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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
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

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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
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

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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
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

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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
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

Table 1.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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
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

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
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
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

Table 2.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. and Date
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.

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