2021) Standard Test Methods for Vulcanized Rubber and Thermoplastic Elastomers--Tension	Withdrawn and replaced with newer version.
J. Nanotechnology			
18-4	18-21	ISO/TS 80004-6 Second edition 2021-03 Nanotechnologies--Vocabulary--Part 6: Nano-object characterization	Withdrawn and replaced with newer version.
18-12	18-22	ISO 17200 First edition 2020-09 Nanotechnology--Nanoparticles in powder form--Characteristics and measurements	Withdrawn and replaced with newer version.
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
9-89		ISO 8638 Third edition 2010-07-01 Cardiovascular implants and extracorporeal systems--Extracorporeal blood circuit for hemodialyzers, hemodialfilters, and hemofilters	Withdrawn. See 9-140.
M. Ophthalmic			
10-37	10-132	ISO 10942 Third edition 2022-01 Ophthalmic instruments--Direct ophthalmoscopes	Extent of recognition. Withdrawn and replaced with newer version.
10-91	10-133	ISO 11979-10 Second edition 2018-03 Ophthalmic implants--Intraocular lenses--Part 10: Clinical investigations of intraocular lenses for correction of ametropia in phakic eyes	Withdrawn and replaced with newer version.
N. Orthopedic			
11-264	11-394	ASTM F1820-22 Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices	Withdrawn and replaced with newer version.
11-306	11-395	ASTM F1814-22 Standard Guide for Evaluating Modular Hip and Knee Joint Components	Withdrawn and replaced with newer version.
11-320	11-396	ISO 7206-13 First edition 2016-07-01 [Including AMD1:2022] Implants for surgery--Partial and total hip joint prostheses--Part 13: Determination of resistance to torque of head fixation of stemmed femoral components [Including Amendment 1 (2022)]	Withdrawn and replaced with newer version including amendment.
O. Physical Medicine			
16-191		ISO 7176-16 Second edition 2012-12-01 Wheelchairs--Part 16: Resistance to ignition of postural support devices	Withdrawn. See 16-233.
P. Radiology			
12-113	12-346	ISO 12005 Third edition 2022-05 Lasers and laser-related equipment--Test methods for laser beam parameters--Polarization	Withdrawn and replaced with newer version.
12-295	12-347	IEC 60601-2-33 Edition 4.0 2022-08 Medical electrical equipment--Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	Extent of recognition. Withdrawn and replaced with newer version.

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-317	12-348	IEC 60601-2-54 Edition 2.0 2022-09 Medical electrical equipment--Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Extent of recognition. Withdrawn and replaced with newer version.
12-342	12-349	NEMA Digital Imaging and Communications in Medicine (DICOM) Set PS3.1-3.20 2022d	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13-109	13-121	ANSI/AAMI/UL 2800-1:2022 Standard for Medical Device Interoperability	Withdrawn and replaced with newer version. See 13-125, 13-126, 13-127.
R. Sterility			
14-409	14-580	ISO 11137-2 Third edition 2013-06 [Including AMD1:2022] Sterilization of health care products--Radiation--Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)]	Withdrawn and replaced with newer version.
14-527	14-581	ASTM F2638-22 Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	Withdrawn and replaced with newer version.
S. Tissue Engineering			
No new entries at this time.			

[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: 059. 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[1]	Reference No. and Date
A. Anesthesiology		
1-158	Medical suction equipment--Part 4: General requirements	ISO 10079-4 First edition 2021-08.
1-159	Respiratory equipment--Particular requirements for basic safety and essential performance of infant cardiorespiratory monitors	ISO 18778 Second edition 2022-06.
1-160	Medical electrical equipment--Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment	ISO 80601-2-84 First edition 2020-07.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3-183	Cardiovascular implants and extracorporeal systems--Blood/tissue contact surface modifications for extracorporeal perfusion systems	ISO 11658 First edition 2012-05-15.
D. Dental/ENT		
4-295	Evaluation of biocompatibility of medical devices used in dentistry	ANSI/ADA Standard No. 41-2020.
4-296	Dentistry--Intra-oral mirrors	ISO 9873 Fourth edition 2019-03.

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

Recognition No.	Title of Standard[1]	Reference No. and Date
4-297	Dentistry--Manual toothbrushes--General requirements and test methods	ISO 20126 Third edition 2022-03.
E. General I (QS/RM)		
5-140	Standard for verification and validation in computational solid mechanics	ASME V&V 10-2019.
5-141	Standard for verification and validation in computational fluid dynamics and heat transfer	ASME V&V 20-2009 (R2021).
F. General II (ES/EMC)		
No new entries at this time.		
G. GH/GPS		
6-483	Medical electrical equipment--Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	IEC 60601-2-35 Edition 2.0 2020-09.
6-485	Sterile hypodermic syringes for single use--Part 4: Syringes with re-use prevention feature	ISO 7886-4 Second Edition 2018-11.
H. IVD		
7-314	Performance Standards for Antifungal Susceptibility Testing of Yeasts	CLSI M27M44S, 3rd Edition.
I. Materials		
No new entries at this time.		
J. Nanotechnology		
No new entries at this time.		
K. Neurology		
No new entries at this time.		
L. OB-Gyn/G/Urology		
9-140	Extracorporeal systems for blood purification--Part 2: Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters	ISO 8637-2 First Edition 2018-07.
9-141	Extracorporeal systems for blood purification--Part 3: Plasmafilters	ISO 8637-3 First Edition 2018-07.
9-142	Standard test method for static and kinetic coefficients of friction of plastic film and sheeting	ASTM D1894-14.
9-143	Sterile urethral catheters for single use	ISO 20696 First edition 2018-06 Corrected 2019-12.
9-144	Sterile drainage catheters and accessory devices for single use	ISO 20697 First edition 2018-06 Corrected 2019-09.
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
11-397	Standard test method for fatigue testing of total knee femoral components under closing conditions	ASTM F3210-22e1.
11-398	Standard test methods for sacroiliac joint fusion devices	ASTM F3574-22.
O. Physical Medicine		
16-233	Wheelchair seating--Part 10: Resistance to ignition of postural support devices--Requirements and test method	ISO 16840-10 Second edition 2021-06 Corrected version 2022-01.
P. Radiology		
No new entries at this time.		
Q. Software/Informatics		
13-122	Health software and health IT systems safety, effectiveness and security--Part 5-1: Security--Activities in the product life cycle	IEC 81001-5-1 Edition 1.0 2021-12.
13-123	Manufacturer disclosure statement for medical device security	ANSI/NEMA HN 1-2019.
13-124	Guidance on the application of ISO 14971 to artificial intelligence and machine learning	AAMI CR34971:2022.

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

Recognition No.	Title of Standard[1]	Reference No. and Date
13-125	Standard for risk concerns for interoperable medical products	ANSI/AAMI/UL 2800-1-1:2022.
13-126	Standard for interoperable item development life cycle	ANSI/AAMI/UL 2800-1-2:2022.
13-127	Standard for Interoperable item integration life cycle	ANSI/AAMI/UL 2800-1-3:2022.
13-128	IEEE/UL Standard for wireless diabetes device security: Information security requirements for connected diabetes solutions	IEEE Std 2621.2-2022/UL 2621-2:2022.
R. Sterility		
14-582	Sterilization of health care products--Radiation--Part 4: Guidance on process control	ISO/TS 11137-4 First edition 2020-06.
14-583	Cleaning validation of health care products--Requirements for development and validation of a cleaning process for medical devices.	ANSI/AAMI ST98:2022.
S. Tissue Engineering		
No new entries at this time.		

[1] 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. To be considered, such recommendations should contain, at a minimum, the information available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process.

Dated: July 28, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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