ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Health care providers (Primary Care Physician, Emergency Physician, Nurse Practitioner and Physician Assistant).	TBI Provider Survey	600	1	15/60	150
	Focus group screener	36	1	5/60	3
	Focus group questionnaire	31	1	5/60	3
	Focus group discussion guide	31	1	85/60	44
Total					200

Jeffrey M. Zirger,

Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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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: 049

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: 049'' (Recognition List Number: 049), 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 June 7, 2018.

ADDRESSES: You may submit comments 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: 049.'' 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: 049.

- 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: 049 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: 049 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: 049'' 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. 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.*

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 (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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077274.htm.*

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. Modifications to the List of Recognized Standards, Recognition List Number: 049

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: 049'' 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 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. Anesthesiology			
1–86		ISO 8185 Third edition 2008–06–15 (Corrected version), Respiratory tract humidifiers for medical use—Particular requirements for respiratory humidification systems.	Withdrawn. See 1–138.
1–95		ISO 5366–3 Second edition 2001–08–15 Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 3: Paediatric Tracheostomy Tubes [Including TECHNICAL CORRIGENDUM 1 (2003)].	Withdrawn. See 1–117.
1–107		ANSI/AAMI/ISO 5356–1:2004 Anaesthetic and respiratory equipment—Conical connectors—Part 1: Cones and sockets.	Transferred. See 1–62.
1–109		ANSI/AAMI/ISO 5362:2006 Anaesthetic reservoir bags	Transferred. See 1–75.
1–121	1–129	ISO 5359 Fourth edition 2014–10–01 Anaesthetic and respiratory equipment—Low-pressure hose assemblies for use with medical gases [Including AMENDMENT 1 (2017)].	Withdrawn and replaced with newer version including amendment.
1–128	1–130	ISO 18082 First edition 2014–06–15 Anaesthetic and respiratory equipment—Dimensions of noninterchangeable screw-threaded (NIST) low-pressure connectors for medical gases [Including AMENDMENT 1 (2017)].	Withdrawn and replaced with newer version including amendment.
B. Biocompatibility			
2–118		ANSI/AAMI/ISO 10993–11:2006/(R)2010 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity.	Transferred. See 2–176.
2–120		ANSI/AAMI/ISO 10993–6:2007/(R)2014 Biological evaluation of medical devices—Part 6: Tests for local effects after implantation.	Withdrawn.
2–153		ANSI/AAMI/ISO 10993–5:2009/(R)2014 Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity.	Transferred. See 2–245.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
2–156		ANSI/AAMI/ISO 10993–1:2009/(R)2013 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.	Transferred. See 2–220.
2–163		ANSI/AAMI/ISO 10993–9:2009/(R)2014 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	Transferred. See 2–168.
2–165		ANSI/AAMI/ISO 10993–14:2001/(R) 2011 Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products form ceramics.	Transferred. See 2–170.
2–171	2–249	ISO 10993–16 Third edition 2017–05 Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	Withdrawn and replaced with newer version.
2–172		ANSI/AAMI/TIR 10993–19:2006 Biological evaluation of medical devices—Part 19: Physicochemical, morphological, and topographical characterization of materials.	Transferred. See 2–167.
2–173		ANSI/AAMI/ISO 10993–10:2010/(R)2014 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.	Transferred. See 2–174.
2–180		ANSI/AAMI/ISO 10993–16:2010/(R)2014 Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables from medical devices.	Withdrawn.
2–181		ANSI/AAMI/ISO 14155:2011 Clinical investigation of medical devices for human subjects—Good clinical practice [Including: Technical Corrigendum 1 (2011)].	Transferred. See 2–205.
2–190		ANSI/AAMI/ISO 10993–13:2010/(R)2014 Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical devices.	Transferred. See 2–169.
2–198		ANSI/AAMI/ISO 10993–12:2012 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials.	Transferred. See 2–191.
2–207	2–250	ASTM F756–17 Standard Practice for Assessment of Hemolytic Properties of Materials.	Withdrawn and replaced with newer version.
2–221		ANSI/AAMI/ISO 10993–2:2006 (R2014) Biological evaluation of medical devices—Part 2: Animal welfare requirements.	Transferred. See 2–222.
2–226		ANSI/AAMI/ISO 10993–3:2014 Biological evaluation of medical devices—Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity.	Transferred. See 2–228.
2–229	2–251	USP 40–NF35:2017 <87> Biological Reactivity Test, In Vitro—Direct Contact Test.	Withdrawn and replaced with newer version.
2–230	2–252	USP 40–NF35:2017 <87> Biological Reactivity Test, In Vitro—Elution Test.	Withdrawn and replaced with newer version.
2–231	2–253	USP 40–NF35:2017 <88> Biological Reactivity Tests, In Vivo	Withdrawn and replaced with newer version.
2–232	2–254	USP 40–NF35:2017 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version. Extent of Recognition.
2–234		ANSI/AAMI/ISO 10993–4:2002/(R) 2013 & A1:2006/(R)2013 Biological evaluation of medical devices—Part 4: Selection of tests for interaction with blood [Including AMENDMENT 1 (2006)].	Withdrawn.
2–236		ANSI/AAMI/ISO 10993–17:2002(R) 2012 Biological evaluation of medical devices—Part 17: Establishment of allowable limits for leachable substances.	Transferred. See 2–237.
2–239		ANSI/AAMI/ISO TIR 10993–20:2006 Biological Evaluation of Medical Devices—Part 20: Principles and methods for immunotoxicology testing of medical devices.	Transferred. See 2–240.
2–242		ANSI/AAMI/ISO TIR 37137:2014 Cardiovascular biological evaluation of medical devices—Guidance for absorbable implants.	Transferred. See 2–241.
		C. Cardiovascular	
3–80		ANSI/AAMI/ISO 81060–1:2007/(R)2013 Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type.	Transferred. See 3–96.
3–83		ANSI/AAMI/ISO 14708–5:2010 Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices.	Transferred. See 3–92.
3–101		ANSI/AAMI/IEC 60601–2–27:2011 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Transferred. See 3–126.
3–106		ANSI/AAMI/IEC 60601–2–25:2011/(R)2016 Medical electrical equipment—Part 2–25: Particular requirements for the basic safety and essential performance of electrocardiographs.	Transferred. See 3–105.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
3–109		ANSI/AAMI/ISO 27186:2010 Active implantable medical devices—Four-pole connector system for implantable cardiac rhythm management devices—Dimensional and test requirements.	Transferred. See 3–89.
3–111		ANSI/AAMI/ISO 25539–3:2011 Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters.	Transferred. See 3–103.
3–112		ANSI/AAMI/ISO 7199:2009 Cardiovascular implants and artificial organs—Blood gas exchangers (oxygenators).	Transferred. See 3–124.
3–117		ANSI/AAMI/ISO 81060–2 Second edition 2013–05–01 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	Transferred. See 3–122.
3–120		ANSI/AAMI/ISO 25539–2:2012 Cardiovascular implants—Endovascular devices—Part 2: Vascular stents.	Transferred. See 3–116.
3–124	3–150	ISO 7199 Third edition 2016–11–15 Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators).	Withdrawn and replaced with newer version.
3–128		ANSI/AAMI/ISO 14117:2012 Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices.	Transferred. See 3–139.
3–130	3–151	ANSI/AAMI/IEC 80601–2–30:2009 & A1:2013/(R2016) Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	Reaffirmation. Extent of Recognition. Transferred. See 3–123.
3–131		ANSI/AAMI/ISO 27185:2012 Cardiac rhythm management devices—Symbols to be used with cardiac rhythm management device labels, and information to be supplied—General requirements.	Transferred. See 3–132.
3–140		ANSI/AAMI/ISO 5840–3:2013 Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques.	Transferred. See 3–133.
3–141		ANSI/AAMI/ISO 5841–3:2013 Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors (IS–1) for implantable pacemakers.	Transferred. See 3–125.
3–146		ANSI/AAMI/ISO 5840–1:2015 Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements.	Transferred. See 3–145.
3–148		ANSI/AAMI/ISO 5840–2:2015 Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes.	Transferred. See 3–147.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–50		ADA Specification No. 18: 1992 Alginate Impression Materials	Withdrawn. See 4–240.
4–89		ANSI/ADA Specification No. 53 Reaffirmed by ANSI: August 2013 Polymer-Based Crown and Bridge Materials.	Reaffirmation.
4–91		ANSI/ADA Standard No. 80/ISO 7491:2000 Reaffirmed by ANSI: May 2013 Dental Materials—Determination of Color Stability.	Transferred. See 4–241.
4–119		ANSI/ADA Specification No. 82:1998/ISO 13716:1999 Reaffirmed by ANSI: January 2009 Dental Reversible/Irreversible Hydrocolloid Impression Material Systems.	Withdrawn. See 4–240.
4–193		ANSI/ADA Standard No. 15–2008/ISO 22112:2005 Reaffirmed by ANSI: May 2013 Artificial Teeth for Dental Prostheses.	Transferred. See 4–151.
4–230		ANSI/ADA Standard No. 30/ISO 3107:2011 Approved by ANSI: February 2013 Dental Zinc Oxide/Eugenol & Zinc Oxide/Non-Eugenol Cements.	Transferred. See 4–198.
4–235		ANSI/ADA Standard No. 100/ISO 27020:2010 Approved by ANSI: November 2012 Orthodontic Brackets and Tubes.	Transferred. See 4–218.
4–237		ANSI/ADA Standard No.120–2009/ISO 20127:2005 Reaffirmed by ANSI: September 8, 2014 Powered Toothbrushes.	Transferred. See 4–238.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
5–65		ANSI/AAMI/ISO 80369–1:2010 Small bore connectors for liquids and gases in healthcare applications—Part 1: General requirements.	Transferred. See 5–63.
5–70		ANSI/AAMI/ISO 14971:2007/(R)2010 (Corrected 4 October 2007) Medical devices—Application of risk management to medical devices.	Transferred. See 5–40.
5–92		ANSI/AAMI/IEC 60601–1–8:2006 and 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.	Transferred. See 5–76.
5–96		ANSI/AAMI/IEC 62366–1:2015 Medical devices—Part 1: Application of usability engineering to medical devices.	Transferred. See 5–114.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
5–100		ANSI/AAMI/ISO 80369–20:2015 Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods.	Transferred. See 5–97.
5–118		ANSI/AAMI/ISO 15223–1:2016 Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements.	Transferred. See 5–117.
5–119		ANSI/AAMI/ISO 80369–5:2016 Small-bore connectors for liquids and gases in healthcare applications—Part 5: Connectors for limb cuff inflation applications.	Transferred. See 5–107.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–2		ANSI/AAMI/IEC 60601–1–2:2007 (R2012) Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests.	Transferred. See 19–1.
19–12		ANSI/AAMI/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.	Transferred. See 19–8.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–149	6–401	ASTM D7160–16 Standard Practice for Determination of Expiration Dating for Medical Gloves.	Withdrawn and replaced with newer version.
6–178		ASTM D6124–06 (Reapproved 2017) Standard Test Method for Residual Powder on Medical Gloves.	Reaffirmation.
6–214		ASTM D6355–07 (Reapproved 2017) Standard Test Method for Human Repeat Insult Patch Testing of Medical Glove.	Reaffirmation.
6–217	6–402	ASTM F1670/F1670M–17 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood.	Withdrawn and replaced with newer version.
6–227		ANSI/AAMI/IEC 60601–2–21:2009 Medical electrical equipment—Part 2–21: Particular requirements for the basic safety and essential performance of infant radiant warmers.	Transferred. See 6–388.
6–229		ANSI/AAMI/IEC 60601–2–2:2009 Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment.	Transferred. See 6–389.
6–232	6–403	ISO 80601–2–56 Second edition 2017–03 Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.	Withdrawn and replaced with newer version.
6–230		ANSI/AAMI/IEC 60601–2–19:2009 Medical electrical equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators.	Transferred. See 6–385.
6–235		ANSI/AAMI/IEC 60601–2–50:2009 Medical electrical equipment—Part 2–50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.	Transferred. See 6–387.
6–270		ASTM F1840–10 (Reapproved 2016) Standard Terminology for Surgical Suture Needles.	Reaffirmation.
6–304	6–404	ISO 7886–1 Second edition 2017–05 Sterile hypodermic syringes for single use—Part 1: Syringes for manual use.	Withdrawn and replaced with newer version.
6–307	6–405	IEC 80601–2–59 Edition 2.0 2017–09 Medical electrical equipment—Part 2–59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening.	Withdrawn and replaced with newer version.
6–323	6–406	ASTM F1862/F1862M–17 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).	Withdrawn and replaced with newer version.
6–337		ANSI/AAMI/IEC 60601–2–20:2009 Medical electrical equipment—Part 2–20: Particular requirements for the basic safety and essential performance of transport incubators [Including AMENDMENT 1 (2016)].	Transferred. See 6–386.
H. In Vitro Diagnostics (IVD)			
7–271		CLSI M100 27th Edition Performance Standards for Antimicrobial Susceptibility Testing.	Extent of recognition.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		I. Materials	
8–113		ASTM F1147–05 (Reapproved 2017) ε[1] Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings.	Reaffirmation.
8–337		ASTM F621–12 (Reapproved 2017) Standard Specification for Stainless Steel Forgings for Surgical Implants.	Reaffirmation.
8–356		ASTM F67–13 (Reapproved 2017) Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).	Reaffirmation.
8–446	8–460	ASTM F2848–17 Standard Specification for Medical-Grade Ultra-High Molecular Weight Polyethylene Yarns.	Withdrawn and replaced with newer version. Extent of recognition.
		J. Nanotechnology	
		No new entries at this time	
		K. Neurology	
17–1		ANSI/AAMI NS28:1988/(R)2015 Intracranial pressure monitoring devices.	Reaffirmation. Extent of recognition.
17–8	17–15	ISO 14708–3 Second edition 2017–04 Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators.	Withdrawn and replaced with newer version.
17–10		ANSI/AAMI/ISO 14708–3:2008/(R)2011 Implants for surgery—Active implantable medical devices—Part 3: Implantable neurostimulators.	Withdrawn.
17–11	17–16	IEC 60601–2–10 Edition 2.1 2016–04 Medical electrical equipment—Part 2–10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	Withdrawn and replaced with newer version.
		L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
9–64		ANSI/AAMI/IEC 60601–2–2:2009 Medical electrical equipment—Part 2–2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories.	Withdrawn. Duplicate recognition. See 6–229.
9–66		ANSI/AAMI/ISO 8638:2010 Cardiovascular implants and extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters.	Transferred. See 9–89.
9–81		ANSI/AAMI/IEC 60601–2–16:2012 Medical electrical equipment—Part 2–16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment.	Transferred. See 9–80
9–91		ANSI/AAMI/ISO 8637:2010 Cardiovascular implants and extracorporeal systems—Hemodialyzers, hemodiafilters, hemofilters, and hemoconcentrators [Including AMENDMENT 1 (2013)].	Transferred. See 9–92.
9–91	9–114	IEC 60601–2–18: Edition 3.0 2009–08, medical electrical equipment—part 2–18: particular requirements for the basic safety and essential performance of endoscopic equipment.	Withdrawn and replaced with new recognition number.
9–93	9–115	ISO 25841 Third edition 2017–08 Female condoms—Requirements and test methods.	Withdrawn and replaced with newer version.
9–103		ANSI/AAMI/ISO 26722:2014 Water treatment equipment for haemodialysis applications and related therapies.	Transferred. See 9–101.
9–104		ANSI/AAMI/ISO 13958:2014 Concentrates for hemodialysis and related therapies.	Transferred. See 9–97.
9–105		ANSI/AAMI/ISO 13959:2014 Water for hemodialysis and related therapies.	Transferred. See 9–98.
9–106		ANSI/AAMI/ISO 11663:2014 Quality of dialysis fluid for hemodialysis and related therapies.	Transferred. See 9–100.
9–107		ANSI/AAMI/ISO 23500:2014 Guidance for the preparation and quality management of fluids for hemodialysis and related therapies.	Transferred. See 9–99.
		M. Ophthalmic	
10–43	10–105	ISO 11979–8 Third edition 2017–04 Ophthalmic Implants—Intraocular lenses—Part 8: Fundamental requirements.	Withdrawn and replaced with newer version.
10–46	10–106	ISO 18369–3 Second edition 2017–08 Ophthalmic optics—Contact lenses—Part 3: Measurement methods.	Withdrawn and replaced with newer version.
10–54	10–107	ISO 18369–4 Second edition 2017–08 Ophthalmic optics—Contact lenses—Part 4: Physicochemical properties of contact lens materials.	Withdrawn and replaced with newer version.
10–80	10–108	ISO 18369–2 Third edition 2017–08 Ophthalmic optics—Contact lenses—Part 2: Tolerances.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
10–83	10–109	ISO 18369–1 Second edition 2017–08 Ophthalmic optics—Contact lenses—Part 1: Vocabulary, classification system and recommendations for labelling specifications.	Withdrawn and replaced with newer version.
		N. Orthopedic	
11–259		ASTM F2887—12 Standard Specification for Total Elbow Prostheses ..	Withdrawn. See 11–321.
		O. Physical Medicine	
16–200	16–201	ISO 7176–19 Second edition 2008–07–15 AMENDMENT 1 2015–11–15. Wheelchairs—Part 19: Wheeled mobility devices for use as seats in motor vehicles [Including AMENDMENT 1 (2015)].	Withdrawn and replaced with a newer version including amendment.
		P. Radiology	
12–139		NEMA UD 2–2004 (R2009) Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3.	Withdrawn. Duplicate recognition. See 12–105.
12–202	12–308	IEC 60601–2–43 Edition 2.1 2017–05 CONSOLIDATED VERSION Medical electrical equipment—Part 2–43: Particular requirements for the safety and essential performance of X-Ray Equipment for interventional procedures.	Withdrawn and replaced with newer version.
12–204	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.	Withdrawn and replaced with newer version.
12–251	12–310	IEC 60601–2–63 Edition 1.1 2017–07 CONSOLIDATED VERSION Medical electrical equipment—Part 2–63: Particular requirements for the basic safety and essential performance of dental extra-oral X-Ray equipment.	Withdrawn and replaced with newer version.
12–252	12–311	IEC 60601–2–65 Edition 1.1 2017–05 CONSOLIDATED VERSION Medical electrical equipment—Part 2–65: Particular requirements for the basic safety and essential performance of dental intra-oral X-Ray equipment.	Withdrawn and replaced with newer version.
12–227	12–312	IEC 61391–1 Edition 1.1 2017–07 CONSOLIDATED VERSION Ultrasonics—Pulse-echo scanners—Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response.	Withdrawn and replaced with newer version.
12–276	12–313	IEC TS 62462 Edition 2.0 2017–07 Ultrasonics—Output test—Guidance for the maintenance of ultrasound physiotherapy systems.	Withdrawn and replaced with newer version.
12–155	12–314	ISO 11554 Fourth edition 2017–07 Optics and photonics—Lasers and laser-related equipment—Test methods for laser beam power, energy and temporal characteristics.	Withdrawn and replaced with newer version.
12–192	12–315	NEMA Standards Publication MS 8–2016 Characterization of the Specific Absorption Rate (SAR) for Magnetic Resonance Imaging Systems.	Withdrawn and replaced with newer version.
12–258	12–316	IEC 62359 Edition 2.1 2017–09 CONSOLIDATED VERSION Ultrasonics—Field characterization—Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields.	Withdrawn and replaced with newer version.
		Q. Software/Informatics	
13–39		ANSI/AAMI/IEC 80001–1:2010 Application of risk management for IT Networks incorporating medical devices—Part 1: Roles, responsibilities and activities.	Transferred. See 13–38.
13–41		ANSI/AAMI/IEC TIR80001–2–1:2012 Application of risk management for IT-networks incorporating medical devices—Part 2–1: Step by step risk management of medical IT-networks; Practical applications and examples.	Transferred. See 13–40.
13–43		ANSI/AAMI/IEC TIR80001–2–2:2012 Technical Information Report Application of risk management for IT-networks incorporating medical devices—Part 2–2: Guidance for the disclosure and communication of medical device security needs, risks and controls.	Transferred. See 13–42.
13–45		ANSI/AAMI/IEC TIR80001–2–3:2012 Technical Information Report Application of risk management for IT-networks incorporating medical devices—Part 2–3: Guidance for wireless networks.	Transferred. See 13–44.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
13–64		ANSI/AAMI/IEC TIR80001–2–4:2012 Technical Information Report Application of risk management for IT-networks incorporating medical devices—Part 2–4: General implementation guidance for healthcare delivery organizations.	Transferred. See 13–63.
		R. Sterility	
14–221		ANSI/AAMI/ISO TIR 11139:2006 Sterilization of health care products—Vocabulary.	Transferred. See 14–325.
14–222		ANSI/AAMI/ISO 18472:2006/(R)2010 Sterilization of health care products—Biological and chemical indicators—Test equipment.	Transferred. See 14–354.
14–227		ANSI/AAMI/ISO 11737–1:2006 (R)2011 Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product.	Transferred. See 14–407.
14–238		ANSI/AAMI/ISO 11140–5:2007/(R)2012 Sterilization of health care products—Chemical indicators—Part 5: Class 2 indicators for Bowie and Dick air removal test sheets and packs.	Transferred. See 14–332.
14–261		ANSI/AAMI/ISO 17665–1:2006/(R)2013 Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Transferred. See 14–333.
14–274		ANSI/AAMI/ISO 15882:2008/(R)2013 Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results.	Transferred. See 14–334.
14–278		ANSI/AAMI/ISO 10993–7:2008(R)2012 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.	Transferred. See 14–408.
14–285		ANSI/AAMI/ISO 14161:2009/(R)2014 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Transferred. See 14–336.
14–287		ANSI/AAMI/ISO 11737–2:2009/(R)2014 Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process.	Transferred. See 14–327.
14–291		ANSI/AAMI/ISO 14937:2009/(R)2013 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.	Transferred. See 14–337.
14–295		ANSI/AAMI ST81:2004/(R)2016 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices.	Reaffirmation.
14–298		ANSI/AAMI/ISO 11137–3:2006/(R)2010 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects.	Withdrawn. See 14–510.
14–330	14–510	ISO 11137–3 Second edition 2017–06 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects of development, validation and routine control.	Withdrawn and replaced with newer version.
14–339		ANSI/AAMI/ISO 20857:2010/(R)2015 Sterilization of health care products—Dry heat—Requirements for the development, validation and routine control of a sterilization process for medical devices.	Transferred. See 14–340.
14–348		ANSI/AAMI/ISO 13408–2:2003/(R)2013 Aseptic processing of health care products—Part 2: Filtration.	Transferred. See 14–138.
14–349		ANSI/AAMI/ISO 13408–3:2006/(R)2015 Aseptic processing of health care products—Part 3: Lyophilization.	Transferred. See 14–239.
14–350		ANSI/AAMI/ISO 13408–4:2005/(R)2014 Aseptic processing of health care products—Part 4: Clean-in-place technologies.	Transferred. See 14–191.
14–351		ANSI/AAMI/ISO 13408–5:2006/(R)2015 Aseptic processing of health care products—Part 5: Sterilization in place.	Transferred. See 14–240.
14–358		ANSI/AAMI/ISO 14160:2011/(R)2016 Sterilization of health care products—Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives—Requirements for characterization, development, validation and routine control of a sterilization process for medical devices.	Transferred. See 14–361.
14–376		ANSI/AAMI/ISO TIR 17665–2:2009 Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ANSI/AAMI/ISO 17665–1.	Transferred. See 14–277.
14–387		ANSI/AAMI/ISO 13408–7:2012 Aseptic processing of health care products—Part 7: Alternative processes for medical devices and combination products.	Transferred. See 14–388.
14–425		ANSI/AAMI/ISO 13408–6:2005/(R) 2013 & A1:2013 Aseptic processing of health care products—Part 6: Isolator systems [Including AMENDMENT1 (2013)].	Transferred. See 14–424.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–426		ANSI/AAMI/ISO 13408–1:2008 (R2011) Aseptic processing of health care products—Part 1: General requirements [Including AMENDMENT1 (2013)].	Transferred. See 14–427.
14–438		ANSI/AAMI/ISO 11137–2:2013 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Transferred. See 14–409.
14–439	14–511	ANSI/AAMI ST79:2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities.	Withdrawn and replaced with newer version.
14–457		ANSI/AAMI/ISO 11607–1:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging [Including AMENDMENT 1 (2013)].	Transferred. See 14–454.
14–458		ANSI/AAMI/ISO 11607–2:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes [Including AMENDMENT 1 (2013)].	Transferred. See 14–455.
14–459		ANSI/AAMI/ISO 11140–1:2014 Sterilization of health care products—Chemical indicators—Part 1: General requirements.	Transferred. See 14–460.
14–461		ANSI/AAMI/ISO 11137–1:2006/(R)2010 Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including AMENDMENT 1 (2013)].	Transferred. See 14–428.
14–479		ANSI/AAMI/ISO 11135:2014 Sterilization of health care products—Ethylene oxide—Requirements for development, validation and routine control of a sterilization process for medical devices.	Transferred. See 14–452.
		S. Tissue Engineering	
15–17		ASTM F2311–08 Standard Guide for Classification of Therapeutic Skin Substitutes.	Withdrawn.
15–23		ASTM F2739–08 Standard Guide for Quantitating Cell Viability within Biomaterial Scaffolds.	Withdrawn. See 15–50.
15–37	15–51	ASTM F2347–15 Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications.	Withdrawn and replaced with newer version.
15–42	15–52	ASTM F2064–17 Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications.	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: 049.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and Date
	A. Anesthesiology	
1–131	Medical suction equipment—Part 1: Electrically powered suction equipment	ISO 10079–1 Third Edition 2015–11–01.
1–132	Medical suction equipment—Part 2: Manually powered suction equipment	ISO 10079–2 Third Edition 2014–05–01.
1–133	Medical suction equipment—Part 3: Suction equipment powered from a vacuum or positive pressure gas source.	ISO 10079–3 Third Edition 2014–05–01.
1–134	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 1: Evaluation and testing within a risk management process.	ISO 18562–1 First edition 2017–03.
1–135	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 2: Tests for emissions of particulate matter.	ISO 18562–2 First edition 2017–03.
1–136	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 3: Tests for emissions of volatile organic compounds.	ISO 18562–3 First edition 2017–03.
1–137	Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 4: Tests for leachables in condensate.	ISO 18562–4 First edition 2017–03.
1–138	Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.	ISO 80601–2–74 First edition 2017–05.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and Date
	B. Biocompatibility	
	No new entries at this time	
	C. Cardiovascular	
	No new entries at this time	
	D. Dental/Ear, Nose, and Throat (ENT)	
4–240	Dentistry—Hydrocolloid impression materials	ISO 21563 First edition 2013–08–15.
4–241	Dental materials—Determination of colour stability	ISO 7491 Second edition 2000–09–01.
	E. General I (Quality Systems/Risk Management) (QS/RM)	
	No new entries at this time	
	F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
	No new entries at this time	
	G. General Hospital/General Plastic Surgery (GH/GPS)	
6–407	Standard Specification for Adult Portable Bed Rails and Related Products	ASTM F3186–17.
	H. In Vitro Diagnostics (IVD)	
7–274	Verification and Validation of Multiplex Nucleic Acid Assays; Approved Guideline	CLSI MM17–A Vol. 28 No. 9 (Replaces MM17–P Vol. 27 No. 21).
	I. Materials	
8–461	Standard Guide for Selecting Test Soils for Validation of Cleaning Methods for Reusable Medical Devices.	ASTM F3208–17.
8–462	Standard Test Method for Determining the Flexural Stiffness of Medical Textiles	ASTM F3260–17.
8–463	Standard Guide for Additive Manufacturing—General Principles—Requirements for Purchased AM Parts.	ISO/ASTM 52901 First edition 2017–08.
8–464	Assessment of the safety of magnetic resonance imaging for patients with an active implantable medical device.	ISO 10974 Second edition 2018.
	J. Nanotechnology	
18–9	Nanotechnologies—Guidance on physico-chemical characterization of engineered nanoscale materials for toxicologic assessment [Including CORRIGENDUM 1 (2012)].	ISO/TR 13014 First edition 2012–05–15.
18–10	Nanotechnologies—Endotoxin test on nanomaterial samples for in vitro systems—Limulus amebocyte lysate (LAL) test.	ISO 29701 First edition 2010–09–15.
	K. Neurology	
	No new entries at this time	
	L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
9–115	Condoms—Guidance on clinical studies—Part 1: Male condoms, clinical function studies based on self-reports.	ISO 29943–1 First edition 2017–07.
9–116	Condoms—Guidance on clinical studies—Part 2: Female condoms, clinical function studies based on self-reports.	ISO 29943–2 First edition 2017–07.
	M. Ophthalmic	
10–110	Ophthalmic implants—Ophthalmic viscosurgical devices [Including AMENDMENT 1 (2017)]	ISO 15798 Third edition 2013–09–15 AMENDMENT 1 2017–05.
	N. Orthopedic	
	No new entries at this time	

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and Date
	O. Physical Medicine	
16–202	RESNA Standard for Wheelchairs Volume 4: Wheelchairs and Transportation	RESNA WC–4:2017.
	P. Radiology	
	No new entries at this time	
	Q. Software/Informatics	
13–104	Software Cybersecurity for Network-Connectable Products, Part 2–1: Particular Requirements for Network Connectable Components of Healthcare and Wellness Systems.	ANSI/UL 2900–2–1, First Edition September 1, 2017.
	R. Sterility	
	No new entries at this time	
	S. Tissue Engineering	
15–53	Standard Guide for Assessing Medical Device Cytocompatibility with Delivered Cellular Therapies.	ASTM F3206 –17.
15–54	Standard Guide for in vivo Evaluation of Rabbit Lumbar Intertransverse Process Spinal Fusion Model.	ASTM F3207–17.

[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.* FDA will be incorporating 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 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. Beginning with recognition list 049, FDA will no longer include in the database the CDRH Office and Division associated with recognized standards, Devices Affected, and Processes Affected. Beginning with recognition list 049 FDA will automatically incorporate, upon publication, a U.S. parallel adoption of an existing recognized international standard.

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 following information available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123739.htm.*

Dated: May 31, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–12222 Filed 6–6–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–1635]

Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Prescription Drug User Fee Act Waivers for Fixed-Combination Antiretroviral Drugs for the President's Emergency Plan for AIDS Relief.'' This draft guidance describes circumstances under which an applicant may be eligible for a barrier-to-innovation waiver for some new drug applications (NDAs) for fixed-combination versions and single-entity versions of previously approved antiretroviral therapies for the treatment of human immunodeficiency virus (HIV).

DATES: Submit either electronic or written comments on the guidance August 6, 2018 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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