4160-01-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: 029

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: 029" (Recognition List Number: 029), 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 of this document 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: 029" 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 e-mail: 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 of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 029 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT:

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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, are identified in table 1 of this document.

Table 1.--Previous Publication of Standard Recognition Lists

February 25, 1998 (63 FR 9561)	June 23, 2006 (71 FR 36121)
October 16, 1998 (63 FR 55617)	November 3, 2006 (71 FR 64718)
July 12, 1999 (64 FR 37546)	May 21, 2007 (72 FR 28500)
November 15, 2000 (65 FR 69022)	September 12, 2007 (72 FR 52142)
May 7, 2001 (66 FR 23032)	December 19, 2007 (72 FR 71924)
January 14, 2002 (67 FR 1774)	September 9, 2008 (73 FR 52358)
October 2, 2002 (67 FR 61893)	March, 18, 2009 (74 FR 11586)
April 28, 2003 (68 FR 22391)	September 8, 2009 (74 FR 46203)
March 8, 2004 (69 FR 10712)	May 5, 2010 (75 FR 24711)
June 18, 2004 (69 FR 34176)	June 10, 2010 (75 FR 32943)
October 4, 2004 (69 FR 59240)	October 4, 2010 (75 FR 61148)
May 27, 2005 (70 FR 30756)	March 14, 2011 (76 FR 13631)
November 8, 2005 (70 FR 67713)	August 2, 2011 (76 FR 46300)
March 31, 2006 (71 FR 16313)	March 16, 2012 (77 FR 15765)

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: 029

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in satisfying premarket reviews 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: 029" to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (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 of this document, FDA lists modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Biocompatibility			
2-115	2-189	ASTM F895 – 11 Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Withdrawn and replaced with newer version
2-164	2-190	ANSI/AAMI/ISO 10993-13:2010 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices	Withdrawn and replaced with newer version
2-165		ANSI/AAMI/ ISO 10993-14:2001/(R)2011 Biological evaluation of medical devices — Part 14: Identification and quantification of degradation products from ceramics	Reaffirmation
B. Cardiovascular			
3-37	1-87	IEC 60601-2-23(1999-12) Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment	Transferred to Anesthesia
3-44		ANSI/AAMI BP22:1994/ (R)2011 Blood pressure transducers	Reaffirmation
3-55		ASTM F1830-97 (Reapproved 2005) Standard Practice for Selection of Blood for in vitro Evaluation of Blood Pumps	Extent of recognition
3-56		ASTM F1841-97 (Reapproved 2005) Standard Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps	Extent of recognition

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
3-62	3-102	IEC 60601-2-31 Edition 2.1 2011-09 Medical electrical equipment – Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	Withdrawn and replaced with newer version
C. General			
5-28		IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Withdrawn
5-30		ANSI / AAMI / IEC 60601-1-2:2001, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests	Withdrawn
5-40		ISO 14971 Second edition 2007-03-01, Medical devices - Application of risk management to medical devices	Extent of recognition
5-52	5-71	ANSI/AAMI ES60601- 1:2005/(R)2012 and 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
5-56		ISO 15223-2 First edition 2010-01-15, Medical devices - Symbols to be used with medical devices labels, labeling, and information to be supplied - Part 2: Symbol development, selection and validation	Contact person
5-59	5-72	ISO/FDIS 15223-1 2012 Medical devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements	Withdrawn and replaced with new version
5-61		ANSI / AAMI / ISO 15223-1:2007, Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied - Part 1: General requirements	Withdrawn
D. General Hospital/General Plastic Surgery			
6-110		ASTM F 882-84 (Reapproved 2002), Standard Performance and Safety Specification for Cryosurgical Medical Instruments	Withdrawn
6-114	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	Withdrawn and replaced with newer version
6-115	6-275	ISO 11608-2 Second edition 2012-04-01 Needle-based injection systems for medical use — Requirements and test methods — Part 2: Needles	Withdrawn and replaced with newer version
6-117		ASTM F2172-02 (Reapproved 2011), Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	Contact person

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-118		ASTM F2196-02, Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices	Withdrawn. See 6-238
6-119		ANSI/AAMI BF7:1989/ (R)2011 Blood transfusion microfilters	Reaffirmation
6-132		ISO 11810-1 First edition 2005-02-15, Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 1: Primary ignition and penetration	Contact person
6-172	6-276	ISO 8536-1 Fourth edition 2011-09-01 Infusion equipment for medical use — Part 1: Infusion glass bottles	Withdrawn and replaced with newer version
6-175		ASTM D5151 – 06 (Reapproved 2011) Standard Test Method for Detection of Holes in Medical Gloves	Reaffirmation
6-178		ASTM D6124 – 06 (Reapproved 2011) Standard Test Method for Residual Powder on Medical Gloves	Reaffirmation and Contact person
6-183		ASTM D5250 – 06 (Reapproved 2011) Standard Specification for Poly(vinyl chloride) Gloves for Medical Application	Reaffirmation and contact person
6-202		ISO 11810-2:2007, Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition	Title and contact person
6-236		IEC 80601-2-59 Edition 1.0 2008-10 Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	Title and contact person
6-237		IEC 80601-2-59 (First edition – 2008) Medical electrical equipment – Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening CORRIGENDUM1	Title and contact person
6-238		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	Contact person
6-241		ISO 1135-4 Fourth edition 2010-04-15, Transfusion equipment for medical use - Part 4: Transfusion sets for single use	Contact person
6-242		ISO 8536-2 Third edition 2010-03-15, Infusion equipment for medical use - Part 2: Closures for infusion bottles	Contact person
6-245		ISO 8536-4 Fifth edition 2010-10-01, Infusion equipment for medical use - Part 4: Infusion sets for single use, gravity feed	Contact person

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
6-273		ISO 23908 First edition 2011-06-11, Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	Contact person
E. In Vitro Diagnostics			
7-54		CLSI D12-A2, Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials - Second Edition; Approved Guideline	Withdrawn
7-76		NCCLS M15-A, Laboratory Diagnosis of Blood-borne Parasitic Diseases; Approved Guideline	Contact person and type of standard
7-146		CLSI M6-A2, Protocols for Evaluating Dehydrated Mueller-Hinton Agar; Approved Standard - Second Edition	Contact person and title
7-148		CLSI M28-A2, Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline - Second Edition	Contact person and title
7-157	7-228	CLSI M11-A8, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard-Eighth Edition	Withdrawn and replaced with newer version
7-171		CLSI M38-A2, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard - Second Edition	Contact person and title
7-179		CLSI M27-S3, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Third Informational Supplement	Contact person and title
7-184		CLSI M40-A, Quality Control of Microbiological Transport Systems; Approved Standard	Contact person and title
7-195	7-229	CLSI M02-A11, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - Eleventh Edition	Withdrawn and replaced with newer version
7-196	7-230	CLSI M07-A9, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard - Ninth Edition	Withdrawn and replaced with newer version
7-197		CLSI M35-A2, Abbreviated Identification of Bacteria and Yeast; Approved Guideline - Second Edition	Contact person and title
7-198		CLSI M23-A3, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline - Third Edition	Contact person and title
7-200		CLSI M48-A, Laboratory Detection and Identification of Mycobacteria; Approved Guideline	Contact person and title
7-215		CLSI M44-A2, Method for Antifungal Disk Diffusion Susceptibility Testing of Yeast; Approved Guideline-Second Edition	Contact person
7-216	7-231	CLSI M100-S22, Performance Standards for Antimicrobial Susceptibility Testing; Twenty-Second Informational Supplement	Withdrawn and replaced with newer version

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
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	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	Contact person
F. Materials			
8-108	8-216	ASTM F1295 – 11 Standard Specification for Wrought Titanium-6Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700)	Withdrawn and replaced with newer version
8-111		ASTM F1160 – 05 (Reapproved 2011) Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/ Metallic Coatings	Reaffirmation
8-112		ASTM F1044 – 05 (Reapproved 2011) Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Reaffirmation
8-113		ASTM F1147 – 05 (Reapproved 2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings	Reaffirmation
8-127		ISO 5834-2:2006, Implants for surgery - Ultra-high-molecular-weight polyethylene - Part 2: Moulded forms	Withdrawn. See 8-208
8-128		ASTM F2213 – 06 (Reapproved 2011) Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Reaffirmation and relevant guidance
8-130	8-217	ASTM F620 – 11 Standard Specification for Titanium Alloy Forgings for Surgical Implants in the Alpha Plus Beta Condition	Withdrawn and replaced with newer version
8-131	8-218	ASTM F799 – 11 Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	Withdrawn and replaced with newer version
8-164	8-219	ASTM F136 – 11 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Withdrawn and replaced with newer version
8-174	8-220	ASTM F629 – 11 Standard Practice for Radiography of Cast Metallic Surgical Implants	Withdrawn and replaced with newer version
8-180	8-221	ASTM F2066 – 11 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)	Withdrawn and replaced with newer version

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Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
8-182	8-222	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
8-186	8-223	ASTM F2759 – 11 Standard Guide for Assessment of the Ultra High Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic and Spinal Devices	Withdrawn and replaced with newer version
8-210	8-227	ASTM F2182 – 11a Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	Withdrawn and replaced with newer version
G. Orthopedics			
11-175		ASTM F1582 – 98 (Reapproved 2011) Standard Terminology Relating to Spinal Implants	Reaffirmation
11-185		ASTM F2267 – 04 (Reapproved 2011) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression	Reaffirmation
11-186	11-235	ASTM F2077 – 11 Test Methods For Intervertebral Body Fusion Devices	Withdrawn and replaced with newer version
11-195		ASTM F1612-95(2005), Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion	Withdrawn. See 11-225
11-203		ASTM F1541 – 02 (Reapproved 2011) Standard Specification and Test Methods for External Skeletal Fixation Devices	Reaffirmation and contact person
11-220		ASTM F2068-09, Standard Specification for Femoral Prostheses - Metallic Implants	Extent of recognition and CFR citations
11-230	11-236	ASTM F1717 – 11a Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Withdrawn and replaced with newer version
H. Physical Medicine			
16-172		ANSI / RESNA WC/Volume 1 -1998, Section 5: Determination of Overall Dimensions, Mass, and Turning Space - Wheelchair	Duplicate. See 16-188
16-186	16-189	ASME A18.1-2011 (Revision of ASME A18.1-2008) Safety Standard for Platform Lifts and Stairway Chairlifts	Withdrawn and replaced with newer version
I. Radiology			
12-102		ANSI / IESNA RP-27.2-00 Recommended Practice for Photobiological Safety for Lamps & Lamp Systems - Measurement Techniques	CFR citation and product codes, devices affected, processes impacted, and contact person
12-153		ANSI / IESNA RP-27.1-05 Recommended Practice for Photobiological Safety for Lamps and Lamp Systems - General Requirements	CFR citation and product codes, devices affected, processes impacted, and contact person

Table 2.--Modifications to the List of Recognized Standards

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
12-179		ANSI/IESNA RP-27.3-07 Recommended Practice for Photobiological Safety for Lamps - Risk Group Classification and Labeling	Extent of recognition, CFR citation and product codes, devices affected, processes impacted, type of standard, contact person, and relevant guidance
J. Software/Informatics			
13-8		IEC 62304 First edition 2006-05 Medical device software – Software life cycle processes	Extent of recognition
K. Sterility			
14-55	14-358	ANSI/AAMI/ ISO 14160:2011 Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	Withdrawn and replaced with newer version
14-123	14-359	ASTM F2096 – 11 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	Withdrawn and replaced with newer version
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	Reaffirmation and contact person
14-229		ASTM F1980 – 07 (Reapproved 2011) Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	Reaffirmation
14-264		AAMI / ANSI ST8:2008, Hospital steam sterilizers	Contact person
14-277		ISO TS 17665-2:2009, Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1	Extent of recognition and contact person
14-292	14-360	ANSI/AAMI ST72:2011 Bacterial endotoxins — Test methods, routine monitoring, and alternatives to batch testing	Withdrawn and replaced with newer version
14-311		AAMI / ANSI ST55:2010, Table-top steam sterilizers	Contact person

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

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 029.

Table 3.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. & Date
A. Anesthesia		
1-86	Respiratory tract humidifiers for medical use — Particular requirements for respiratory humidification systems	ISO 8185 Third edition 2007-07-01
1-87	Medical electrical equipment – Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	60601-2-23 Edition 3.0 2011-02
1-88	Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	ISO 80601-2-12 First edition 2011-04-15
1-89	Medical electrical equipment Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	ISO 80601-2-12:2011 TECHNICAL CORRIGENDUM 1
B. Cardiovascular		
3-101	Medical electrical equipment — Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	ANSI/AAMI/IEC 60601-2-27:2011
3-103	Cardiovascular implants — Endovascular devices — Part 3: Vena cava filters	ISO 25539-3 First edition 2011-12-01
3-104	Standard Guide for Identification of Shelf-life Test Attributes for Endovascular Devices	ASTM F2914 – 12
C. General Hospital/General Plastic Surgery		
6-277	Prefilled syringes — Part 4: Glass barrels for injectables	ISO 11040-4 Second edition 2007-02-01
6-278	Prefilled syringes — Part 5: Plunger stoppers for injectables	ISO 11040-5 Third edition 2012-01-15
6-279	Medical electrical equipment – Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators CORRIGENDUM 1	IEC 60601-2-19 (Second edition – 2009)
6-280	Medical electrical equipment – Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators CORRIGENDUM 1	IEC 60601-2-20 (Second edition – 2009)
6-281	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 CORRIGENDUM 1	IEC 80601-2-35 (Second edition – 2009)
D. Materials		
8-224	Standard Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants	ASTM F2102 – 06$^{\varepsilon 1}$
8-225	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air	ASTM F2003 – 02 (Reapproved 2008)
8-226	Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application	ASTM F603 – 12
E. OB-GYN/Gastroenterology		
9-75	Optics and Optical instruments – Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics	ISO 8600-3 First edition 1997-07-01

Table 3.--New Entries to the List of Recognized Standards

Recognition No.	Title of Standard[1]	Reference No. & Date
9-76	Water for haemodialysis and related therapies	ISO 13959 Second edition 2009-04-15
9-77	Guidance for the preparation and quality management of fluids for haemodialysis and related therapies	ISO 23500 First edition 2011-05-15
9-78	Quality of dialysis fluid for haemodialysis and related therapies	ISO 11663 First edition 2009-04-15
F. Ophthalmic		
10-73	American National Standard for Ophthalmics – Instruments – General-Purpose Clinical Visual Acuity Charts	ANSI Z80.21-2010
10-74	Ophthalmic instruments — Fundus cameras	ISO 10940 Second edition 2009-08-01
G. Orthopedic		
11-237	Implants for surgery - Partial and total hip joint prostheses - Part 6: Determination of endurance properties of head and neck region of stemmed femoral components	ISO 7206-6 First edition 1992-03-l5
11-238	Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials	ASTM F 2033 – 12
11-239	Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads	ASTM F2345 – 03 (Reapproved 2008)
11-240	Standard Specification and Test Method for Metallic Bone Plates	ASTM F382 – 99 (Reapproved 2008)
11-241	Standard Specification and Test Methods for Metallic Medical Bone Screws	ASTM F543 – 07$^{\epsilon 1}$
11-242	Standard Specification for Rigid Polyurethane Foam for Use as a Standard Material for Testing Orthopaedic Devices and Instruments	ASTM F1839 – 08$^{\epsilon 2}$
11-243	Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs	ASTM F2346 – 05 (Reapproved 2011)
H. Radiology		
12-249	Photobiological safety of lamps and lamp systems	IEC 62471 First edition 2006-07
I. Software/Informatics		
13-31	Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard	CLSI AUTO12-A
13-32	Medical device software - Software life cycle processes	ANSI/AAMI/IEC 62304:2006
J. Sterility		
14-361	Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO 14160 Second edition 2011-07-01

[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 minor 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 minor revisions to the list of recognized consensus standards, as needed, in the Federal Register once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of 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. 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: 029" 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 no longer necessary to send two copies of mailed 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: 029. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: August 14, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012-20323 Filed 08/17/2012 at 8:45 am; Publication Date: 08/20/2012]