the information package in accordance with the guidance.

Dated: October 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–22954 Filed 10–19–18; 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: 050

**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: 050'' (Recognition List Number: 050), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

**DATES:** Submit electronic or written comments concerning this document at any time. These modifications to the list of recognized standards are effective October 22, 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: 050.'' 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: 050.

- 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: 050 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: 050 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: 050'' 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, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

**FOR FURTHER INFORMATION CONTACT:** Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 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 (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device

premarket review submissions or other requirements.

In the **Federal Register** notice of September 13, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled ''Appropriate use of Voluntary Consensus Standards in Premarket Submission 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: 050

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: 050'' 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** | | | |
| 1–85 | 1–139 | ISO 80601–2–61 Second edition 2017–12 (Corrected version 2018–02) Medical electrical equipment—Part 2–61: Particular requirements for basic safety and essential performance of pulse oximeter equipment. | Withdrawn and replaced with newer version. |
| 1–96 | 1–140 | ISO 80601–2–55 Second edition 2018–02 Medical electrical equipment—Part 2–55: Particular requirements for the basic safety and essential performance of respiratory gas monitors. | Withdrawn and replaced with newer version. |
| **B. Biocompatibility** | | | |
| 2–176 | 2–255 | ISO 10993–11 Third edition 2017–09 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity. | Withdrawn and replaced with newer version. |
| 2–204 | 2–256 | ASTM F720–17 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test. | Withdrawn and replaced with newer version. |
| 2–233 | 2–257 | ASTM F2382–17e1 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT). | Withdrawn and replaced with newer version. |
| **C. Cardiovascular** | | | |
| 3–110 | | AAMI TIR41:2011/(R)2017 Technical Information Report Active implantable medical devices—Guidance for designation of left ventricle and implantable cardioverter defibrillator lead connectors and pulse generator connector cavities for implantable pacemakers and implantable cardioverter defibrillators. | Reaffirmation. |
| 3–123 | 3–152 | IEC 80601–2–30 Edition 1.1 2013–07 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. | Withdrawn and replaced with newer version. |
| **D. Dental/Ear, Nose, and Throat (ENT)** | | | |
| 4–214 | 4–242 | ISO 10139–1 Third edition 2018–03 Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use. | Withdrawn and replaced with newer version. |
| **E. General I (Quality Systems/Risk Management) (QS/RM)** | | | |
| 5–42 | | ASTM D903–98 (Reapproved 2017) Standard Test Method for Peel or Stripping Strength of Adhesive Bonds. | Reaffirmation. |
| **F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)** | | | |
| 19–8 | | IEC 60601–1–2 Edition 4.0 2014–02 Medical electrical equipment—Part 1–2: General requirements for basic safety and essential performance—Collateral Standard: Electromagnetic disturbances—Requirements and tests. | Extent of recognition. |
| 19–19 | | IEC TR 60601–4–2 Edition 1.0 2016–05 Medical electrical equipment—Part 4–2: Guidance and interpretation—Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. | 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] |
|---|---|---|---|
| 19–21 | 19–30 | AIM Standard 7351731 Rev. 2.00 Medical Electrical Equipment and System Electromagnetic Immunity Test for Exposure to Radio Frequency Identification Readers—An AIM Standard. | Withdrawn and replaced with newer version. |
| | | **G. General Hospital/General Plastic Surgery (GH/GPS)** | |
| 6–123 | | ASTM E667–98 (Reapproved 2017) Standard Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers. | Reaffirmation. |
| 6–254 | | ASTM F2100–11 (Reapproved 2018) Standard Specification for Performance of Materials Used in Medical Face Masks. | Reaffirmation. |
| 6–301 | 6–408 | ISO 10555–1 Second edition 2013–06–15 Intravascular catheters—Sterile and single-use catheters—Part 1: General requirements [Including AMENDMENT 1 (2017)]. | Withdrawn and replaced with newer version including amendment. |
| 6–352 | 6–409 | ASTM F703–18 Standard Specification for Implantable Breast Prostheses | Withdrawn and replaced with newer version. |
| | | **H. In Vitro Diagnostics (IVD)** | |
| 7–127 | 7–275 | CLSI EP07 3rd Edition Interference Testing in Clinical Chemistry | Withdrawn and replaced with newer version. |
| 7–171 | 7–276 | CLSI M38 3rd Edition Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi. | Withdrawn and replaced with newer version. |
| 7–201 | 7–277 | CLSI GP41 7th Edition Collection of Diagnostic Venous Blood Specimens | Withdrawn and replaced with newer version. |
| 7–204 | 7–278 | CLSI M27 4th Edition Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts. | Withdrawn and replaced with newer version. |
| 7–217 | | CLSI M60 1st Edition Performance Standards for Antifungal Susceptibility Testing of Yeasts. | Title change. |
| 7–240 | | CLSI M27–S4 Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement. | Withdrawn. See 7–217. |
| 7–245 | | CLSI EP09–A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition. | Withdrawn. |
| 7–254 | 7–279 | CLSI M07 11th Edition Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically. | Withdrawn and replaced with newer version. |
| 7–258 | 7–280 | CLSI M02 13th Edition Performance Standards for Antimicrobial Disk Susceptibility Tests. | Withdrawn and replaced with newer version. |
| 7–271 | 7–281 | CLSI M100 28th Edition Performance Standards for Antimicrobial Susceptibility Testing. | Withdrawn and replaced with newer version. |
| | | **I. Materials** | |
| 8–57 | 8–465 | ISO 5832–2 Fourth edition 2018–03 Implants for surgery—Metallic materials—Part 2: Unalloyed titanium. | Withdrawn and replaced with newer version. |
| 8–112 | | ASTM F1044–05 (Reapproved 2017)e1 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings. | Reaffirmation. |
| 8–128 | 8–466 | ASTM F2213–17 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment. | Withdrawn and replaced with newer version. |
| 8–330 | 8–467 | ASTM F1978–18 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser. | Withdrawn and replaced with newer version. |
| 8–334 | 8–468 | ASTM F2459–18 Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis. | Withdrawn and replaced with newer version. |
| 8–372 | 8–469 | ASTM F560–17 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400). | Withdrawn and replaced with newer version. |
| 8–380 | | ASTM F1160–14 (Reapproved 2017)e1 Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings. | Reaffirmation. |
| 8–382 | 8–470 | ASTM F2102–17 Standard Guide for Evaluating the Extent of Oxidation in Polyethylene Fabricated Forms Intended for Surgical Implants. | Withdrawn and replaced with newer version. |
| 8–390 | 8–471 | ASTM F1925–17 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants. | Withdrawn and replaced with newer version. |
| 8–412 | | ASTM F2537–06 (Reapproved 2017) Standard Practice for Calibration of Linear Displacement Sensor Systems Used to Measure Micromotion. | Reaffirmation. |
| 8–414 | 8–472 | ASTM F2847–17 Standard Practice for Reporting and Assessment of Residues on Single-Use Implants and Single-Use Sterile Instruments. | Withdrawn and replaced with newer version. |
| 8–419 | 8–473 | ASTM F2885–17 Standard Specification for Metal Injection Molded Titanium-6Aluminum-4Vanadium Components for Surgical Implant Applications. | Withdrawn and replaced with newer version. Extent of recognition. |
| 8–420 | 8–474 | ASTM F2886–17 Standard Specification for Metal Injection Molded Cobalt-28Chromium-6Molybdenum Components for Surgical Implant Applications. | 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] |
|---|---|---|---|
| 8–436 | 8–475 | ASTM F2026–17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications. | Withdrawn and replaced with newer version. |
| 8–448 | 8–476 | ASTM F2004–17 Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis. | Withdrawn and replaced with newer version. |
| 8–454 | 8–477 | ASTM F2129–17b Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices. | Withdrawn and replaced with newer version. |
| | | **J. Nanotechnology** | |
| | | No new entries at this time. | |
| | | **K. Neurology** | |
| | | No new entries at this time. | |
| | | **L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)** | |
| 9–43 | 9–117 | ISO 16038 Second edition 2017–11 Male condoms—Guidance on the use of ISO 4074 and ISO 23409 in the quality management of condoms. | Withdrawn and replaced with newer version. |
| 9–67 | | ASTM D7661–10 (Reapproved 2017) Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. | Reaffirmation. |
| 9–92 | 9–118 | ISO 8637–1 First edition 2017–11 Extracorporeal systems for blood purification—Part 1: Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators. | Withdrawn and replaced with newer version. |
| 9–95 | 9–119 | IEC 60601–2–36 Edition 2.0 2014–04 Medical electrical equipment—Part 2–36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy. | Withdrawn and replaced with new recognition number. |
| 9–112 | 9–120 | ASTM D3492–16 Standard Specification for Rubber Contraceptives (Male Condoms). | Withdrawn and replaced with newer version. |
| | | **M. Ophthalmic** | |
| 10–56 | | ANSI Z80.12–2007 (R2017) American National Standard for Ophthalmics—Multifocal Intraocular Lenses. | Reaffirmation. |
| 10–57 | | ANSI Z80.13–2007 (R2017) American National Standard for Ophthalmics—Phakic Intraocular Lenses. | Reaffirmation. |
| 10–60 | 10–111 | ISO 11981 Third edition 2017–11 Ophthalmic optics—Contact lenses and contact lens care products—Determination of physical compatibility of contact lens care products with contact lenses. | Withdrawn and replaced with newer version. |
| 10–67 | 10–112 | ISO 11986 Third edition 2017–11 Ophthalmic optics—Contact lenses and contact lens care products—Determination of preservative uptake and release. | Withdrawn and replaced with newer version. |
| 10–84 | | ANSI Z80.11–2012 (R2017) American National Standard for Ophthalmics—Laser Systems for Corneal Reshaping. | Reaffirmation. |
| | | **N. Orthopedic** | |
| 11–185 | | ASTM F2267–04 (Reapproved 2018) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression. | Reaffirmation. |
| 11–197 | | ASTM F983–86 (Reapproved 2018) Standard Practice for Permanent Marking of Orthopaedic Implant Components. | Reaffirmation. |
| 11–199 | | ASTM F565–04 (Reapproved 2018) Standard Practice for Care and Handling of Orthopedic Implants and Instruments. | Reaffirmation. |
| 11–203 | 11–322 | ASTM F1541–17 Standard Specification and Test Methods for External Skeletal Fixation Devices. | Withdrawn and replaced with newer version. |
| 11–224 | 11–323 | ASTM F2706–17 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model. | Withdrawn and replaced with newer version. |
| 11–226 | 8–478 | ASTM F1089–18 Standard Test Method for Corrosion of Surgical Instruments .. | Withdrawn and replaced with newer version. Transferred. |
| 11–227 | 11–324 | ASTM F366–17 Standard Specification for Fixation Pins and Wires | Withdrawn and replaced with newer version. |
| 11–228 | 11–325 | ASTM F564–17 Standard Specification and Test Methods for Metallic Bone Staples. | Withdrawn and replaced with newer version. |
| 11–245 | 11–326 | ASTM F384–17 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices. | Withdrawn and replaced with newer version. |
| 11–257 | 11–327 | ASTM F543–17 Standard Specification and Test Methods for Metallic Medical Bone Screws. | Withdrawn and replaced with newer version. |
| 11–261 | 11–328 | ASTM F1378–17 Standard Specification for Shoulder Prostheses | 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] |
|---|---|---|---|
| 11–271 | 11–329 | ASTM F2180–17 Standard Specification for Metallic Implantable Strands and Cables. | Withdrawn and replaced with newer version. |
| 11–284 | 11–330 | ASTM F2028–17 Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation. | Withdrawn and replaced with newer version. |
| 11–288 | 11–331 | ASTM F2077–17 Test Methods for Intervertebral Body Fusion Devices | Withdrawn and replaced with newer version. |
| 11–296 | 11–332 | ASTM F2193–18 Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System. | Withdrawn and replaced with newer version. |
| 11–297 | 11–333 | ASTM F382–17 Standard Specification and Test Method for Metallic Bone Plates. | Withdrawn and replaced with newer version. |
| 11–310 | | ASTM F1611–00 (Reapproved 2018) Standard Specification for Intramedullary Reamers. | Reaffirmation. |
| 11–315 | 11–334 | ASTM F1829–17 Standard Test Method for Static Evaluation of Anatomic Glenoid Locking Mechanism in Shear. | Withdrawn and replaced with newer version. |
| 11–318 | 11–335 | ASTM F3141–17a Standard Guide for Total Knee Replacement Loading Profiles. | Withdrawn and replaced with newer version. |
| | | **O. Physical Medicine** | |
| 16–159 | 16–202 | ISO 7176–2 Third edition 2017–10 Wheelchairs—Part 2: Determination of dynamic stability of electric wheelchairs. | Withdrawn and replaced with newer version. |
| 16–185 | | ANSI RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2, Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters. | Extent of recognition. |
| 16–193 | 16–203 | ASME A18.1–2017 Safety Standard for Platform Lifts and Stairway Chairlifts | Withdrawn and replaced with newer version. |
| | | **P. Radiology** | |
| 12–202 | | IEC 60601–2–43 Edition 2.0 2010–03 Medical electrical equipment—Part 2–43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures. | Recognition restored with transition period. |
| 12–204 | | IEC 60601–2–28 Edition 2.0 2010–03 Medical electrical equipment—Part 2–28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis. | Recognition restored with transition period. |
| 12–296 | 12–317 | IEC 60601–2–54 CONSOLIDATED VERSION Edition 1.1 2015–04 Medical electrical equipment—Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including: Amendment 2 (2018)]. | Withdrawn and replaced with newer version including amendment. |
| | | **Q. Software/Informatics** | |
| | | No new entries at this time. | |
| | | **R. Sterility** | |
| 14–138 | 14–512 | ISO 13408–2 Second edition 2018–01 Aseptic processing of health care products—Part 2: Sterilizing filtration. | Withdrawn and replaced with newer version. |
| 14–275 | | ANSI/AAMI ST41:2008/(R)2018 Ethylene oxide sterilization in health care facilities: Safety and effectiveness. | Reaffirmation. |
| 14–293 | | ANSI/AAMI ST50:2004/(R)2018 Dry heat (heated air) sterilizers | Reaffirmation. |
| 14–294 | | ANSI/AAMI ST40:2004/(R)2018 Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities. | Reaffirmation. |
| 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. | Withdrawn. See 14–515. |
| 14–344 | 14–513 | ASTM F2825–18 Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery. | Withdrawn and replaced with newer version. |
| 14–407 | 14–514 | ISO 11737–1 Third edition 2018–01 Sterilization of health care products—Microbiological methods—Part 1: Determination of a population of microorganisms on products. | 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.

[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: 050.

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** | |
| 3–153 | Standard Guide for Coating Inspection and Acute Particulate Characterization of Coated Drug-Eluting Vascular Stent Systems. | ASTM F2743–11. |
| 3–154 | Standard Guide for Fatigue-to-Fracture (FtF) Methodology for Cardiovascular Medical Devices. | ASTM F3211–17. |
| 3–155 | Medical electrical equipment—Part 2–47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. | IEC 60601–2–47 Edition 2.0 2012–02. |
| 3–156 | Implants for surgery—Active implantable medical devices—Part 1: General requirements for safety, marking and for information to be provided by the manufacturer. | ISO 14708–1 Second edition 2014–08–15. |
| | **D. Dental/Ear, Nose, and Throat (ENT)** | |
| 4–243 | Corrosion Test Methods | ANSI/ADA Standard No. 97:2002/ISO 10271:2001 Reaffirmed by ANSI: May 29, 2013. |
| 4–244 | Dentistry—Test methods for rotary instruments | ISO 8325 Second edition 2004–09–15. |
| 4–245 | Dentistry—Corrosion test methods for metallic materials | ISO 10271 Second edition 2011–08–01. |
| 4–246 | Dentistry—Pre-capsulated dental amalgam | ISO 20749 First edition 2017–03. |
| 4–247 | Dentistry—Laser welding and filler materials | ISO 28319 Second edition 2018–04. |
| | **E. General I (Quality Systems/Risk Management) (QS/RM)** | |
| 5–118 | Guidance for the creation of physiologic data and waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms. | AAMI TIR66:2017. |
| 5–119 | Medical devices—Connectors for reservoir delivery systems for healthcare applications—Part 3: Enteral application. | ISO 18250–3 First edition 2018–06. |
| | **F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)** | |
| 19–31 | American National Standard Recommended Practice for the Immunity Measurement of Electrical and Electronic Equipment. | ANSI C63.15–2017 (Revision of ANSI C63.15–2016). |
| | **G. General Hospital/General Plastic Surgery (GH/GPS)** | |
| | No new entries at this time. | |
| | **H. In Vitro Diagnostics (IVD)** | |
| 7–282 | Performance Standards for Antifungal Susceptibility Testing of Yeasts | CLSI M60 1st Edition. |
| 7–283 | Essential Tools for Implementation and Management of a Point-of-Care Testing Program. | CLSI POCT04 3rd Edition. |
| 7–284 | Supplemental Tables for Interference Testing in Clinical Chemistry | CLSI EP37 1st Edition. |
| | **I. Materials** | |
| 8–479 | Implants for surgery—Homopolymers, copolymers and blends on poly(lactide)—In vitro degradation testing. | ISO 13781 Second edition 2017–07. |

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

| Recognition No. | Title of standard [1] | Reference No. and date |
|---|---|---|
| | **J. Nanotechnology** | |
| | No new entries at this time. | |
| | **K. Neurology** | |
| | No new entries at this time. | |
| | **L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)** | |
| | No new entries at this time. | |
| | **M. Ophthalmic** | |
| 10–113 ..... | American National Standard for Ophthalmics—Toric Intraocular Lenses ..... | ANSI Z80.30–2018. |
| | **N. Orthopedic** | |
| 11–336 ..... | Wear of implant materials—Polymer and metal wear articles—Isolation and characterization. | ISO 17853 Third edition 2011–03–01. |
| 11–337 ..... | Implants for surgery—Roentgen stereophotogrammetric analysis for the assessment of migration of orthopaedic implants. | ISO 16087 First edition 2013–10–01. |
| 11–338 ..... | Implants for surgery—Determination of impact resistance of ceramic femoral heads for hip joint prostheses. | ISO 11491 First edition 2017–07. |
| 11–339 ..... | Implants for surgery—Partial and total hip joint prostheses—Part 2: Articulating surfaces made of metallic, ceramic and plastics materials [Including AMENDMENT1 (2016)]. | ISO 7206–2 Third edition 2011–04–01 AMENDMENT 1 2016–09–15. |
| 11–340 ..... | Standard Guide for Assessment of Hard-on-Hard Articulation Total Hip Replacement and Hip Resurfacing Arthroplasty Devices. | ASTM F3018–17. |
| 11–341 ..... | Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Unicondylar Knee Joint Replacements. | ASTM F3140–17. |
| | **O. Physical Medicine** | |
| | No new entries at this time. | |
| | **P. Radiology** | |
| 12–318 ..... | Medical electrical equipment—Part 2–64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment. | IEC 60601–2–64 Edition 1.0 2014–09. |
| 12–319 ..... | Medical electrical equipment—Part 2–68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment. | IEC 60601–2–68 Edition 1.0 2014–09. |
| 12–320 ..... | Medical electrical equipment—Medical light ion beam equipment—Performance characteristics. | IEC 62667 Edition 1.0 2017–08. |
| | **Q. Software/Informatics** | |
| | No new entries at this time. | |
| | **R. Sterility** | |
| 14–515 ..... | Processing of health care products—Information to be provided by the medical device manufacturer for the processing of medical devices. | ISO 17664 Second edition 2017–10. |
| 14–516 ..... | Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration. | ASTM F3039–15. |
| 14–517 ..... | Standard Guide for Application of Test Soils for the Validation of Cleaning Methods for Reusable Medical Devices. | ASTM F3293–18. |
| | **S. Tissue Engineering** | |
| 15–55 ..... | Standard Guide for Micro-computed Tomography of Tissue Engineered Scaffolds .... | ASTM F3259–17. |

[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.

**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: October 16, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–22977 Filed 10–19–18; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0143]**

### Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements associated with our Foreign Supplier Verification Programs (FSVP) for Food Importers.

**DATES:** Submit either electronic or written comments on the collection of information by December 21, 2018.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before December 21, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 21, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

*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–2011–N–0143 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Foreign Supplier Verification Programs for Food Importers.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

- 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.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined