4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451] (formerly 2004N-0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 031

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: 031" (Recognition List Number: 031), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit written or electronic comments concerning this document at any time. See section VII for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of "Modifications to the List of Recognized Standards, Recognition List Number: 031" to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301-847-8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see FOR

FURTHER INFORMATION CONTACT). Submit electronic comments by email: standards@cdrh.fda.gov. This document may also be accessed on FDA's Internet site 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: 031 modifications and other standards related information.

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.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 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 "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 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: 031

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: 031" 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			
1-74	1-91	ISO 5360 Third edition 2012-01-15 Anaesthetic vaporizers--Agent-specific filling systems	Withdrawn and replaced with newer version.
1-35	1-93	ISO 5361 Second edition 2012-10-01 Anaesthetic and respiratory equipment--Tracheal tubes and connectors	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
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	Transition period extended.
1-88		ISO 80601-2-12 Medical electrical equipment--Part 2-12: Particular requirements for the safety of lung ventilators--Critical care ventilators	Transition period extended.
B. Biocompatibility			
2-119		ASTM F813-07 (Reapproved 2012) Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Reaffirmation.
2-122		ASTM F719-81 (Reapproved 2012) Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Reaffirmation.
2-123		ASTM F720-81 (Reapproved 2012) Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	Reaffirmation.
2-124		ASTM F750-87 (Reapproved 2012) Standard Practice for Evaluating Materials Extracts by Systemic Injection in the Mouse	Reaffirmation.
2-125	2-197	ASTM F749-13 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Withdrawn and replaced with newer version.
2-135	2-198	ANSI/AAMI/ISO 10993-12:2012 Biological evaluation of medical devices--Part 12:Sample preparation and reference materials	Withdrawn and replaced with newer version.
2-146		ASTM F2148-07 (Reapproved 2012) Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Reaffirmation.
2-152		ISO 10993-10:2002/Amd.1:2006(E) Biological evaluation of medical devices--Part 10: Tests for irritation and delayed-type hypersensitivity AMENDMENT 1	Withdrawn, see 2-174.
2-192	2-199	USP 36-NF31:2013 <87> Biological Reactivity Test, In Vitro--Direct Contact Test	Withdrawn and replaced with newer version.
2-193	2-200	USP 36-NF31:2013Biological Tests <87> Biological Reactivity Tests, In Vitro--Elution Test	Withdrawn and replaced with newer version.
2-194	2-201	USP 36-NF31:2013 Biological Tests <88> Biological Reactivity Tests, In Vivo Procedure Preparation of Sample	Withdrawn and replaced with newer version.
2-195	2-202	USP 36-NF31:2013 Biological Tests <88> Biological Reactivity Tests, In Vitro Classification of Plastics--Intracutaneous Test	Withdrawn and replaced with newer version.
2-196	2-203	USP 36-NF31:2013 Biological Tests <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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
C. Cardiovascular			
3-38	3-115	IEC 60601-2-34 Edition 3.0 2011-05 Medical Electrical Equipment--Part 2-34: Particular Requirements for the Basic Safety and Essential Performance of Invasive Blood Pressure Monitoring Equipment	Newer version with transition period.
3-55		ASTM F1830-97 (Reapproved 2013) Standard Practice for Selection of Blood for In Vitro Evaluation of Blood Pumps	Reaffirmation.
3-56		ASTM F1841-97 (Reapproved 2013) Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps	Reaffirmation.
3-66		ASTM F2081-06 (Reapproved 2013) Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents	Reaffirmation.
3-79		ASTM F2079-09 (Reapproved 2013) Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents	Reaffirmation.
3-86		ASTM F2394-07 (Reapproved 2013) Standard Guide for Measuring Securement of Balloon Expandable Vascular Stent Mounted on Delivery System	Reaffirmation.
3-87		ASTM F2477-07 (Reapproved 2013) Standard Test Methods for in vitro Pulsatile Durability	Reaffirmation.
3-81	3-117	ANSI/AAMI/ISO 81060-2 Second edition 2013-05-01, Non-Invasive Sphygmomanometers--Part 2: Clinical Validation of Automated Measurement Type	Withdrawn and replaced with newer version.
3-94	3-116	ISO 25539-2 Second edition 2012-12-01 Cardiovascular Implants--Endovascular Devices--Part 2: Vascular Stents Part 2: Vascular Stent	Withdrawn and replaced with newer version.
D. Dental/ENT			
4-75		ISO 7785-1 Second edition 1997-08-01 Dental Handpieces--Part 1: High-Speed Air Turbine Handpieces	Withdrawn, see 4-206.
4-76		ISO 7785-2 Second edition 1995-08-0 Dental Handpieces--Part 2: Straight and Geared Angle Handpieces	Withdrawn, see 4-206.
4-83		ISO 11498 First edition 1997-02-15 Dental Handpieces: Dental Low-Voltage Electrical Motors	Withdrawn, see 4-206.
4-84		ISO 13294 First edition 1997-05-01 Dental Handpieces--Dental Air-Motors	Withdrawn, see 4-206.
4-90		ANSI S3.39:1987 (Reaffirmed by ANSI June 15, 2012) American National Standard Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	Reaffirmation.
4-119		ANSI/ADA Specification No. 82:1998/ISO 13716:1999 Reaffirmed by ANSI: January 2009 Dental Reversible/Irreversible Hydrocolloid Impression Material Systems	Reaffirmation.
4-123	4-203	ANSI/ASA S3.6-2010 (Revision of ANSI S3.6-2004) Specification for Audiometers	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
4-167		ANSI/ASA S3.21-2004 (R2009) Methods for Manual Pure-Tone Threshold Audiometry	Reaffirmation.
4-172	4-204	ANSI/ASA S3.42-2012/Part 2 / IEC 60118-15:2012 American National Standard Testing Hearing Aids--Part 2: Methods for characterizing signal processing in hearing aids with a speech-like signal (a nationally adopted international standard)	Withdrawn and replaced with newer version.
4-187		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	Transition period extended.
E. General			
5-53		IEC 60601-1-2 Edition 3.0 2007-03 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic compatibility--Requirements and tests	Transition period extended.
5-54		ANSI/AAMI/IEC 60601-1-2:2007/(R)2012 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic compatibility--Requirements and tests	Reaffirmation and transition period extended.
5-55	5-76	IEC 60601-1-8 Edition 2.1 2012-11 Medical electrical equipment--Part 1-8: General requirements for basic safety and essential performance--Collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems	Withdrawn and replaced with newer version. Transition period extended.
5-71	5-77	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Withdrawn and replaced with new version.
5-74	5-77	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text), Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)	Withdrawn and replaced with new version.
F. General Hospital/General Plastic Surgery			
6-9	6-300	IEC 60601-2-21 Edition 2.0 2009-02 Medical electrical equipment--Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	Newer version with transition period.
6-29	6-298	IEC 60601-2-19 Edition 2.0 2009-02 Medical electrical equipment--Part 2-19: Particulars for the basic safety and essential performance of infant incubators	Newer version with transition period.
6-32	6-299	IEC 60601-2-20 Edition 2.0 2009-02 Medical electrical equipment--Part 2-20: Particular requirements for the basic safety and essential performance of infant radiant warmers	Newer version with transition period.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-116	6-294	ISO 11608-3 Second edition 2012-10-01 Needle-based injection systems for medical use--Requirements and test methods--Part 3: Finished containers	Withdrawn and replaced with newer version.
6-119	6-295	ANSI/AAMI BF7:2012 Blood transfusion microfilters	Withdrawn and replaced with newer version.
6-147		ASTM D6978--05 (Reapproved 2013) Standard Practice for Assessment of Resistance of Medical Gloves to Permeation by Chemotherapy Drugs	Reaffirmation.
6-174		ISO 11608-4 First edition 2006-03-15 Pen-injectors for medical use--Part 4: Requirements and test methods for electronic and electromechanical pen-injectors	Contact person.
6-179		ISO 21649 First edition 2006-06-01, Needle-free injectors for medical use--Requirements and test methods	Contact person.
6-112	6-296	ANSI/AAMI PB70:2012 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	Withdrawn and replaced with newer version.
6-214		ASTM D6355--07 (Reapproved 2012) Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves	Reaffirmation.
6-216		ISO 8536-7 Third edition 2009-01-15 Infusion equipment for medical use--Part 7: Caps made of aluminium-plastics combinations for infusion bottles	Contact person.
6-227		ANSI/AAMI/IEC 60601-2-21:2009, Medical electrical equipment--Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	Transition period extended.
6-228		IEC 60601-2-2 Edition 5.0 2009-02, Medical Electrical Equipment--Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories	Transition period extended.
6-229		ANSI/AAMI/IEC 60601-2-2:2009, Medical electrical equipment--Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	Transition period extended.
6-230		ANSI/AAMI/IEC 60601-2-19:2009, Medical Electrical Equipment--Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	Transition period extended.
6-231		ANSI/AAMI/IEC 60601-2-20:2009, Medical Electrical Equipment--Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	Transition period extended.
6-233		IEC 60601-2-52 Edition 1.0 2009-12 Medical electrical equipment -- Part 2-52: Particular requirements for basic safety and essential performance of medical beds	Transition period extended.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-234		IEC 60601-2-50 Edition 2.0 2009-03 Medical electrical equipment--Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	Contact person.
6-235		ANSI/AAMI/IEC 60601-2-50:2009 Medical Electrical Equipment--Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	Contact person.
6-239		ISO 8536-6 Second edition 2009-11-15 Infusion equipment for medical use--Part 6: Freeze drying closures for infusion bottles	Contact person.
6-240		ISO 8536-3 Third edition 2009-06-01 Infusion equipment for medical use--Part 3: Aluminum caps for infusion bottles	Contact person.
6-241	6-297	ISO 1135-4 Fifth edition 2012-03-01 Transfusion equipment for medical use--Part 4: Transfusion sets for single use	Withdrawn and replaced with newer version.
6-274		ISO 11608-1 Second edition 2012-04-01 Needle-based injection systems for medical use--Requirements and test methods--Part 1: Needle-based injection systems	Contact person.
6-275		ISO 11608-2 Second edition 2012-04-01 Needle-based injection systems for medical use--Requirements and test methods--Part 2: Needles	Contact person.
6-276		ISO 8536-1 Fourth edition 2011-09-01 Infusion equipment for medical use--Part 1: Infusion glass bottles	Contact person.
G. In Vitro Diagnostics			
7-3		CLSI / NCCLS GP10-A 1995, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline	Withdrawn, see 7-234.
7-4		CLSI / NCCLS GP14-A 1996, Labeling of Home-Use In Vitro Testing Products; Approved Guideline	Withdrawn.
7-37		NCCLS I/LA6-A, Detection and Quantitation of Rubella IgG Antibody: Evaluation and Performance Criteria for Multiple Component Test Products, Specimen Handling, and Use of Test Products in the Clinical Laboratory; Approved Guideline	Withdrawn.
7-41		NCCLS I/LA19-A, Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997)	Withdrawn.
7-154		CLSI MM02-A2, Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays	Withdrawn.
7-171		CLSI M38-A2, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard--Second Edition	Extent of recognition, process affected, and contact person.
7-178		CLSI M22-A3, Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard--Third Edition	Extent of recognition, process affected, and contact person.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
7-179	7-240	CLSI M27-S4, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Fourth Informational Supplement	Withdrawn and replaced with newer version.
7-200		CLSI M48-A, Laboratory Detection and Identification of Mycobacteria; Approved Guideline	Extent of recognition, type of standard, and process affected.
7-206		CLSI I/LA 20-A2 Analytical Performance Characteristics and Clinical Utility of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies and Defined Allergen Specificities; Approved Guideline--Second Edition	Relevant guidance.
7-215		CLSI M44-A2, Method for Antifungal Disk Diffusion Susceptibility Testing of Yeast; Approved Guideline--Second Edition.	Extent of recognition, process affected, and contact person.
7-217		CLSI M44-S3, Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Third Informational Supplement	Extent of recognition, process affected, and contact person.
7-218		CLSI M45-A2, Methods for Antimicrobial Dilution and Disk Susceptibility Testing of Infrequently Isolated or Fastidious Bacteria; Approved Guideline--Second Edition	Extent of recognition and process affected.
7-222		CLSI M24-A2, Susceptibility Testing of Mycobacteria, Nocardiae and other Aerobic Actinomycetes; Approved Standards--Second Edition	Extent of recognition, process affected, contact person, and title and type of standard.
7-228		CLSI M11-A8, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard--Eighth Edition	Extent of recognition, process affected, and contact person.
7-229		CLSI M02-A11, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard--Eleventh Edition	Extent of recognition, process affected, and contact person.
7-230		CLSI M07-A9, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard--Ninth Edition	Extent of recognition, process affected, and contact person.
7-231	7-241	CLSI M100-S23, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Third Informational Supplement	Withdrawn and replaced with newer version.
7-234		CLSI EP24-A2, Assessment of the Diagnostic Accuracy of Laboratory Tests Using Receiver Operating Characteristic Curves; Approved Guideline--Second Edition	Extent of recognition.
H. Materials			
8-122	8-335	ASTM F2063-12 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	Withdrawn and replaced with newer version.
8-147	8-336	ASTM F562-13 Standard Specification for Wrought 35Cobalt-35Nickel-20Chromium-10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	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
8-153		ASTM F2119-07 (Reapproved 2013) Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants	Reaffirmation.
8-154	8-337	ASTM F621-12 Standard Specification for Stainless Steel Forgings for Surgical Implants	Withdrawn and replaced with newer version.
8-156	8-338	ASTM F139-12 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer version.
8-158		ASTM F1713-08 (Reapproved 2013) Standard Specification for Wrought Titanium-13Niobium-13 Zirconium Alloy for Surgical Implant Applications (UNS R58130)	Reaffirmation.
8-166	8-339	ASTM F1091-12 Standard Specification for Wrought Cobalt-20Chromium-15Tungsten-10Nickel Alloy Surgical Fixation Wire (UNS R30605)	Withdrawn and replaced with newer version.
8-203	8-340	ASTM F2026-12 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications	Withdrawn and replaced with newer version.
8-219	8-341	ASTM F136-12a Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Withdrawn and replaced with newer version.
8-222	8-342	ASTM F1537-11 Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Withdrawn and replaced with newer version.
8-332	8-343	ASTM F899-12b Standard Specification for Wrought Stainless Steels for Surgical Instruments	Withdrawn and replaced with newer version.
I. OB-GYN/Gastroenterology			
9-31		ANSI/AAMI ID54:1996/ (R)2012 Enteral feeding set adapters and connectors	Reaffirmation.
9-60		IEC 60601-2-16 Edition 3.0 2008-04 Medical electrical equipment -- Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration	Withdrawn, see 9-80.
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	Transition period extended.
9-72	9-81	ANSI/AAMI/ IEC 60601-2-16:2012 Medical electrical equipment--Part 2-16: Particular requirements for basic safety and essential performance of hemodialysis, hemodiafiltration and hemofiltration equipment	Newer version with transition period.
9-62		IEC 60601-2-2 Edition 5.0 2009-02 Medical electrical equipment--Part 2-2: Particular requirements for the basic safety and essential performance of frequency surgical equipment and high frequency surgical accessories	Transition period extended.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
9-63		IEC 60601-2-16 (Third edition--2008), Medical electrical equipment--Part 2-16: Particular requirements for basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment CORRIGENDUM 1	Withdrawn, see 9-80.
9-64		ANSI/AAMI/IEC 60601-2-2:2009 Medical electrical equipment--Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgery equipment and high frequency surgical accessories	Transition period extended.
9-80		IEC 60601-2-16 Edition 4.0 2012-03 Medical electrical equipment--Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	Transition period extended.
		J. Ophthalmic	
10-15	10-77	ISO 9394 Third edition 2012-10-01 Ophthalmic optics--Contact lenses and contact lens care products--Determination of biocompatibility by ocular study with rabbit eyes	Withdrawn and replaced with newer version.
10-36	10-78	ISO 11979-3 Third edition 2012-12-01 Ophthalmic implants--Intraocular lenses--Part 3: Mechanical properties and test methods	Withdrawn and replaced with newer version.
10-40	10-79	ISO 11979-1 Third edition 2012-09-15 Ophthalmic implants--Intraocular lenses--Part 1: Vocabulary	Withdrawn and replaced with newer version.
10-45	10-80	ISO 18369-2 Second edition 2012-12-01 Ophthalmic optics--Contact lenses--Part 2: Tolerances	Withdrawn and replaced with newer version.
10-56		ANSI Z80.12-2007 (R2012) American National Standard for Ophthalmics--Multifocal Intraocular Lenses	Reaffirmation.
10-57		ANSI Z80.13-2007 (R2012) American National Standard for Ophthalmics--Phakic Intraocular Lenses	Reaffirmation.
10-76		ISO 11979-8 Second edition 2006-07-01 AMENDMENT 1 2011-05-15 Ophthalmic implants--Intraocular lenses--Part 8: Fundamental requirements	Withdrawn.
		K. Orthopedics	
11-73	11-252	ISO 5838-1 Third edition 2013-03-01 Implants for surgery--Metallic skeletal pins and wires--Part 1: General requirements	Withdrawn and replaced with a newer version.
11-206	11-253	ASTM F1800-12 Standard Practice for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Withdrawn and replaced with a newer version.
11-208	11-254	ISO 14630 Fourth edition 2012-12-01 Non-active surgical implants--General requirements	Withdrawn and replaced with a newer version.
11-213		ASTM F1223-08 (Reapproved 2012) Standard Test Method for Determination of Total Knee Replacement Constraint	Reaffirmation.
11-215		ASTM F897-02 (Reapproved 2013) Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	Reaffirmation.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
11-242		ASTM F1839-08 (Reapproved 2012) Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments	Reaffirmation.
11-246	11-255	ASTM F1717-13 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Withdrawn and replaced with a newer version.
L. Physical Medicine			
16-24	16-190	ISO 7176-11 Second edition 2012-12-01 Wheelchairs--Part 11: Test dummies	Withdrawn and replaced with a newer version.
16-28	16-191	ISO 7176-16 Second edition 2012-12-01 Wheelchairs--Part 16: Resistance to ignition of postural support devices	Withdrawn and replaced with a newer version.
16-50	16-192	ISO 7176-3 Third edition 2012-12-15 Wheelchairs--Part 3: Determination of effectiveness of brakes	Withdrawn and replaced with a newer version.
M. Radiology			
12-34	12-201	IEC 60601-2-54 Edition 1.0 2009-06 Medical electrical equipment--Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Newer version with transition period.
12-54	12-254	IEC 60601-2-8 Edition 2.0 2010-11 Medical electrical equipment--Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	Newer version with extended transition period.
12-127	12-201	IEC 60601-2-54 Edition 1.0 2009-06 Medical electrical equipment--Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	Newer version with transition period.
12-133	12-255	IEC 60601-2-11 Edition 3.0 2013-01 Medical electrical equipment--Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	Newer version with transition period.
12-202		IEC 60601-2-43 Edition 2.0 2010-03 Medical electrical equipment--Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	Transition period extended.
12-203	12-256	IEC 60601-2-44 Edition 3.1 2012-09 Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Newer version with extended transition period.
12-204		IEC 60601-2-28 Edition 2.0 2010-03 Medical electrical equipment--Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	Transition period extended.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-205		IEC 60601-2-5 Edition 3.0 2009-07 Medical electrical equipment--Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	Transition period extended.
12-206		IEC 60601-2-1 Edition 3.0 2009-10 Medical electrical equipment--Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	Transition period extended.
12-207		IEC 60601-2-33 Edition 3.0 2010-03 Medical electrical equipment--Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnostic	Transition period extended.
12-208		IEC 60601-2-22 Third Edition 2007-05 Medical electrical equipment--Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	Transition period extended.
12-209		IEC 60601-2-37 Edition 2.0 2007-08 Medical electrical equipment--Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	Transition period extended.
12-210		IEC 60601-1-3 Edition 2.0 2008-01 Medical electrical equipment--Part 1-3: General requirements for basic safety and essential performance--Collateral Standard: Radiation protection in diagnostic X-ray equipment	Transition period extended.
12-211		IEC 60601-2-29 Edition 3.0 2008-06 Medical electrical equipment Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	Transition period extended.
12-224		IEC 60601-2-44 (Third edition -2009) Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography CORRIGENDUM 1	Withdrawn, see 12-256.
12-236		IEC 60601-2-45 Edition 3.0 2011-02 Medical electrical equipment--Part 2-45: Particular requirements for the safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	Transition period extended.
12-250		IEC 60601-2-44 Edition 3.0 2012-08 Amendment 1 Medical electrical equipment--Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	Withdrawn, see 12-256.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
N. Sterility			
14-64	14-378	ASTM F1929-12 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Withdrawn and replaced with newer version.
14-230		ASTM F2203-02 (Reapproved 2012) Standard Test Method for Linear Measurement Using Precision Steel Rule	Reaffirmation.
14-231		ASTM F2217-02 (Reapproved 2012) Standard Practice for Coating/Adhesive Weight Determination	Reaffirmation.
14-235		ASTM F1140 -07 (Reapproved 2012) Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	Reaffirmation.
14-236		ASTM F2054-07 (Reapproved 2012) Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	Reaffirmation.
14-244	14-379	ISO 14644-8 Second edition 2013-02-15 Cleanrooms and associated controlled environments--Part 8: Classification of air cleanliness by chemical concentration (ACC)	Withdrawn and replaced with newer version.
14-264		ANSI/AAMI ST8:2008 Hospital steam sterilizers	Contact person.
14-275		ANSI/AAMI ST41:2008/(R)2012 Ethylene oxide sterilization in health care facilities: Safety and effectiveness	Reaffirmation.
14-281	14-380	ASTM F17-12 Standard Terminology Relating to Flexible Barrier Packaging	Withdrawn and replaced with newer version.
14-295		ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices--Information to be provided by the manufacturer for the processing of resterilizable medical devices	Relevant guidance.
14-311		ANSI/AAMI ST55:2010 Table-top steam sterilizers	Contact person
14-312	14-394	ANSI/AAMI ST79:2010 & A1:2010 & A2:2011 & A3:2012 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities	Withdrawn and replaced with newer version.
14-341		ASTM E2303-11$^{\epsilon 1}$ Standard Guide for Absorbed-Dose Mapping in Radiation Processing Facilities	Editorial change.
14-345	14-381	ISO/ASTM 51261 Second edition 2013-04-15 Practice for calibration of routine dosimetry systems for radiation processing	Withdrawn and replaced with newer version.
14-346	14-382	ISO/ASTM 51276 Third edition 2012-07-15 Practice for use of a polymethylmethacrylate dosimetry system	Withdrawn and replaced with newer version.
14-347	14-383	ISO/ASTM 51702 Third edition 2013-04-15 Practice for dosimetry in a gamma facility for radiation processing	Withdrawn and replaced with newer version.
14-349		ANSI/AAMI/ISO 13408-3:2006/(R)2012 Aseptic processing of health care products--Part 3: Lyophilization	Reaffirmation.
14-350		ANSI/AAMI/ISO 13408-4:2005/(R)2012 Aseptic processing of health care products--Part 4: Clean-in-place technologies	Reaffirmation.

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

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
14-351		ANSI/AAMI/ISO 13408-5:2006/(R)2012 Aseptic processing of health care products--Part 5: Sterilization in place	Reaffirmation.
O. Tissue Engineering			
15-5	15-37	ASTM F2347--11 Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications	Withdrawn and replaced with newer version.
15-14		ASTM F2603 −06 (Reapproved 2012) Standard Guide for Interpreting Images of Polymeric Tissue Scaffolds	Reaffirmation.
15-29		ASTM F2259 −10 (Reapproved 2012)$^{\epsilon 1}$ Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy	Reaffirmation.
15-32		ASTM F2260 −03 (Reapproved 2012)$^{\epsilon 1}$ Standard Test Method for Determining Degree of Deacetylation in Chitosan Salts by Proton Nuclear Magnetic Resonance (^{1}H NMR) Spectroscopy	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: 031.

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

Recognition No.	Title of Standard[1]	Reference No. and Date
A. Anesthesia		
1-90	Oxygen concentrators for medical use--Safety requirements	ISO 8359 Second edition 1996-12-15 Amendment 1 2012-07-01
1-92	Sleep apnoea breathing therapy--Part 2: Masks and application accessories	ISO 17510-2 Second edition 2007-10-01
B. Dental/ENT		
4-205	Dentistry--Handpieces and motors	ISO 14457 First edition 2012-09-15
C. General		
5-75	Medical devices--Symbols to be used with medical device labels, labeling, and information to be supplied--Part 1: General requirements	ANSI/AAMI/ISO 15223-1 2012
D. In Vitro Diagnostics		
7-242	Hemolysis, Icterus, and Lipemia/Turbidity Indices as Indicators of Interference in Clinical Laboratory Analysis; Approved Guideline	CLSI C56-A
7-243	Method for Antifungal Disk Diffusion Susceptibility Testing of Nondermatophyte Filamentous Fungi; Approved Guideline	CLSI M51-A

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

Recognition No.	Title of Standard[1]	Reference No. and Date
E. Neurology		
17-11	Medical electrical equipment--Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	IEC 60601-2-10 Edition 2.0 2012-06
F. Radiology		
12-251	Medical electrical equipment--Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment	IEC 60601-2-63 Edition 1.0 2012-09
12-252	Medical electrical equipment--Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	IEC 60601-2-65 Edition 1.0 2012-09
12-253	Medical electrical equipment--Medical electron accelerators--Functional performance characteristics	IEC 60976 Edition 2.0 2007-10
G. Software/Informatics		
13-37	Laboratory Automation: Data Content for Specimen Identification; Approved Standard	NCCLS AUTO7-A
H. Sterility		
14-384	Biological evaluation of medical devices--Part 7: Ethylene oxide sterilization residuals	ISO 10993-7:2008 TECHNICAL CORRIGENDUM 1 Published 2009-11-15
14-385	Aseptic processing of health care products--Part 1: General requirements	ANSI/AAMI/ISO 13408-1:2008/ (R2011)
14-386	Aseptic processing of health care products--Part 1: General requirements	ISO 13408-1 Second edition 2008-06-15
14-387	Aseptic processing of health care products--Part 7: Alternate processes for medical devices and combination products	ANSI/AAMI/ISO 13408-7:2012
14-388	Aseptic processing of health care products--Part 7: Alternate processes for medical devices and combination products	ISO 13408-7 First edition 2012-08-01
14-389	Cleanrooms and associated controlled environments--Part 9: Classification of surface cleanliness by particle concentration	ISO 14644-9 First edition 2012-08-15
14-390	Cleanrooms and associated controlled environments--Part 10: Classification of surface cleanliness by chemical concentration	ISO 14644-10 First edition 2013-03-01
14-391	Practice for dosimetry in an X-ray (bremsstrahlung) facility for radiation processing	ISO/ASTM 51608 Second edition 2005-05-15
14-392	Practice for dosimetry in an electron beam facility for radiation processing at energies between 300 keV and 25 MeV	ISO/ASTM 51649 Second edition 2005-05-15
14-393	Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV	ISO/ASTM 51818 Second edition 2009-06-15
I. Tissue Engineering		
15-38	Standard Guide for Characterization of Ceramic and Mineral Based Scaffolds used for Tissue-Engineered Medical Products (TEMPs) and as Device for Surgical Implant Applications	ATSM F2883--11

[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 Number: 033, FDA will no longer be announcing minor revisions to the list of recognized consensus standards such as technical contact person, relevant guidance, processes affected, CFR 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 the contact person (see FOR FURTHER INFORMATION CONTACT). 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 includes the guidance as well as the current list of recognized standards and other standards-related documents. After publication in the Federal Register, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 031" will be available on the CDRH home page. You may access the CDRH home page at http://www.fda.gov/MedicalDevices.

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.

This Federal Register document on modifications in FDA's recognition of consensus standards is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see FOR FURTHER INFORMATION CONTACT) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Comments are to be identified with the docket number found in brackets in the heading of this document. 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: 031. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: July 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-19019 Filed 08/05/2013 at 8:45 am; Publication Date: 08/06/2013]