Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Dennis Bensley, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0696, *dennis.bensley@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 25, 2003 (68 FR 8772), FDA published the notice of availability for a draft guidance for industry entitled ''Comparability Protocols—Chemistry, Manufacturing, and Controls Information,'' giving interested persons until June 25, 2003, to comment on the draft guidance and those comments were considered as the guidance was finalized. A summary of changes include describing comparability protocols submitted in CMC (J)INAD technical data submissions or (J)INAD protocols without substantial data. In accordance with the performance goals and procedures for the ADUFA and AGDUFA reauthorizations for fiscal years 2014 through 2018, comparability protocols may be submitted as comparability protocols without substantial data in a (J)INAD file. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated February 2003 only as it applies to the preparation and submission to the Center for Veterinary Medicine of comparability protocols for postapproval changes in CMC information for new animal drugs.

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the current thinking of FDA on Comparability Protocols—Chemistry, Manufacturing, and Controls Information for New Animal Drugs. 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 statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032; the collections of information in section 512(n)(1) of the FD&C Act (21 U.S.C. 360b) have been approved under OMB control number 0910–0669.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–07573 Filed 4–1–16; 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: 041

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: 041'' (Recognition List Number: 041), 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 April 4, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, 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: 041.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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: 041.

• 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 041 is available on the Internet at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 041 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: 041'' 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.

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 (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 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 standards 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 hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document 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: 041

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: 041'' 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	
1–92	1–106	ISO 17510 First Edition 2015–08–01 Medical Devices—Sleep Apnoea Breathing Therapy—Masks and Application Accessories.	Withdrawn and replaced with newer version.
1–93		ISO 5361 Second Edition 2012–10–01 Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors.	Extent of recognition.
		B. Biocompatibility	
2–180		ANSI/AAMI/ISO 10993–16:2010/(R) 2014 Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	Reaffirmation.
		C. Cardiovascular	
3–119		ISO 5841–3 Third Edition 2013–04–15 Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors [is-i] for implantable pacemakers.	Withdrawn—Duplicate recognition—See 3–125.
3–138		ASTM F2942–13 Standard Guide For the In Vitro Axial, Bending, and Rotational Durability Test of Vascular Stents.	Extent of recognition.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–121	4–221	ISO 7494–2 Second Edition 2015–04–01 Dentistry—Dental units—Part 2: Air, water, suction and wastewater system.	Withdrawn and replaced with newer version.
4–132	4–222	ISO 6874 Third Edition 2015–09–01 Dentistry—Polymer-based pit and fissure sealants.	Withdrawn and replaced with newer version.
4–178	4–223	ISO 6872 Fourth Edition 2015–06–01 Dentistry—Ceramic materials	Withdrawn and replaced with newer version.
4–190		ANSI/ASA S3.35–2010 (R2015) Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions.	Reaffirmation.
4–194		ANSI/ADA Specification No. 78: 2006, Dental Obturating Cones (Modified adoption of ISO 6877–1:1995, Dental Obturating Points).	Extent of recognition.
4–202		ANSI/ADA Specification No. 58 Root Canal Files, Type H (Hedstrom)	Extent of recognition.
4–209	4–224	ISO 24234 Second Edition 2015–05–01 Dentistry—Dental amalgam ...	Withdrawn and replaced with newer version.
4–210	4–225	ISO 4823 Fourth Edition 2015–08–01 Dentistry—Elastomeric impression materials.	Withdrawn and replaced with newer version.
4–213		ISO 7494–1 Second Edition 2011–08–15 Dentistry—Dental units—Part 1: General requirements and test methods.	Extent of recognition.
4–214		ISO 10139–1 Second Edition 2005–02–15 Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use [Including: Technical Corrigendum 1 (2006)].	Extent of recognition.
		E. General I (Quality Systems/Risk Management (QS/RM)	
5–43	5–98	ANSI/ESD S20.20–2014 Protection of Electrical and Electronic Parts, Assemblies, and Equipment (Excluding Electrically Initiated Explosive Devices).	Withdrawn and replaced with newer version.
5–80	5–99	ASTM D4332–14 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.	Withdrawn and replaced with newer version.
		F. General II (Electrical Safety/Electromagnetic Compatibility)(ES/EMC)	
19–7	19–16	ANSI/AAMI HA60601–1–11:2015 (IEC 60601–1–11:2015, MOD) 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.	Withdrawn and replaced with newer version.
19–7		AAMI/ANSI HA60601–1–11:2011, Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601–1–11:2010 MOD).	Transition period.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–169	6–355	ASTM D3772—15 Standard Specification for Industrial Rubber Finger Cots.	Withdrawn and replaced with newer version.
6–243	6–356	ASTM D5712—15 Standard Test Method for Analysis of Aqueous Extractable Protein in Latex, Natural Rubber, and Elastomeric Products Using the Modified Lowry Method.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–167	7–259	CLSI GP23–A Nongynecologic Cytologic Specimens: Collection And Cytopreparatory Techniques; Approved Guideline.	Withdrawn and replaced with newer version.
7–132	7–260	CLSI MM03–A2 Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline.	Withdrawn and replaced with newer version.
7–229		CLSI M02–A11 Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—Eleventh Edition.	Withdrawn. See 7–258.
I. Materials			
8–103		ASTM F1807–97 (Reapproved 2014) Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials.	Reaffirmation.
8–107		ASTM F746–04 (Reapproved 2014) Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.	Reaffirmation.
8–114		ASTM F2255–05 (Reapproved 2015) Standard Test Method for Strength Properties of Tissue Adhesives in Lap-Shear by Tension Loading.	Reaffirmation.
8–115		ASTM F2256–05 (Reapproved 2015) Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading.	Reaffirmation.
8–116		ASTM F2258–05 (Reapproved 2015) Standard Test Method for Strength Properties of Tissue Adhesives in Tension.	Reaffirmation.
8–121		ASTM F2005–05 (Reapproved 2015) Standard Terminology for Nickel-Titanium Shape Memory Alloys.	Reaffirmation.
8–134	8–392	ASTM F2082–15 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery.	Withdrawn and replaced with newer version.
8–135		ASTM F2392–04 (Reapproved 2015) Standard Test Method for Burst Strength of Surgical Sealants.	Reaffirmation.
8–136		ASTM F2458–05 (Reapproved 2015) Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants.	Reaffirmation.
8–167	8–393	ASTM F1350–15 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).	Withdrawn and replaced with newer version.
8–168	8–394	ASTM F1472–14 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Withdrawn and replaced with newer version.
8–170	8–395	ASTM F961–14 Standard Specification for 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Forgings for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8–177	8–396	ASTM F2129–15 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Withdrawn and replaced with newer version.
8–179		ASTM F754–08 (Reapproved 2015) Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders.	Reaffirmation.
8–184	8–397	ASTM F2516–14 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials.	Withdrawn and replaced with newer version.
8–189	8–398	ASTM F1108–14 Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants (UNS R56406).	Withdrawn and replaced with newer version.
8–190	8–399	ASTM F90–14 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy for Surgical Implant Applications (UNS R30605).	Withdrawn and replaced with newer version.
8–192	8–400	ASTM F1854–15 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants.	Withdrawn and replaced with newer version.
8–200		ASTM F2003–02 (Reapproved 2015) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	Reaffirmation.
8–204	8–401	ASTM F2118–14 Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials.	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
8–206	8–402	ASTM F688–14 Standard Specification for Wrought Cobalt-35Nickel-20Chromium 10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8–225		ASTM F2003–02 (Reapproved 2015) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	Withdrawn. See 8–200.
8–363	8–403	ASTM D638–14 Standard Test Method for Tensile Properties of Plastics.	Withdrawn and replaced with newer version.
8–367	8–404	ASTM E647–15 Standard Test Method for Measurement of Fatigue Crack Growth Rates.	Withdrawn and replaced with newer version.
8–369		ASTM F2003–02 (Reapproved 2015) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	Withdrawn. See 8–200.
8–386	8–405	ISO 5832–4 Third Edition 2014–09–15 Implants for surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy.	Withdrawn and replaced with newer version.
8–387	8–406	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.
		J. Nanotechnology	
18–1		ASTM E2490–09 (Reapproved 2015) Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS).	Reaffirmation.
		K. Obstetrics-Gynecology (OB–GYN)/Gastroenterology	
9–61		IEC 60601–2–18 Edition 3.0 2009–08 Medical Electrical Equipment—Part 2–18: Particular requirements for the basic safety and essential performance of endoscopic equipment.	Withdrawn. Merged with 4–187.
9–83	9–110	ISO 8600–1 Fourth Edition 2015–10–15 Endoscopes—Medical endoscopes and endotherapy devices—Part 1: General requirements.	Withdrawn and replaced with newer version.
9–96		CEN EN 1618:1997 Catheters Other Than Intravascular Catheters—Test Methods for Common Properties.	Duplicate recognition number. See 9–113.
9–102	9–111	ISO 4074 Third Edition 2015–10–15 Natural rubber latex male condoms—Requirements and test methods.	Withdrawn and replaced with newer version.
9–109	9–112	ASTM D3492–15 Standard Specification for Rubber Contraceptives (Male Condoms).	Withdrawn and replaced with newer version.
		L. Ophthalmic	
10–73		ANSI Z80.21–2010 (R2015) Ophthalmics—Instruments—General-Purpose Clinical Visual Acuity Charts.	Reaffirmation.
		M. Orthopedic	
11–207	11–296	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.
11–214	11–297	ASTM F382—14 Standard Specification and Test Method for Metallic Bone Plates.	Withdrawn and replaced with newer version.
11–216	11–298	ASTM F1264—14 Standard Specification and Test Methods for Intramedullary Fixation Devices.	Withdrawn and replaced with newer version.
11–220	11–299	ASTM F2068—15 Standard Specification for Femoral Prostheses—Metallic Implants.	Withdrawn and replaced with newer version.
11–227		ASTM F366–10 (Reapproved 2015) Standard Specification for Fixation Pins and Wires.	Reaffirmation.
11–228		ASTM F564–10 (Reapproved 2015) Standard Specification and Test Methods for Metallic Bone Staples.	Reaffirmation.
11–247		ASTM F2789–10 (Reapproved 2015) Standard Guide for Mechanical and Functional Characterization of Nucleus Devices.	Reaffirmation.
11–256		ISO 14243–3 First Edition 2004–09–25 Implants for surgery—Wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test [Including: Technical Corrigendum 1(2006)].	Withdrawn. See 11–292.
11–262	11–301	ASTM F2091–15 Standard Specification for Acetabular 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
11–278	11–302	ASTM F1717–15 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
		N. Physical Medicine	
16–158	16–195	ISO 7176–1 Third Edition 2014–10–01 Wheelchairs—Part 1: Determination of static stability.	Withdrawn and replaced with newer version.
		O. Radiology	
12–139		NEMA UD 2–2004 (R2009) Acoustic output measurement standard for diagnostic ultrasound equipment, Revision 3.	Reaffirmation.
12–187		NEMA MS 3–2008 (R2014) Determination of Image Uniformity in Diagnostic Magnetic Resonance Images.	Reaffirmation.
12–188		NEMA MS 1–2008 (R2014) Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging.	Reaffirmation.
12–195		NEMA MS 6–2008 (R2014) Determination of Signal-to-Noise Ratio and Image Uniformity for Single-Channel, Non-Volume Coils in Diagnostic Magnetic Resonance Imaging (MRI).	Reaffirmation.
12–196		NEMA MS 2–2008 (R2014) Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images.	Reaffirmation.
12–207		IEC 60601–2–33 Ed. 3.0 2010 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Extent of recognition.
12–209	12–293	IEC 60601–2–37 Ed. 2.1 b:2015 Medical electrical equipment—Part 2–37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	Withdrawn and replaced with newer version.
12–236	12–294	IEC 60601–2–45 Ed. 3.1 b:2015 Medical electrical equipment—Part 2–45: Particular requirements for basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices.	Withdrawn and replaced with newer version.
12–257	12–297	ISO 2919 Third Edition 2012–02–15 Radiation protection—Sealed radioactive sources—General requirements and classification.	Duplicate recognition number. See 12–297.
12–271	12–295	IEC 60601–2–33 Ed. 3.2 b:2015 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Withdrawn and replaced with newer version.
12–274	12–296	IEC 60601–2–54 Ed. 1.1 b:2015 Medical electrical equipment—Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.	Withdrawn and replaced with newer version.
12–288		NEMA MS 9–2008 (R2014) Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images (MRI).	Reaffirmation.
		P. Software/Informatics	
13–8	13–79	IEC 62304 Edition 1.1 2015–06 Medical device software—Software life cycle processes.	Withdrawn and replaced with newer version.
13–50	13–80	IEEE Std. 11073–20601: 2014 Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol [including: Corrigendum 1 (2015)].	Withdrawn and replaced with newer version.
13–51		IEEE Std. 11073–20601a-2010 Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol Amendment 1.	Withdrawn. See 13–80.
		Q. Sterility	
14–227		ANSI/AAMI/ISO 11737–1:2006 (R)2011 Sterilization of health care products—Microbiological methods—Part 1: Determination of the population of microorganisms on product.	Extent of recognition.
14–261		ANSI/AAMI/ISO 17665–1:2006/(R)2013 Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–277		ISO/TS 17665–2 First Edition 2009–01–15 Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ISO 17665–1.	Extent of recognition.
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.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–291		ANSI/AAMI/ISO 14937:2009/(R)2013 Sterilization of healthcare products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–296		ANSI/AAMI/ISO 11138–1:2006/(R)2010 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Extent of recognition.
14–298		ANSI/AAMI/ISO 11137–3:2006/(R)2010 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects.	Extent of recognition.
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.
14–330		ISO 11137–3 First Edition 2006–04–15 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects.	Extent of recognition.
14–333		ISO 17665–1 First Edition 2006–08–15 Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–337		ISO 14937 Second Edition 2009–10–15 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–338		ISO 11138–1 Second Edition 2006–07–01 Sterilization of health care products—Biological indicators—Part 1: General requirements.	Extent of recognition.
14–339		ANSI/AAMI/ISO 20857:2010 Sterilization of health care products—Dry heat—Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–340		ISO 20857 First Edition 2010–08–15 Sterilization of health care products—Dry heat—Requirements for the development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
14–349		ANSI/AAMI/ISO 13408–3:2006/(R)2015 Aseptic processing of health care products—Part 3: Lyophilization.	Reaffirmation.
14–351		ANSI/AAMI/ISO 13408–5:2006/(R)2015 Aseptic processing of health care products—Part 5: Sterilization in place.	Reaffirmation.
14–376		ANSI/AAMI/ISO TIR17665–2:2009 Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ANSI/AAMI/ISO 17665–1.	Extent of recognition.
14–407		ISO 11737–1 Second Edition 2006–04–01 Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products [Including: Technical Corrigendum 1 (2007)].	Extent of recognition.
14–409		ISO 11137–2 Third Edition 2013–06–01 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Extent of recognition.
14–428		ISO 11137–1 First Edition 2006–04–15 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)].	Extent of recognition.
14–438		ANSI/AAMI/ISO 11137–2:2013 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Extent of recognition.
14–452		ISO 11135 Second Edition 2014, Sterilization of health care products—Ethylene oxide—Requirements for development, validation, and routine control of a sterilization process for medical devices.	Extent of recognition.
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)].	Extent of recognition.
		R. Tissue Engineering	
15–8	15–42	ASTM F2064–14 Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications.	Withdrawn and replaced with newer version.
15–22	15–43	ASTM F2791–15 Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions.	Withdrawn and replaced with newer version.
15–24		ASTM F2721–09 (Reapproved 2014) Standard Guide for Pre-clinical in vivo Evaluation in Critical Size Segmental Bone Defects.	Reaffirmation.

[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: 041.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
	A. Anesthesia	
1–107	Anaesthetic and Respiratory Equipment—Conical Connectors—Part 1: Cones and Sockets.	ANSI/AAMI/ISO 5356–1:2004.
1–108	Anaesthetic and Respiratory Equipment—Tracheal Tubes and Connectors.	ANSI/AAMI/ISO 5361:2012.
1–109	Anaesthetic Reservoir Bags	ANSI/AAMI/ISO 5362:2006.
1–110	Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 1: Tubes and Connectors for Use in Adults.	ANSI/AAMI/ISO 5366–1:2000.
1–111	Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 3: Paediatric Tracheostomy Tubes.	ANSI/AAMI/ISO 5366–3:2001.
1–112	Lung Ventilators—Part 4: Particular Requirements for Operator-Powered Resuscitators.	ANSI/AAMI/ISO 10651–4:2002.
1–113	Lung Ventilators for Medical Use—Particular Requirements for Basic Safety and Essential Performance—Part 5: Gas-powered Emergency Resuscitators.	ANSI/AAMI/ISO 10651–5:2006.
1–114	Inhalational Anaesthesia Systems—Draw-over Anaesthetic Systems.	ISO 18835 First Edition 2015–04–01.
1–115	Medical Electrical Equipment—Part 2–70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment.	ISO 80601–2–70 First Edition 2015–01–15.
	B. Biocompatibility	
2–223	Standard Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices.	ASTM F2901–13.
2–225	Standard Practice for Testing for Classical Complement Activation in Serum By Solid Materials.	ASTM F2567–06 (Reapproved 2010).
	C. Cardiovascular	
3–140	Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques.	ANSI/AAMI/ISO 5840–3: 2013.
3–141	Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors (IS–1) for implantable pacemakers.	ANSI/AAMI/ISO 5841–3: 2013.
	D. Dental/ENT	
4–226	Dentistry—Powered polymerization activators	ISO 10650 First Edition 2015–09–01.
	E. General I (Quality Systems/Risk Management)	
5–100	Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods.	ANSI/AAMI/ISO 80369–20:2015.
5–101	Small-bore connectors for liquids and gases in healthcare applications—Part 6: Connectors for neuraxial applications.	AAMI/CN6:2015.
	F. General II (ES/EMC)	
19–17	American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters.	ANSI/IEEE C63.18–2014.
19–18	Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements [Including: Corrigendum 1 (2011)].	IEC 61010–1 Edition 3.0 2010–06.

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

Recognition No.	Title of standard [1]	Reference No. and date
	G. GH/GPS	
6–357	Intravascular Catheters—Sterile and Single-use Catheters—Part 6: Subcutaneous Implanted Ports.	ISO 10555–6 First Edition 2015–04–15.
6–358	Infusion Equipment for Medical Use—Part 8: Infusion Sets for Single Use with Pressure Infusion Apparatus.	ISO 8536–8 Second Edition 2015–06–15.
6–359	Infusion Equipment for Medical Use—Part 9: Fluid Lines for Single Use with Pressure Infusion Equipment.	ISO 8536–9 Second Edition 2015–06–15.
6–360	Infusion Equipment for Medical Use—Part 10: Accessories for Fluid Lines for Single Use with Pressure Infusion Equipment.	ISO 8536–10 Second Edition 2015–06–15.
6–361	Infusion Equipment for Medical Use—Part 11: Infusion Filters for Single Use with Pressure Infusion Equipment.	ISO 8536–11 Second Edition 2015–06–15.
	H. Materials	
8–407	Standard Specification for Additive Manufacturing File Format (AMF) Version 1.1.	ISO/ASTM 52915 First Edition 2013–06–01.
8–408	Standard Guide for Evaluating Mechanical Properties of Metal Materials Made via Additive Manufacturing Processes.	ASTM F3122–14.
8–409	Standard Specification for Additive Manufacturing Titanium-6 Aluminum-4 Vanadium with Powder Bed Fusion.	ASTM F2924–14.
8–410	Standard Guide for Assessment of Absorbable Polymeric Implants.	ASTM F2902–12.
8–411	Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants.	ASTM F2579–10.
8–412	Standard Practice for Calibration of Linear Displacement Sensor Systems Used to Measure Micromotion.	ASTM F2537–06 (Reapproved 2011).
8–413	Standard Test Methods for Measurement of Straightness of Bar, Rod, Tubing, and Wire to be used for Medical Devices.	ASTM F2819–10 (Reapproved 2015).
8–414	Standard Practice for Reporting and Assessment of Residues on Single Use Implants.	ASTM F2847–10.
8–415	Standard Test Method for Measurement of Percent Crystallinity of Polyetheretherketone (PEEK) Polymers by Means of Specular Reflectance Fourier Transform Infrared Spectroscopy (R–FTIR)..	ASTM F2778–09 (Reapproved 2015).
8–416	Standard Test Method for Small Punch Testing of Polymeric Biomaterials Used in Surgical Implants.	ASTM F2977–13.
8–417	Test Method for Standard Test Method for Evaluating the Potential for Galvanic Corrosion for Medical Implants.	ASTM F3044–14.
8–418	Standard Test Methods for Determining Radiopacity for Medical Use.	ASTM F640–12.
8–419	Standard Specification for Metal Injection Molded Titanium-6 Aluminum-4 Vanadium Components for Surgical Implant Applications.	ASTM F2885–11.
8–420	Standard Specification for Metal Injection Molded Cobalt-28 Chromium-6 Molybdenum Components for Surgical Implant Applications.	ASTM F2886–10.
	I. Ophthalmic	
10–100	Ophthalmic optics—Contact lens care products—Method to assess contact lens care products with contact lenses in a lens case, challenged with bacterial and fungal organisms.	ISO 18259 First Edition 2014–10–01.
	J. Orthopedic	
11–303	Standard Guide for High Demand Hip Simulator Wear Testing of Hard-on-hard Articulations.	ASTM F3047M–15.

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

Recognition No.	Title of standard [1]	Reference No. and date
11–304	Measuring Accuracy after Mechanical Disturbances.	ASTM F3107–14.
	K. Physical Medicine	
16–196	Wheelchairs—Part 7: Measurement of seating and wheel dimensions.	ISO 7176–7 First Edition 1998–05–15.
16–197	Wheelchairs—Part 8: Requirements and test methods for static, impact, and fatigue strengths.	ISO 7176–8 Second Edition 2014–12–15.
16–198	Wheelchairs—Part 22: Set-up procedures	ISO 7176–22 Second Edition 2014–09–01.
	L. Software/Informatics	
13–81	Health informatics—Personal health device communication—Part 10419: Device Specialization—Insulin Pump.	IEEE Std. 11073–10419: 2015.
	M. Sterility	
14–479	Sterilization of health care products—Ethylene oxide—Requirements for development, validation, and routine control of a sterilization process for medical devices.	ANSI/AAMI/ISO 11135:2014.
	N. Tissue Engineering	
15–44	Standard Guide for in vivo Evaluation of Osteoinductive Potential for Materials Containing Demineralized Bone (DBM) Active Standard.	ASTM F2529–13.

[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: 041'' 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.*

Dated: March 29, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Solicitation for Applications From Individuals Interested in Being Appointed to the Chronic Fatigue Syndrome Advisory Committee

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.