those interested in participating in this voluntary program.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section of the FD&C act; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
704(g); Request for Accreditation	1	1	1	80	80

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04717 Filed 3–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 051

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: 051'' (Recognition List Number: 051), 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 March 14, 2019.

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: 051.'' 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: 051.

- 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: *http://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: 051 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: 051 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: 051'' to Scott Colburn (see **FOR FURTHER INFORMATION CONTACT**). 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 (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** 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 standard recognition program and is available at *https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf.* Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.*

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Additional information on the Agency's standards program is available at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 051

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: 051'' 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 [2]
		A. Anesthesiology	
1–104	1–141	ISO 80601–2–13 First edition 2011–08–11 Medical electrical equipment—Part 2–13: Particular requirements for basic safety and essential performance of an anaesthetic workstation [Including: AMENDMENT 1 (2015) and AMENDMENT 2 (2018)].	Withdrawn and replaced with newer version including amendment. Extent of Recognition.
1–108		ANSI/AAMI/ISO 5361:2012 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Withdrawn. See 1–118.
1–110		ANSI/AAMI/ISO 5366–1:2000 Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 1: Tubes and connectors for use in adults.	Withdrawn. See 1–117.
1–111		ANSI/AAMI/ISO 5366–3:2001 Anaesthetic and respiratory equipment—Tracheostomy Tubes—Part 3: Paediatric Tracheostomy Tubes.	Withdrawn. See 1–117.
1–114		ISO 18835 First Edition 2015–04–01 Inhalational Anaesthesia Systems—Draw-over Anaesthetic Systems.	Extent of Recognition.
1–117		ISO 5366 First edition 2016–10–01 Anaesthetic and respiratory equipment—Tracheostomy tubes and connectors.	Extent of Recognition.
1–118		ISO 5361 Third edition 2016–09–01 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Extent of Recognition.
1–120		ISO 18190 First edition 2016–11–01 Anaesthetic and respiratory equipment—General requirements for airways and related equipment.	Extent of Recognition.
1–138		ISO 80601–2–74 First edition 2017–05 Medical electrical equipment—Part 2–74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.	Extent of Recognition.
		B. Biocompatibility	
2–136		ASTM E1262–88 (Reapproved 2018) Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay.	Reaffirmation.
2–141		ASTM F1984–99 (Reapproved 2018) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials.	Reaffirmation.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change [2]
2–145		ASTM F1439–03 (Reapproved 2018) Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials.	Reaffirmation.
2–220	2–258	ISO 10993–1 Fifth edition 2018–08 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.	Withdrawn and replaced with newer version.
2–251	2–259	USP 41–NF36:2018 <87> Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version.
2–252	2–260	USP 41–NF36:2018 <87> Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version.
2–253	2–261	USP 41–NF36:2018 <88> Biological Reactivity Test, In Vivo	Withdrawn and replaced with newer version.
2–254	2–262	USP 41–NF36:2018 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version. Extent of Recognition.
C. Cardiovascular			
3–44		AAMI BP22:1994 (R2016) Blood Pressure Transducers	Reaffirmation.
3–52		ANSI/AAMI EC12:2000/(R) 2015 Disposable ECG electrodes	Reaffirmation.
3–55		ASTM F1830–97 (Reapproved 2017) Standard Practice for Selection of Blood for in vitro Evaluation of Blood Pumps.	Reaffirmation.
3–56		ASTM F1841–97 (Reapproved 2017) Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps.	Reaffirmation. Extent of Recognition.
3–66		ASTM F2081–06 (Reapproved 2017) Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents.	Reaffirmation.
3–79		ASTM F2079–09 (Reapproved 2017) Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents.	Reaffirmation.
3–86		ASTM F2394–07 (Reapproved 2017) Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System.	Reaffirmation. Extent of Recognition.
3–99		AAMI TIR 42:2010 Evaluation of Particulates Associated with Vascular Medical Devices.	Extent of Recognition.
3–122		IEC 81060–2 Second edition 2013–05–01 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	Extent of Recognition.
3–123		IEC 80601–2–30 Edition 2.0 2018–03 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	Title change. Extent of recognition.
3–124		ISO 7199:2009 Cardiovascular implants and artificial organs—Blood gas exchangers (oxygenators).	Withdrawn.
3–126		IEC 60601–2–27 Edition 3.0 2011–03 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Extent of recognition.
3–127		ANSI/AAMI/IEC 60601–2–47:2012/(R) 2016 Medical electrical equipment—Part 2–47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.	Reaffirmation.
3–138		ASTM F2942–13 Standard Guide for the In Vitro Axial, Bending, and Rotational Durability Test of Vascular Stents.	Extent of Recognition.
3–142		ISO/TS 17137 First edition 2014–05–15 Cardiovascular implants and extracorporeal systems—Cardiovascular absorbable implants.	Extent of Recognition.
D. Dental/Ear, Nose, and Throat (ENT)			
4–126	4–248	ISO 10477 Third edition 2018–06 Dentistry—Polymer-based crown and veneering materials.	Withdrawn and replaced with newer version.
4–150	4–249	ANSI/ADA Standard No. 19—2018 Elastomeric Impression Materials	Withdrawn and replaced with newer version.
4–162		ANSI S3.4–2007 (Reaffirmed 2017) American National Standard Procedure for the Computation of Loudness of Steady Sounds.	Reaffirmation.
4–163		ANSI S3.5–1997 (Reaffirmed 2017) American National Standard Methods for Calculation of the Speech Intelligibility Index.	Reaffirmation.
4–171		ANSI S3.37–1987 (Reaffirmed 2017) American National Standard Preferred Earhook Nozzle Thread for Postauricular Hearing Aids.	Reaffirmation.
4–213	4–250	ISO 7494–1 Third edition 2018–06 Dentistry—Stationary dental units and dental patient chairs—Part 1: General requirements.	Withdrawn and replaced with newer version.
4–217		ANSI/ASA S3.36–2012 (Reaffirmed 2018) American National Standard Specification for a Manikin for Simulated in-situ Airborne Acoustic Measurements.	Reaffirmation.
4–223	4–251	ISO 6872 Fourth edition 2015–06–01 Dentistry—Ceramic materials [including AMENDMENT 1 2018–04].	Withdrawn and replaced with newer version including amendment.
4–226	4–252	ISO 10650 Second edition 2018–08 Dentistry—Powered polymerization activators	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 [2]
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–39	5–120	IEC 60812 Edition 3.0 2018–08 Failure modes and effects analysis (FMEA and FMECA).	Withdrawn and replaced with newer version. Title change.
5–63	5–121	ISO 80369–1 Second edition 2018–11 Small-bore connectors for liquids and gases in healthcare applications—Part 1: General requirements.	Withdrawn and replaced with newer version.
5–105		ISO 16142–1 First edition 2016–03–01 Medical devices—Recognized essential principles of safety and performance of medical devices—Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on selection of standards.	Withdrawn.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–13	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.	Withdrawn and replaced with newer version. Title change.
	19–33	IEC 62133–2 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 2: Lithium systems.	
19–18	19–34	IEC 61010–1 Edition 3.1 2017–01 Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–239	6–410	ISO 8536–6 Third edition 2016–12–01 Infusion equipment for medical use—Part 6: Freeze drying closures for infusion bottles.	Withdrawn and replaced with newer version.
6–338		ASTM D7866–14 Standard Specification for Radiation Attenuating Protective Gloves.	Extent of recognition.
6–383	6–411	ASTM D6499–18 Standard Test Method for Immunological Measurement of Antigenic Protein in Hevea Natural Rubber (HNR) and its Products.	Withdrawn and replaced with newer version.
6–391	6–412	USP 41–NF36:2018 Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–392	6–413	USP 41–NF36:2018 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–393	6–414	USP 41–NF36:2018 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–394	6–415	USP 41–NF36:2018 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–395	6–416	USP 41–NF36:2018 <861> Sutures—Diameter	Withdrawn and replaced with newer version.
6–396	6–417	USP 41–NF36:2018 <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–397	6–418	USP 41–NF36:2018 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–398	6–419	USP 41–NF36:2018 Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
6–399	6–420	USP 41–NF36: 2018 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–139		CLSI QMS24 3rd Edition September 2016 Replaces GP27–A2 and GP29–A2. Using Proficiency Testing and Alternative Assessment to Improve Medical Laboratory Quality.	Title change.
7–178		CLSI M22–A3 Vol. 24 No. 19 Replaces M22–A2 Vol. 16 No. 16 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition.	Extent of recognition.
7–200	7–285	CLSI M48 2nd Edition Laboratory Detection and Identification of Mycobacteria	Withdrawn and replaced with a newer version.
7–215		CLSI M44–A2 Vol. 29 No. 17 Replaces MM44–A Vol. 24 No. 15 Method for Antifungal Disk Diffusion Susceptibility Testing of Yeast; Approved Guideline—Second Edition.	Extent of recognition.
7–222		CLSI M24–A2 (Replaces M24–A) Susceptibility Testing of Mycobacteria, Nocardiae and other Aerobic Actinomycetes; Approved Standards—Second Edition.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change [2]
7–228	7–286	CLSI M11 9th Edition Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria.	Withdrawn and replaced with a newer version. Extent of recognition.
7–232		CLSI MM05–A2 Vol. 32 No. 6 Replaces MM05–A Vol. 23 No. 17 Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline—Second Edition.	Extent of recognition.
7–262		CLSI M45 3rd Edition Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria.	Extent of recognition.
7–269		CLSI MM23 1st Edition Molecular Diagnostic Methods for Solid Tumors (Nonhematological Neoplasms).	Extent of recognition.
7–282		CLSI M60 1st Edition Performance Standards for Antifungal Susceptibility Testing of Yeasts.	Withdrawn. Duplicate version.
		I. Materials	
8–179		ASTM F754–08 (Reapproved 2015) Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders.	Extent of recognition.
8–335	8–480	ASTM F2063–18 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.	Withdrawn and replaced with newer version.
8–345	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).	Withdrawn and replaced with newer version.
8–365	8–482	ASTM D1505–18 Standard Test Method for Density of Plastics by the Density-Gradient Technique.	Withdrawn and replaced with newer version.
8–371	8–483	ASTM F601–18 Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants.	Withdrawn and replaced with newer version.
8–375	8–484	ASTM F2066–18 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150).	Withdrawn and replaced with newer version.
8–462	8–485	ASTM F3260–18 Standard Test Method for Determining the Flexural Stiffness of Medical Textiles.	Withdrawn and replaced with newer version.
		J. Nanotechnology	
18–2		ASTM E2535–07 (Reapproved 2018) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings.	Reaffirmation.
18–5		ASTM E2859–11 (Reapproved 2017) Standard Guide for Size Measurement of Nanoparticles Using Atomic Force Microscopy.	Reaffirmation.
18–6		ASTM E2865–12 (Reapproved 2018) Standard Guide for Measurement of Electrophoretic Mobility and Zeta Potential of Nanosized Biological Materials.	Reaffirmation.
18–7		ASTM E2834–12 (Reapproved 2018) Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Nanoparticle Tracking Analysis (NTA).	Reaffirmation.
18–8		ASTM E2578–07 (Reapproved 2018) Standard Practice for Calculation of Mean Sizes/Diameters and Standard Deviations of Particle Size Distributions.	Reaffirmation.
		K. Neurology	
17–14		ANSI/AAMI NS4:2013/(R) 2017 Transcutaneous electrical nerve stimulators	Reaffirmation.
		L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
9–68		ISO 23409 First edition 2011–02–15 Male Condoms—Requirements and test methods for condoms made from synthetic materials.	Extent of Recognition.
9–80	9–121	IEC 60601–2–16 Edition 5.0 2018–04 Medical electrical equipment—Part 2–16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment.	Withdrawn and replaced with newer version.
9–89		ANSI AAMI ISO 8638:2010 (R2015) Cardiovascular implants and extracorporeal systems—Extracorporeal blood circuit for hemodialyzers, hemodiafilters and hemofilters.	Reaffirmation.
9–93	9–122	ISO 25841 Third edition 2017–08 Female condoms—Requirements and test methods.	Withdrawn and replaced with newer version.
9–111		ISO 4074 Third edition 2015–10–15 Natural latex rubber condoms—Requirements and test methods.	Extent of Recognition.
9–112		ASTM D3492–16 Standard Specification for Rubber Contraceptives (Male Condoms).	Extent of Recognition.
		M. Ophthalmic	
10–74		ISO 10940 Second edition 2009–08–01 Ophthalmic instruments—Fundus cameras.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change [2]
10–85		ISO 11980 Third edition 2012–11–15 Corrected version 2012–12–01 Ophthalmic optics—Contact lenses and contact lens care products—Guidance for clinical investigations.	Title change. Extent of recognition.
10–86		ISO 14729 First edition 2001–04–15 Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses [Including: Amendment 1 (2010)].	Extent of recognition.
10–89		ANSI Z80.7–2013 (R2018) American National Standard for Ophthalmic Optics—Intraocular Lenses.	Reaffirmation. Extent of recognition.
10–93		ANSI Z80.27–2014 American National Standard for Ophthalmics—Implantable Glaucoma Devices.	Extent of recognition.
10–108		ISO 18369–2 Third Edition 2017–08 Ophthalmic optics—Contact lenses—Part 2: Tolerances.	Extent of recognition.
		N. Orthopedic	
11–184		ISO 8827 First edition 1988–10–15 Implants for surgery—Staples with parallel legs for orthopaedic use—General requirements.	Extent of Recognition.
11–234	11–342	ASTM F732–17 Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses.	Withdrawn and replaced with newer version.
11–243	11–343	ASTM F2346–18 Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs.	Withdrawn and replaced with newer version.
11–272		ASTM F1714–96 (Reapproved 2018) Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices.	Reaffirmation.
11–295	11–344	ASTM F2580–18 Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis.	Withdrawn and replaced with newer version.
11–302	11–345	ASTM F1717–18 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
11–323	11–346	ASTM F2706–18 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
11–331	11–347	ASTM F2077–18 Test Methods for Intervertebral Body Fusion Devices	Withdrawn and replaced with newer version.
		O. Physical Medicine	
16–29	16–204	ISO 7176–6 Third edition 2018–06 Wheelchairs—Part 6: Determination of maximum speed of electrically powered wheelchairs.	Withdrawn and replaced with newer version.
16–202	16–205	RESNA WC–4:2017 Standard for Wheelchairs Volume 4: Wheelchairs and Transportation.	Withdrawn and replaced with new recognition number.
		P. Radiology	
12–102		ANSI/IES RP–27.2–00/R17 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Measurement Techniques.	Reaffirmation.
12–179	12–321	ANSI/IES RP–27.3–17 Recommended Practice for Photobiological Safety for Lamps—Risk Group Classification and Labeling.	Withdrawn and replaced with newer version.
12–231	12–322	NEMA MS 5–2018 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
12–247	12–323	ISO 11990 Third edition 2018–08 Lasers and laser-related equipment—Determination of laser resistance of tracheal tube shaft and tracheal tube cuffs.	Withdrawn and replaced with newer version. Title change.
12–305	12–324	ISO 13694 Third edition 2018–11 Optics and Photonics—Lasers and laser-related equipment—Test methods for laser beam power (energy) density distribution.	Withdrawn and replaced with newer version.
		Q. Software/Informatics	
13–32		ANSI AAMI IEC 62304:2006 Medical device software—Software life cycle processes.	Transition period.
13–79		IEC 62304 Edition 1.1 2015–06 CONSOLIDATED VERSION Medical device software—Software life cycle processes.	Title change and transition period.
		R. Sterility	
14–314		ANSI/AAMI ST67:2011/(R) 2017 Sterilization of health care products—Requirements and guidance for selecting a sterility assurance level (SAL) for products labeled 'sterile'.	Reaffirmation.
14–311	14–518	ANSI/AAMI ST55:2016 Table-top steam sterilizers	Withdrawn and replaced with newer version.
14–396		ANSI/AAMI ST77:2013/(R) 2018 Containment devices for reusable medical device sterilization.	Reaffirmation.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change [2]
14–410	14–519	ASTM F17–18 Standard Terminology Relating to Primary Barrier Packaging	Withdrawn and replaced with newer version.
14–503	14–520	USP 41–NF36:2018 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–504	14–521	USP 41–NF36:2018 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–505	14–522	USP 41–NF36:2018 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–506	14–523	USP 41–NF36:2018 <161> Medical Devices—Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14–507	14–524	USP 41–NF36:2018 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–508	14–525	USP 41–NF36:2018 <55> Biological Indicators—Resistance Performance Tests	Withdrawn and replaced with newer version.
14–509	14–526	USP 41–NF36:2018 <1229.5> Biological Indicators for Sterilization	Withdrawn and replaced with newer version.
S. Tissue Engineering			
15–47		ISO 22442–3 First edition 2007–12–15 Medical devices utilizing animal tissues and their derivatives—Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents.	Extent of Recognition.

[1] All standard titles in this table conform to the style requirements of the respective organizations.
[2] Standards that are ''Withdrawn'' or ''Withdrawn and replaced with newer version'' will have a transition period with an expiration date as noted in the recognition database *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.*

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: 051.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
A. Anesthesiology		
	No new entries at this time..	
B. Biocompatibility		
	No new entries at this time..	
C. Cardiovascular		
3–157	Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses.	ANSI/AAMI/ISO 25539–1: 2017.
3–158	Standard Guide for Coating Characterization of Drug Coated Balloons	ASTM F3320–18.
3–159	Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.	ISO 5910 First edition 2018–06.
D. Dental/Ear, Nose, and Throat (ENT)		
4–253	Polymer-based Restorative Materials	ANSI/ADA Standard No. 27–2016.
4–254	Athletic Mouth Protectors and Materials	ANSI/ADA Standard No. 99–2001 (Reaffirmed 2013).
4–255	Dental CAD/CAM Machinable Zirconia Blanks	ANSI/ADA Standard No. 131–2015.
4–256	Scanning Accuracy of Dental Chairside and Laboratory CAD/CAM Systems	ANSI/ADA Standard No. 132–2015.
4–257	Dentistry—Fluoride varnishes	ISO 17730 First edition 2014–11–01.
E. General I (Quality Systems/Risk Management) (QS/RM)		
5–122	Assessing Credibility of Computational Modeling Through Verification and Validation: Application to Medical Devices.	ASME V&V 40–2018.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
	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
G. General Hospital/General Plastic Surgery (GH/GPS)		
	No new entries at this time..	
H. In Vitro Diagnostics (IVD)		
	No new entries at this time..	
I. Materials		
8–486	Standard Guide for in vitro Degradation Testing of Absorbable Metals	ASTM F3268–18.
8–487	Additive manufacturing—Design—Requirements, guidelines and recommendations.	ISO/ASTM52910–18.
8–488	Standard for Additive Manufacturing—Post Processing Methods—Standard Specification for Thermal Post-Processing Metal Parts Made Via Powder Bed Fusion.	ASTM F3301–18a.
8–489	Standard for Additive Manufacturing—Finished Part Properties—Standard Specification for Titanium Alloys via Powder Bed Fusion.	ASTM F3302–18.
8–490	Standard for Additive Manufacturing—Process Characteristics and Performance: Practice for Metal Powder Bed Fusion Process to Meet Critical Applications.	ASTM F3303–18.
J. Nanotechnology		
18–11	Nanotechnologies—Nanomaterial risk evaluation	ISO/TR 13121 First edition 2011–05–15.
18–12	Nanotechnology—Nanoparticles in powder form—Characteristics and measurements.	ISO/TS 17200 First edition 2013–06–01.
K. Neurology		
	No new entries at this time..	
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)		
	No new entries at this time..	
M. Ophthalmic		
10–114	American National Standard for Ophthalmics—Methods of Reporting Optical Aberrations of Eyes.	ANSI Z80.28–2017.
10–115	American National Standard for Ophthalmics—Accommodative Intraocular Lenses.	ANSI Z80.29–2015.
N. Orthopedic		
11–348	Implants for surgery—Cleanliness of orthopedic implants—General requirements.	ISO 19227 First edition 2018–03.
O. Physical Medicine		
16–206	Walking aids manipulated by both arms—Requirements and test methods—Part 2: Rollators.	ISO 11199–2 Second edition 2005–04–15.
P. Radiology		
	No new entries at this time..	
Q. Software/Informatics		
13–105	Classification of defects in health software	ANSI/AAMI SW91:2018.
13–106	Health informatics—Point-of-care medical device communication Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.	IEEE Std 11073–10207–2017.
13–107	Health informatics—Point-of-care medical device communication—Part 20702: Medical devices communication profile for web services.	ISO/IEEE 11073–20702 First edition 2018–09.
R. Sterility		
	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
	S. Tissue Engineering	
15–56	Standard Test Method for Evaluating Growth of Engineered Cartilage Tissue using Magnetic Resonance Imaging.	ASTM F3224–17.

[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.* 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. Beginning with list 52, FDA will no longer announce in the **Federal Register** updates to current recognized standards for reapproved or reaffirmed standards because reapproved or reaffirmed standards have not changed from the recognized standard. International and national standards developing organizations use the designations of reapproved or reaffirmed to indicate a standard has been reviewed but no changes were made to the standard at that time.

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: March 8, 2019.

Lowell J. Schiller,

Acting Associate Commissioner for Policy.

[FR Doc. 2019–04710 Filed 3–13–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request, Information Collection Request Title: HIV Quality Measures (HIVQM) Module, OMB No. 0906–0022—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR must be received no later than May 13, 2019.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer, at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: HIV Quality Measures (HIVQM) Module OMB No. 0906–0022—Revision.

Abstract: HRSA Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low-income people living with HIV (PLWH). Nearly two-thirds of clients (patients) live at or below 100 percent of the Federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million PLWH—more than 50 percent of all people living with diagnosed HIV in the United States.

All parts of the RWHAP must follow the legislative requirements for the establishment of clinical quality management programs to assess their HIV services according to the most recent HHS guidelines and to develop strategies to improve access to quality HIV services. The HIVQM Module supports recipients and subrecipients in their clinical quality management, performance measurement, service delivery, and monitoring of client health outcomes; and supports the requirement imposed by the Uniform Administrative Requirements, Cost Principles, and Audit Requirements that recipients relate performance accomplishments of their Federal awards. 45 CFR 75.301. The module is accessible via the Ryan White Services Report, an existing online portal that RWHAP recipients already use for required data collection of their services. While the use of the module is voluntary for RWHAP recipients, its use is strongly encouraged.

The HRSA performance measures are comprised of the following categories: (1) Core, (2) all ages, (3) adolescent/adult, (4) HIV-infected children, (5) HIV-exposed children, (6) medical case management, (7) oral health, (8) AIDS drug assistance program, and (9) systems level performance measures. Recipients can choose the performance measures they want to monitor and may enter data on their measures into the module up to 4 times a year and then generate reports to assess their performance. Recipients may also compare their performance against other recipients regionally and nationally.

Need and Proposed Use of the Information: The HIVQM Module provides recipients an easy-to-use and