*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 3, 2015, from 12:30 p.m. to 5 p.m., and November 4, 2015, from 8 a.m. to 5 p.m.

*Location:* NCTR SAB, 3900 NCTR Rd., Conference rm. B–12, Jefferson, AR 72079. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm*.

*Contact Person:* Donna Mendrick, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2208, Silver Spring, MD 20993–0002, 301–796–8892; or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

*Agenda:* On November 3, 2015, the SAB Chair will welcome the participants, and the NCTR Director will provide a Center-wide update on scientific initiatives and accomplishments during the past year. The SAB will be presented with an overview of the Division of Biochemistry Subcommittee and the Subcommittee Site Visit Report. Representatives from the Office of the Chief Scientist and Office of Medical Products and Tobacco will discuss research needs and opportunities for collaborations with NCTR.

On November 4, 2015, the Center for Drug Evaluation and Research, Center for Devices and Radiological Health, Center for Biologics Evaluation and Research, Center for Tobacco Products, Center for Veterinary Medicine, and Office of Regulatory Affairs will each briefly discuss their Center-specific research strategic needs. Following the public session, the SAB will hear an update from each of NCTR's research divisions.

Following an open discussion of all the information presented, the open session of the meeting will close so the SAB members can discuss personnel issues at NCTR at the end of each day.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

*Procedure:* On November 3, 2015, from 12:30 p.m. to 5 p.m., and November 4, 2015, from 8 a.m. to 4:15 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before October 27, 2015. Oral presentations from the public will be scheduled between approximately 11:45 a.m. and 12:45 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before October 19, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by October 20, 2015.

*Closed Committee Deliberations:* On November 4, 2015, from 4:15 p.m. to 5 p.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). This portion of the meeting will be closed to permit discussions of information concerning individuals associated with the research programs at NCTR.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donna Mendrick at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: August 10, 2015.

**Jill Hartzler Warner,**

*Associate Commissioner for Special Medical Programs.*

[FR Doc. 2015–20051 Filed 8–13–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2004–N–0451; formerly Docket No. 2004N–0226]**

### Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 040

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) 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: 040'' (Recognition List Number: 040), 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. See section VII for the effective date of the recognition of standards announced in this document.

**ADDRESSES:** An electronic copy of Recognition List Number: 040 is available on the Internet at *http://*

*www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 040 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: 040'' to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149.

Submit electronic comments on this document to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993, 301–796–6287, *standards@cdrh.fda.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 (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 a notice published in the **Federal Register** 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.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://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 HTML and PDF versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

## II. Modifications to the List of Recognized Standards, Recognition List Number: 040

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. FDA will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA will use the term ''Recognition List Number: 040'' to identify these 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. Anesthesia** | | | |
| 1–46 | 1–103 | ISO 5367 Fifth edition 2014–10–15 Anaesthetic and respiratory equipment—Breathing sets and connectors. | Withdrawn and replaced with newer version. |
| 1–82 | | IEC 60601–2–13 Edition 3.1 2009–08, Medical electrical equipment—Part 2–13: Particular requirements for the safety and essential performance of anaesthetic systems. | Withdrawn. See 1–104. |
| **B. Biocompatibility** | | | |
| 2–179 | 2–220 | ISO 10993–1 Fourth edition 2009–10–15 Biological evaluation of medical devices—Part 1:. Evaluation and Testing within a risk management process [Including: Technical Corrigendum 1 (2010)]. | Withdrawn and replaced with newer version including Technical Corrigendum. |
| 2–208 | 2–215 | USP 38–NF33:2015 <87> Biological Reactivity Test, In Vitro—Direct Contact Test. | Withdrawn and replaced with newer version. |
| 2–209 | 2–216 | USP 38–NF33:2015 <87> Biological Reactivity Test, In Vitro—Elution Test. | Withdrawn and replaced with newer version. |
| 2–210 | 2–217 | USP 38–NF33:2015 <88> Biological Reactivity Tests, In Vivo, Procedure Preparation of Sample. | Withdrawn and replaced with newer version. |
| 2–211 | 2–218 | USP 38–NF33:2015 <88> Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test. | Withdrawn and replaced with newer version. |
| 2–212 | 2–219 | USP 38–NF33:2015 <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test. | 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 |
|---|---|---|---|
| **C. Cardiovascular** | | | |
| 3–76 | | ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine The Corrosion Susceptibility of Small Implant Devices. | Transferred. See 8–177. |
| 3–117 | | ANSI/AAMI/ISO 81060–2:2013 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type. | Extent of recognition. |
| 3–122 | | ISO 81060–2 Second edition 2013–05–01 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type. | Extent of recognition. |
| **D. Dental/Ear, Nose, and Throat (ENT)** | | | |
| 4–105 | | ANSI/ADA Standard No.75 (Reaffirmed by ANSI: September 8, 2014) Resilient Lining Materials For Removable Dentures, Part 1: Short-Term Materials. | Reaffirmation. |
| 4–130 | | ANSI/ADA Standard No. 17 (Reaffirmed by ANSI: September 8, 2014) Denture Base Temporary Relining Resins. | Reaffirmation. |
| 4–150 | | ANSI/ADA Specification No. 19–2004/ISO 4823:2000 (Reaffirmed by ANSI: October 6, 2014) Dental Elastomeric Impression Materials. | Reaffirmation. |
| 4–184 | | ANSI/ASA S3.25–2009 (Revision of ANSI S3.25–1989) (Reaffirmed by ANSI September 11, 2014) American National Standard For an Occluded Ear Simulator. | Reaffirmation. |
| 4–191 | 4–220 | ANSI/ASA S3.22–2014 AMERICAN NATIONAL STANDARD Specification of Hearing Aid Characteristics. | Withdrawn and replaced with newer version. |
| **E. General I (Quality Systems/Risk Management (QS/RM))** | | | |
| 5–67 | | ANSI/AAMI/IEC 62366:2007/(R)2013 Medical devices—Application of usability engineering to medical devices. | Withdrawn. See 5–96. |
| 5–87 | | IEC 62366 Edition 1.1 2014–01 Medical devices—Application of usability engineering to medical devices. | Withdrawn. See 5–95. |
| 5–94 | | AAMI/CN20 (PS):2014 Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods. | Withdrawn. See 5–97. |
| **F. General II (Electrical Safety/Electromagnetic Compatibility (ES/EMC))** | | | |
| 19–6 | | IEC 60601–1–11 Edition 1.0 2010–04 Medical Electrical Equipment—Part 1–11: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment [Including: Technical Corrigendum 1 (2011)]. | Transition Period Added. |
| **G. General Hospital/General Plastic Surgery (GH/GPS)** | | | |
| 6–110 | | ASTM F1441–03 (Reapproved 2014) Standard Specification for Soft-Tissue Expander Devices. | Reaffirmation. |
| 6–185 | | ASTM F881 – 94 (Reapproved 2014) Standard Specification for Silicone Elastomer Facial Implants. | Reaffirmation. |
| 6–200 | | ASTM E1061–01 (Reapproved 2014) Standard Specification for Direct-Reading Liquid Crystal Forehead Thermometers. | Reaffirmation. |
| 6–274 | 6–341 | ISO 11608–1 Third Edition 2014–12–15 Needle-based injection systems for medical use—Requirements and test methods—Part 1: Needle-based injection systems. | Withdrawn and replaced with newer version. |
| 6–301 | | ISO 10555–1 Second Edition 2013–07–01 Sterile, single-use intravascular catheters—Part 1: General requirements. | Extent of Recognition. |
| 6–308 | 6–342 | IEC 80601–2–35 Edition 2.0 2009–10 Medical electrical equipment—Part 2–35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads or mattresses and intended for heating in medical use [Including: Technical Corrigendum 1 (2012) and Technical Corrigendum 2 (2015)]. | Withdrawn and replaced with newer version including Technical Corrigendum. |
| 6–326 | 6–343 | USP 38–NF 33:2015 Sodium Chloride Irrigation | Withdrawn and replaced with newer version. |
| 6–327 | 6–344 | USP 38–NF 33:2015 Sodium Chloride Injection | Withdrawn and replaced with newer version. |
| 6–328 | 6–345 | USP 38–NF33:2015 Nonabsorbable Surgical Suture | Withdrawn and replaced with newer version. |
| 6–329 | 6–346 | USP 38–NF33:2015 <881> Tensile Strength | 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 |
|---|---|---|---|
| 6–330 | 6–347 | USP 38–NF33:2015 <861> Sutures—Diameter | Withdrawn and replaced with newer version. |
| 6–331 | 6–348 | USP 38–NF33:2015 <871> Sutures—Needle Attachment | Withdrawn and replaced with newer version. |
| 6–332 | 6–349 | USP 38–NF33:2015 Sterile Water for Irrigation | Withdrawn and replaced with newer version. |
| 6–333 | 6–350 | USP 38–NF33:2015 Heparin Lock Flush Solution | Withdrawn and replaced with newer version. |
| 6–334 | 6–351 | USP 38–NF33:2015 Absorbable Surgical Suture | Withdrawn and replaced with newer version. |
| | | **H. In Vitro Diagnostics (IVD)** | |
| 7–110 | 7–251 | CLSI EP05–A3 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Third Edition. | Withdrawn and replaced with newer version. |
| 7–143 | 7–252 | CLSI EP14–A3 Evaluation of Matrix Effects; Approved Guideline—Third Edition. | Withdrawn and replaced with newer version. |
| 7–153 | 7–253 | CLSI EP15–A3 User Verification of Performance for Precision and Estimation of Bias; Approved Guideline-Third Edition. | Withdrawn and replaced with newer version. |
| 7–230 | 7–254 | CLSI M07–A10 Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard—Ninth Edition. | Withdrawn and replaced with newer version. |
| 7–123 | 7–255 | CLSI MM09–A2 Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine; Approved Guideline—Second Edition. | Withdrawn and replaced with newer version. |
| 7–247 | 7–256 | CLSI M100–S25 Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Fifth Informational Supplement. | Withdrawn and replaced with newer version. |
| | | **I. Materials** | |
| 8–59 | 8–386 | ISO 5832–4 Third edition 2014–09–15 Implants for surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy. | Withdrawn and replaced newer version. |
| 8–63 | 8–387 | ISO 5832–11 Second edition 2014–09–15 Implants for surgery—Metallic materials—Part 11: Wrought titanium 6-aluminium 7-niobium alloy. | Withdrawn and replaced with newer version. |
| 8–177 | | ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices. | Updated to incorporate transferred recognitions 3–76 and 17–9. |
| | | **J. Neurology** | |
| 17–9 | | ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices. | Transferred. See 8–177. |
| 17–4 | | ASTM F647–94(2014) Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application. | Reaffirmation. |
| | | **K. Obstetrics-Gynecology-Urology-Gastroenterology (OB–GYN–GU)/Gastroenterology** | |
| 9–73 | 9–104 | ANSI/AAMI/ISO 13958:2014 Concentrates for hemodialysis and related therapies. | Withdrawn and replaced with newer version. |
| 9–97 | | ISO 13958 Third edition 2014–04–01 Concentrates for haemodialysis and related therapies. | Extent of recognition. |
| 9–69 | 9–105 | ANSI/AAMI 13959:2014 Water for hemodialysis and related therapies | Withdrawn and replaced with newer version. |
| 9–100 | | ISO 11663 Second edition 2014–04–01 Quality of dialysis fluid for haemodialysis and related therapies. | Extent of recognition. |
| 9–71 | 9–106 | ANSI/AAMI/ISO 11663:2014 Quality of dialysis fluid for hemodialysis and related therapies. | Withdrawn and replaced with newer version. |
| 9–70 | 9–107 | ANSI/AAMI 23500:2014 Guidance for the preparation and quality management of fluids for hemodialysis and related therapies. | Withdrawn and replaced with newer version. |
| 9–102 | | ISO 4074 Second edition 2014–08–15 Natural latex rubber condoms—Requirements and test methods. | Extent of recognition. |
| 9–90 | 9–108 | ISO 8009 Second edition 2014–11–15 Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests. | Withdrawn and replaced with newer version. |
| 9–56 | 9–109 | ASTM D3492–08 Standard Specification for Rubber Contraceptives (Male Condoms). | 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 |
|---|---|---|---|
| | | **L. Ophthalmic** | |
| 10–29 | 10–94 | ISO 14730 Second edition 2014–10–01 Ophthalmic Optics—Contact lens care products—antimicrobial preservative efficacy testing and guidance on determining discard date. | Withdrawn and replaced with newer version. |
| 10–55 | 10–95 | ISO 11979–6 Third edition 2014–10–01 Ophthalmic implants—intraocular lenses—Part 6: Shelf-life and transport stability. | Withdrawn and replaced with newer version. |
| 10–62 | 10–96 | ANSI Z80.10–2014 American National Standard for Opthalmics Ophthalmic Instruments—Tonometers. | Withdrawn and replaced with newer version. |
| 10–68 | 10–97 | ISO 13212 Third edition 2014–09–01 Ophthalmic Optics-Contact lens care products—Guidelines for determination of shelf-life. | Withdrawn and replaced with newer version. |
| 10–82 | 10–98 | ISO 11979–2 Second edition 2014–08–15 Ophthalmic implants—Intraocular lenses—Part 2: Optical properties and test methods. | Withdrawn and replaced with newer version. |
| | | **M. Orthopedic** | |
| 11–240 | 11–287 | ASTM F382–14 Standard Specification and Test Method for Metallic Bone Plates. | Withdrawn and replaced newer version. |
| 11–235 | 11–288 | ASTM F2077–14 Test Methods for Intervertebral Body Fusion Devices | Withdrawn and replaced with newer version. |
| 11–207 | 11–289 | ASTM F2193–14 Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System. | Withdrawn and replaced with newer version. |
| 11–183 | | ASTM F1875–98 (Reapproved 2014) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface. | Reaffirmation. |
| 11–266 | | ASTM F2665–09 (Reapproved 2014) Standard Specification for Total Ankle Replacement Prosthesis. | Reaffirmation. |
| 11–224 | | ASTM F2706–08 (Reapproved 2014) Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model.. | Reaffirmation. |
| 11–80 | 11–290 | ISO 8828 Second edition 2014–11–15 Implants for surgery—Guidance on Care and Handling of Orthopaedic Implants. | Withdrawn and replaced with newer version. |
| 11–248 | 11–291 | ISO 14242–1 Third edition 2014–10–15 Implants for surgery—Wear of total hip-joint prostheses—Part 1: Loading and displacement parameters for wear testing machines and corresponding environmental conditions for test. | Withdrawn and replaced with newer version. |
| 11–250 | 11–292 | ISO 14243–3 Second edition 2014–11–01 Implants for surgery—Wear of total knee prostheses—Part 3: Loading and displacement parameters for wear—testing machines with displacement control and corresponding environmental conditions for test. | Withdrawn and replaced with newer version. |
| | | **N. Radiology** | |
| 12–102 | | ANSI/IESNA RP–27.2–2000 (Reaffirmed 2011) Photobiological Safety for Lamp & Lamp Systems-Measurement Techniques. | Reaffirmation. |
| 12–212 | 12–289 | IEC 62220–1–1 Edition 1.0 2015–03 Medical electrical equipment—Characteristics of digital x-ray imaging devices—Part 1–1: Determination of the detective quantum efficiency—Detectors used in radiographic imaging. | Withdrawn and replaced with newer version. |
| 12–229 | 12–290 | IEC 61910–1 Edition 1.0 2014–09 Medical electrical equipment—Radiation dose documentation—Part 1: Radiation dose structured reports for radiography and radioscopy. | Withdrawn and replaced with newer version. |
| 12–278 | 12–291 | IEC 62127–2 Edition 1.1 2013–02 Ultrasonics Hydrophones—Part 2: Calibration for ultrasonic fields up to 40 MHz. | Withdrawn and replaced with newer version. |
| | | **O. Sterility** | |
| 14–193 | 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 (2014)]. | Withdrawn and replaced with newer version including Amendment. |
| 14–194 | 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 (2014)]. | Withdrawn and replaced with newer version including Amendment. |
| 14–195 | 14–459 | ANSI/AAMI/ISO 11140–1:2014 Sterilization of health care products—Chemical indicators—Part 1: General requirements. | Withdrawn and replaced with newer version. |
| 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. | Reaffirmation. |

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

| Old recognition No. | Replacement recognition No. | Title of standard [1] | Change |
|---|---|---|---|
| 14–297 | 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)]. | Withdrawn and replaced with newer version including Amendment. |
| 14–300 | 14–462 | ASTM D4169—14 Standard Practice for Performance Testing of Shipping Containers and Systems. | Withdrawn and replaced with newer version. |
| 14–327 | | ISO 11737–2 Second edition 2009–11–15 Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process. | Extent of Recognition. |
| 14–350 | | ANSI/AAMI/ISO 13408–4:2005/(R)2014, Aseptic processing of health care products—Part 4: Clean-in-place technologies. | Reaffirmation. |
| 14–353 | 14–460 | ISO 11140–1 Third edition 2014–11–01 Sterilization of health care products—Chemical indicators—Part 1: General requirements. | Withdrawn and replaced with newer version. |
| 14–391 | 14–463 | ISO/ASTM 51608 Third edition 2015–03–15 Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing at energies between 50 KeV and 7.5 MeV. | Withdrawn and replaced with newer version. |
| 14–392 | 14–464 | ISO/ASTM 51649 Third edition 2015–03–15 Practice for dosimetry in an electron beam facility for radiation processing at energies between 300 keV and 25 MeV. | Withdrawn and replaced with newer version. |
| 14–431 | 14–465 | ISO/ASTM 51707 Third edition 2015–03–15 Guide for estimation of measurement uncertainty in dosimetry for radiation processing. | Withdrawn and replaced with newer version. |
| 14–440 | 14–466 | USP 38–NF33:2015 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests. | Withdrawn and replaced with newer version. |
| 14–441 | 14–467 | USP 38–NF33:2015 <71> Sterility Tests | Withdrawn and replaced with newer version. |
| 14–442 | 14–468 | USP 38–NF33:2015 <85> Bacterial Endotoxins Test | Withdrawn and replaced with newer version. |
| 14–443 | 14–477 | USP 38–NF33:2015 <151> Pyrogen Test (USP Rabbit Test) | Withdrawn and replaced with newer version. |
| 14–444 | 14–469 | USP 38–NF33:2015 <161> Transfusion and Infusion Assemblies and Similar Medical Devices. | Withdrawn and replaced with newer version. |
| 14–445 | 14–470 | USP 38–NF33:2015 Biological Indicator for Steam Sterilization—Self Contained. | Withdrawn and replaced with newer version. |
| 14–446 | 14–471 | USP 38–NF33:2015 Biological Indicator for Dry-Heat Sterilization, Paper Carrier. | Withdrawn and replaced with newer version. |
| 14–447 | 14–472 | USP 38–NF33:2015 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier. | Withdrawn and replaced with newer version. |
| 14–448 | 14–473 | USP 38–NF33:2015 Biological Indicator for Steam Sterilization, Paper Carrier. | Withdrawn and replaced with newer version. |
| 14–449 | 14–474 | USP 38–NF33:2015 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms. | Withdrawn and replaced with newer version. |
| 14–450 | 14–475 | USP 38–NF33:2015 <55> Biological Indicators—Resistance Performance Tests. | Withdrawn and replaced with newer version. |
| 14–451 | 14–476 | USP 38–NF33:2015 <1035> Biological Indicators for Sterilization | 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: 040.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

| Recognition No. | Title of standard [1] | Reference No. and date |
|---|---|---|
| | **A. Anesthesia** | |
| 1–104 | Medical electrical equipment—Part 2–13: Particular Requirements for basic safety and essential performance of an anaesthetic workstation [Including: Amendment 1 (2015)]. | ISO 80601–2–13 First Edition 2011–08–01 and Amendment 1 2015. |
| 1–105 | Medical electrical equipment—Part 2–72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients. | ISO 80601–2–72 First Edition 2015–04–11. |

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

| Recognition No. | Title of standard [1] | Reference No. and date |
|---|---|---|
| | **B. Biocompatibility** | |
| 2–221 | Biological Evaluation of Medical Devices: Part 2—Animal Welfare Requirements .. | ANSI/AAMI/ISO 10993–2:2006 (R2014). |
| 2–222 | Biological Evaluation of Medical Devices: Part 2—Animal Welfare Requirements .. | ISO 10993–2 Second edition 2006–07–15. |
| | **C. Cardiovascular** | |
| 3–135 | Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products. | ISO/TS 12417–1 First edition 2011–06–01. |
| 3–136 | Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products. | ANSI/AAMI/ISO TIR12417:2011. |
| 3–137 | Standard Guide for Testing Absorbable Stents | ASTM F3036–13. |
| 3–138 | Standard Guide for in vitro Axial, Bending, and Torsional Durability Testing of Vascular Stents. | ASTM F2942–13. |
| 3–139 | Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices. | ISO 14117 First edition 2012–07–15. |
| | **D. General I (Quality Systems/Risk Management)** | |
| 5–95 | Medical devices—Part 1: Application of usability engineering to medical devices .. | IEC 62366–1 Edition 1.0 2015–02. |
| 5–96 | Medical devices—Part 1: Application of usability engineering to medical devices .. | ANSI/AAMI/IEC 62366–1:2015. |
| 5–97 | Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods. | ISO 80369–20 First edition 2015–05–15. |
| | **E. General II (ES/EMC)** | |
| 19–14 | Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment. | IEC 60601–1–11 Edition 2.0 2015–01. |
| 19–15 | Medical electrical equipment—Part 1–12: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment. | IEC 60601–1–12 Edition 1.0 2014–06. |
| | **F. GH/GPS** | |
| 6–352 | Standard Specification for Implantable Breast Prostheses | ASTM F703–07. |
| 6–353 | Standard Specification for Implantable Saline Filled Breast Prosthesis | ASTM F2051 – 00 (Reapproved 2014). |
| 6–354 | Standard Specification for Radiation Attenuating Protective Gloves | ASTM D7866–14. |
| | **G. IVD** | |
| 7–257 | Principles and procedures for Detection of Anaerobes in Clinical Specimens; Approved Guideline. | CLSI M56–A. |
| 7–258 | Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standards- Twelfth Edition. | CLSI M02–A12. |
| | **H. Materials** | |
| 8–388 | Implants for surgery—Ceramic materials—Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement. | ISO 6474–2 First edition 2012–04–15. |
| 8–389 | Implants for surgery—Differential scanning calorimetry of poly ether ether ketone (PEEK) polymers and compounds for use in implantable medical devices. | ISO 15309 First edition 2013–12–01. |
| 8–390 | Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants. | ASTM F1925–09. |
| 8–391 | Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal To 70% Glycolide. | ASTM F2313–10. |
| | **I. Nanotechnology** | |
| 18–4 | Technical Specification—Nanotechnologies—Vocabulary—Part 6: Nano-object characterization. | ISO/TS 80004–6 First edition 2013–11–01. |
| | **J. Neurology** | |
| 17–14 | Transcutaneous electrical nerve stimulators | ANSI/AAMI NS4:2013. |

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

| Recognition No. | Title of standard [1] | Reference No. and date |
|---|---|---|
| | **K. OB–GYN–GU/Gastroenterology** | |
| 9–103 | Water treatment equipment for hemodialysis and related therapies | ANSI/AAMI 26722:2014. |
| | **L. Ophthalmic** | |
| 10–99 | Anionic and non-ionic surface active agents—Determination of critical micellization concentration—Method by measuring surface tension with a plate, stirrup, or ring,. | ISO 4311 First edition 1979–06–01. |
| | **M. Orthopedic** | |
| 11–293 | Standard Test Method for Impingement of Acetabular Prostheses | ASTM F2582–14. |
| 11–294 | Standard Specification for Articulating Total Wrist Implants | ASTM F1357–14. |
| 11–295 | Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis. | ASTM F2580–13. |
| | **N. Physical Medicine** | |
| 16–194 | Wheelchairs Part 25:Batteries and chargers for powered wheelchairs | ISO 7176–25 First edition 2013–07–15. |
| | **O. Radiology** | |
| 12–292 | IEEE Recommended Practice for Three-Dimensional (3D) Medical Modeling | IEEE Std 3333.2.1–2015. |
| | **P. Software/Informatics** | |
| 13–73 | Systematized Nomenclature of Medicine—Clinical Terms | IHTSDO SNOME–CT RF2 Release 2015. |
| 13–74 | Health informatics—Personal health device communication, Part 10424: Device Specialization—Sleep Apnoea Breathing Therapy Equipment (SABTE). | IEEE Std 11073–10424–2014. |
| 13–75 | Health informatics—Point-of-care medical device communication—Part 10102: Nomenclature—Annotated ECG. | ISO/IEEE 11073–10102 First edition 2014–03–01. |
| 13–76 | Health informatics—Standard communication protocol—Part 91064: Computer-assisted electrocardiography. | ISO 11073–91064 First edition 2009–05–01. |
| 13–77 | Information technology—Security techniques—Vulnerability disclosure | ISO/IEC 29147 First edition 2014–02–15. |
| 13–78 | Information technology—Security techniques—Vulnerability handling processes | ISO/IEC 30111 First edition 2013–11–01. |
| | **Q. Sterility** | |
| 14–478 | Flexible and semi-rigid endoscope processing in health care facilities | ANSI/AAMI ST91:2015. |

[1] All standard titles in this table conform to the style requirements of the respective organizations.

## IV. List of Recognized Standards

FDA maintains the Agency's current list of FDA Recognized Consensus Standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* FDA will incorporate 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 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 Recognition List 033, FDA no longer announces minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

## 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 *standards@cdrh.fda.gov.* To be properly considered, such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

## VI. Electronic Access

You may obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page, *http://www.fda.gov/MedicalDevices,* includes a link to standards-related documents including the guidance and the current list of recognized standards. After publication in the **Federal Register**, this notice announcing ''Modification to the List of

Recognized Standards, Recognition List Number: 040'' will be available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for ''FDA Recognized Consensus Standards'' at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.*

### VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* 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: 040. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: August 10, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015–19991 Filed 8–13–15; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–D–0386]**

## Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses; Draft Guidance for Industry and Food and Drug Administration Staff: Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses.'' This draft guidance provides recommendations to facilitate study designs to establish the performance characteristics of in vitro diagnostic devices (IVDs) intended for the detection, or detection and differentiation, of human papillomaviruses (HPVs). This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance November 12, 2015.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled ''Establishing the Performance Characteristics of In Vitro Diagnostic Devices for the Detection or Detection and Differentiation of Human Papillomaviruses'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Natalia Comella, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, Rm. 4536, Silver Spring, MD 20993–0002, 301–796–6226, *Natalia.Comella@fda.hhs.gov,* or Marina V. Kondratovich, Center for Devices and Radiological Health, Food and Drug Administration, New Hampshire Ave., Bldg. 66, Rm. 4672, Silver Spring, MD 20993–0002, 301–796–6036, *Marina.Kondratovich@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

### I. Background

This draft guidance provides recommendations to facilitate study designs to establish the performance characteristics of IVDs intended for the detection, or detection and differentiation, of HPVs. These devices are used either in conjunction with cervical cytology to aid in screening for cervical cancer or as first-line primary cervical cancer screening devices. These devices include those that detect a group of HPV genotypes, particularly high risk HPVs, as well as devices that detect more than one genotype of HPV and further differentiate among them to indicate which genotype of HPV is present or which genotypes of HPV are present.

When finalized, this draft guidance is expected to provide detailed information on the types of studies the FDA recommends to support a premarket application for these devices. This draft guidance specifically addresses devices that qualitatively detect HPV nucleic acid from cervical specimens, but many of the recommendations will also be applicable to devices that detect HPV proteins. The draft guidance is limited to studies intended to establish the performance characteristics of in vitro diagnostic HPV devices that are used in conjunction with cervical cytology for cancer screening or as first-line primary cervical cancer screening devices. This draft guidance does not address HPV testing from non-cervical specimens such as pharyngeal, vaginal, penile, or anal specimens, or testing for susceptibility to HPV infection. It does not address quantitative or semi-quantitative assays for HPV.

### II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on evaluating the performance characteristics of IVDs intended for the detection, or detection and differentiation, of HPVs. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statute and regulations.

### III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons