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: 034

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: 034'' (Recognition List Number: 034), 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: 034'' 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: 034 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.

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its 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: 034

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: 034'' to identify these current modifications.

In table 1 of this document, 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 of this document, 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	
1–15		ISO 5361–4:1987, Tracheal tubes—Part 4: Cole type	Withdrawn. See 1–93.
1–18	1–94	ISO 8359 Second edition 1996–12–15, Oxygen concentrators for medical use—Safety requirements [Including: AMENDMENT 1 2012–07–01].	Withdrawn and replaced with newer version including amendment.
1–36	1–95	ISO 5366–3 Second edition 2001–08–15, Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 3: Pediatric tracheostomy tubes [Including: TECHNICAL CORRIGENDUM 1 Published 2003–01–15].	Withdrawn and replaced with newer version including technical corrigendum.
1–44		ISO 5366–1 Fourth edition 2000–12–15, Anaesthetic and respiratory equipment—Tracheostomy tubes—Part 1: Tubes and connectors for use in adults.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
1–46		ISO 5367 Fourth edition 2000–06–01 Breathing tubes intended for use with anaesthetic apparatus and ventilators.	Extent of recognition.
1–47		AS 4259–1995 Ancillary devices for expired air resuscitation	Extent of recognition.
1–56	1–97	CGA V–7.1:2011 Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases.	Withdrawn and replaced with newer version.
1–57		ASTM F1101–90 (Reapproved 2003)$^{\varepsilon 1}$, Standard Specification for Ventilators Intended for Use During Anesthesia.	Extent of recognition.
1–58		ASTM G175–03 (Reapproved 2011), Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications.	Extent of recognition.
1–65		ISO 21647:2004 Medical electrical equipment—Particular requirements for the basic safety and essential performance of respiratory gas monitors.	Withdrawn. See 1–96.
1–69		ASTM F1464–93 (Reapproved 2005) Standard Specification for Oxygen Concentrators for Domiciliary Use.	Extent of recognition.
1–70		ASTM F1246–91 (Reapproved 2005) Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits.	Extent of recognition.
1–78		ASME PVHO–1–2007 Safety Standard for Pressure Vessels for Human Occupancy.	Extent of recognition.
1–81		CGA V–5:2008 (Reaffirmed 2013), Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications).	Reaffirmation.
1–83		ISO 21647:2004 TECHNICAL CORRIGENDUM 1, Medical electrical equipment—Particular requirements for the basic safety and essential performance of respiratory gas monitors.	Withdrawn. See 1–96.
1–84		ISO 5366–3:2001 Anaesthetic and Respiratory Equipment—Tracheostomy Tubes—Part 3: Pediatric Tracheostomy Tubes TECHNICAL CORRIGENDUM 1.	Withdrawn. See 1–95.
1–86		ISO 8185 Third edition 2007–07–01 Corrected versions 2008–06–15 Respiratory tract humidifiers for medical use—Particular requirements for respiratory humidification systems.	Extent of recognition.
1–88	1–98	ISO 80601–2–12 First edition 2011–04–15 Medical electrical equipment—Part 2–12: Particular requirements for the safety of lung ventilators—Critical care ventilators [Including: TECHNICAL CORRIGENDUM 1 Published 2011–10–15].	Withdrawn and replaced with newer version including technical corrigendum.
1–89		ISO 80601–2–12 TECHNICAL CORRIGENDUM 1 Medical electrical equipment Part 2–12: Particular requirements for basic safety and essential performance of critical care ventilators.	Withdrawn. See 1–98.
1–90		ISO 8359 Second edition 1996–12–15 AMENDMENT 1 2012–07–01 Oxygen concentrators for medical use—Safety requirements.	Withdrawn. See 1–94.
1–92		ISO 17510–2 Second Edition 2007–10–01, Sleep apnoea breathing therapy—Part 2: Masks and application accessories.	Extent of recognition.
1–93	ISO 5361	Second edition 2012–10–01 Anaesthetic and respiratory equipment—Tracheal tubes and connectors.	Extent of recognition.
		B. Biocompatibility	
2–123	2–204	ASTM F720–13 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test.	Withdrawn and replaced with newer version.
2–182	2–205	ISO 14155 Second edition 2011–02–01 Clinical investigations of medical devices for human subjects—Good clinical practices [Including TECHNICAL CORRIGENDUM 1:2011].	Withdrawn and replaced with newer version including technical corrigendum.
2–183		ISO 14155:2011 and TECHNICAL CORRIGENDUM 1 Published 2011–07–15 Clinical investigation of medical devices for human subjects—Good clinical practice.	Withdrawn. See 2–205.
2–93		ASTM F763–04 (Reapproved 2010), Standard Practice for Short-Term Screening of Implant Materials.	Extent of recognition.
2–94		ASTM F981–04 (Reapproved 2010) Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone.	Extent of recognition.
2–114		ASTM F1877–05 (Reapproved 2010) Standard Practice for Characterization of Particles.	Extent of recognition.
2–118		ANSI/AAMI/ISO 10993–11:2006/(R) 2010 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity.	Extent of recognition.
2–120		ANSI/AAMI/ISO 10993–6:2007/(R) 2010 Biological evaluation of medical devices—Part 06: Tests for local effects after implantation.	Extent of recognition.
2–126		ASTM F748–06 (Reapproved 2010) Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
2–133		ASTM F1408–97 (Reapproved 2008) Standard Practice for Subcutaneous Screening Test for Implant Materials.	Extent of recognition.
2–134		ASTM F2065–00 (Reapproved 2010) Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials.	Extent of recognition.
2–136		ASTM E1262–88 (Reapproved 2008) Standard Guide for Performance of the Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay.	Extent of recognition.
2–137		ASTM E1263–97 (Reapproved 2008) Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes.	Withdrawn.
2–138		ASTM E1280–97 (Reapproved 2008) Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity.	Withdrawn.
2–139		ASTM E1397–91 (Reapproved 2008) Standard Practice for the In Vitro Rat Hepatocyte DNA Repair Assay.	Withdrawn.
2–140		ASTM E1398–91 (Reapproved 2008) Standard Practice for the In Vivo Rat Hepatocyte DNA Repair Assay.	Withdrawn.
2–141		ASTM F1984–99 (Reapproved 2008) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials.	Extent of recognition.
2–142		ASTM F1983–99 (Reapproved 2008) Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Application.	Extent of recognition.
2–143		ASTM F1904–98 (Reapproved 2008) Standard Practice for Testing the Biological Responses to Particles in vivo.	Extent of recognition.
2–144		ASTMF619–03 (Reapproved 2008) Standard Practice for Extraction of Medical Plastics.	Extent of recognition.
2–145		ASTM F1439–03 (Reapproved 2008) Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials.	Extent of recognition.
2–153		ANSI/AAMI/ISO 10993–5:2009, Biological evaluation of medical devices—Part 5: Tests for In Vitro cytotoxicity.	Extent of recognition.
2–154		ASTM F756–08 Standard Practice for Assessment of Hemolytic Properties of Materials.	Extent of recognition.
2–155		ASTM F2147–01 (Reapproved 2010) Standard Practice for Guinea Pig: Split Adjuvant and Closed Patch Testing for Contact Allergens.	Extent of recognition.
2–156		ANSI/AAMI/ISO 10993–1:2009 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management.	Extent of recognition.
2–162		ASTM F1903–10 Standard Practice for Testing for Biological Responses to Particles in vitro.	Extent of recognition.
2–163		ANSI/AAMI/ISO 10993–9:2009 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	Extent of recognition.
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.	Extent of recognition.
2–167		ISO/TS 10993–19 First edition 2006–06–01 Biological evaluation of medical devices—Part 19: Physico-chemical, morphological, and topographical characterization of materials.	Extent of recognition.
2–168		ISO 10993–9 Second edition 2009–12–15 Biological evaluation of medical devices—Part 9: Framework for identification and quantification of potential degradation products.	Extent of recognition.
2–169		ISO 10993–13 Second edition 2010–06–15 Biological evaluation of medical devices—Part 13: Identification and quantification of degradation products from polymeric medical devices.	Extent of recognition.
2–170		ISO 10993–14 First edition 2001–11–15 Biological evaluation of medical devices—Part 14: Identification and quantification of degradation products from ceramics.	Extent of recognition.
2–171		ISO 10993–16 Second edition 2010–02–15 Biological evaluation of medical devices—Part 16: Toxicokinetic study design for degradation products and leachables.	Extent of recognition.
2–172		ANSI/AAMI/ISO TIR 10993–19:2006 Biological evaluation of medical devices—Part 19: Physicochemical, morphological, and topographical characterization of materials.	Extent of recognition.
2–173		ANSI/AAMI/ISO 10993–10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.	Extent of recognition.
2–174		ISO 10993–10:2010 Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization.	Extent of recognition.
2–175		ISO 10993–3 Second edition 2003–10–15 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
2–176		ISO 10993–11 Second edition 2006–08–15 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity.	Extent of recognition.
2–177		ISO 10993–06 Second edition 2007–04–15 Biological evaluation of medical devices—Part 6: Tests for local effects after implantation.	Extent of recognition.
2–179		ISO 10993–1 Fourth edition 2009–10–15 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process.	Extent of recognition.
2–181		ANSI/AAMI/ISO 14155:2011, Clinical investigation of medical devices for human subjects—Good clinical practice.	Extent of recognition.
2–189		ASTM F895–11, Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity.	Extent of recognition.
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.	Extent of recognition.
2–191		ISO 10993–12 Fourth edition 2012–07–01, Biological evaluation of medical devices—Part 12: Sample preparation and reference materials.	Extent of recognition.
		C. Cardiovascular	
3–41		ANSI/AAMI EC11:1991/(R)2007 Diagnostic electrocardiographic devices.	Withdrawn. See 3–106.
3–52		ANSI/AAMIEC12:2000/(R)2010 Disposable ECG electrodes	Extent of recognition.
3–54		ANSI/AAMI/ISO 7198:1998/2001/(R)2010 Cardiovascular implants—Tubular vascular prostheses.	Extent of recognition.
3–58		ANSI/AAMI/ISO 5840:2005/(R)2010 Cardiovascular implants—Cardiac valve prostheses.	Extent of recognition.
3–63		ISO 11318 Second edition 2002–08–01 Cardiac Defibrillators—Connector assembly DF–1 for implantable defibrillators—Dimensions and test requirements.	Extent of recognition.
3–72		ANSI/AAMI EC53:1995/(R) 2008 ECG cables and leadwires	Extent of recognition.
3–73	3–118	ANSI/AAMI EC57:2012 Testing and reporting performance results of cardiac rhythm and ST-segment measurement algorithms.	Withdrawn and replaced with newer version.
3–75		ANSI/AAMI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003, Manual, electronic or automated sphygmomanometers.	Withdrawn. See 3–80, 3–122 and 3–123.
3–76		ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Extent of recognition.
3–78		ANSI/AAMI/IEC 80601–2–30:2009 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.	Extent of recognition.
3–80		ANSI/AAMI/ISO 81060–1:2007/(R) 2013 Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type.	Reaffirmation.
3–83		ANSI/AAMI/ISO 14708–5:2010 Implants for surgery—Active implantable medical devices—Part 5: Circulatory support devices.	Extent of recognition.
3–85	3–120	ANSI/AAMI/ISO 25539–2:2012 Cardiovascular implants—Endovascular devices—Part 2: Vascular stents.	Withdrawn and replaced with newer version.
3–88		ASTM F2514–08 Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial.	Extent of recognition.
3–90		ISO 7198 First edition 1998–08–01 Cardiovascular implants—Tubular vascular prostheses.	Extent of recognition.
3–93		ISO 25539–1:2003 First edition 2001–11–13 AMENDMENT 1 2005–07–15 Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses Amendment 1: Test methods.	Withdrawn. See 3–121.
3–97	3–122	ISO 81060–2 Second edition 2013–05–01 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	Withdrawn and replace with newer version.
3–98		ISO 81060–2:2009 TECHNICAL CORRIGENDUM Published 2011–02–15 Non-invasive sphygmomanometers—Part 2: Clinical validation of automated measurement type.	Withdrawn. See 3–122.
3–100		ANSI/AAMI/IEC 60601–2–27:2011 Medical electrical equipment—Part 2–27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.	Withdrawn. See 3–101.
3–107	3–123	IEC 80601–2–30 Edition 1.1 2013–07 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	Withdrawn and replaced with newer version.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
3–108		IEC 80601–2–30 (First edition 2009) Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers CORRIGENDUM 1.	Withdrawn. See 3–123.
3–113	3–124	ISO 7199 Second edition 2009–04–15 Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators) [Including: AMENDMENT 1 (2012)].	Withdrawn and replaced with newer version including amendment.
3–114	3–119	ISO 5841–3 Third edition 2013–40–15 Implants for surgery—Cardiac pacemakers—Part 3: Low-profile connectors (IS–1) for implantable pacemakers.	Withdrawn and replace with newer version.
		D. Dental/ENT	
4–50		ADA Specification No.18:1992 Alginate Impression Materials	Extent of recognition.
4–62		ISO 1563 Second edition 1990–09–01 Dental alginate impression material.	Withdrawn.
4–63		ISO 1564 Second edition 1995–11–01 Dental aqueous impression materials based on agar.	Withdrawn.
4–86		ANSI/ADA Specification No. 38 2000 (Reaffirmed 2010), Metal-Ceramic Dental Restorative Systems.	Extent of recognition.
4–89		ANSI/ADA Specification No. 53: 1999 (Reaffirmed 2008) Polymer-Based Crowns and Bridge Materials.	Extent of recognition.
4–91		ANSI/ADA Specification No. 80/ISO 7491:2000 (Reaffirmed 2013) Dental Materials—Determination of Color Stability.	Reaffirmation and extent of recognition.
4–92		ANSI/ADA Specification No. 88:2000 (Reaffirmed 2010) Dental Brazing Alloys.	Reaffirmation and extent of recognition.
4–96		ANSI/ADA Specification No. 30:2000 (Reaffirmed 2012) Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements.	Reaffirmation and extent of recognition.
4–97		ANSI/ADA Specification No. 57: (Reaffirmed 2012) Endodontic Sealing Materials.	Extent of recognition.
4–105		ANSI/ADA Specification No. 75:1997 (Reapproved 2003) Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials.	Extent of recognition.
4–109		ISO 13716 First edition 1999–05–01 Dentistry—reversible-irreversible hydrocolloid impression material system.	Withdrawn.
4–126		ISO 10477 Second edition 2004–10–01 Dentistry—Polymer-based crown and bridge materials.	Extent of recognition.
4–130		ADA Specification No. 17:1983 (Reaffirmed 2006) Denture Base Temporary Relining Resins.	Extent of recognition.
4–134	4–207	ISO 7494–1 Second edition 2011–08–15 Dentistry—Dental units—Part 1: General requirements and test methods.	Withdrawn and replaced with newer version.
4–135	4–213	ISO 10139–1 Second edition 2005–02–15 Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use [Including: TECHNICAL CORRIGENDUM 1 (2006)].	Withdrawn and replaced with newer version including technical corrigendum.
4–137		ISO 6877 Second edition 2006–04–01 Dentistry—Root-canal obturating points.	Extent of recognition.
4–139		ANSI/ADA Specification No. 48 (Reaffirmed 2009) Visible Light Curing Units.	Reaffirmation and extent of recognition.
4–143	4–208	ANSI/ADA Specification No. 96:2012 Dental-Water-Based Cements	Withdrawn and replaced with newer version.
4–144	4–209	ISO 24234 First edition 2004–10–15 Dentistry—Mercury and alloys for dental amalgam [Including: AMENDMENT 1 (2011)].	Withdrawn and replaced with newer version including amendment.
4–146		ISO 22674 First edition 2006–11–15 Dentistry—Metallic materials for fixed and removable restorations and appliances.	Extent of recognition.
4–149		ANSI/ADA Specification No. 39/ISO 6874:2005 (Reaffirmed 2011) Pit and Fissure Sealants.	Reaffirmation and extent of recognition.
4–150		ANSI/ADA Specification No. 19:2004/ISO 4823:2000 Dental—Elastometric Impression Materials.	Extent of recognition.
4–151		ISO 22112 First edition 2005–11–01 Dentistry—Artificial teeth for dental prostheses.	Extent of recognition.
4–153		ISO 9917–1 Second edition 2007–10–01 Dentistry—Water-based cements—Part 1: Powder/liquid acid-base cements.	Extent of recognition.
4–154	4–210	ISO 4823 Third edition 2000–12–15 Dentistry—Elastometric impression materials [Including: AMENDMENT 1 (2000) TECHNICAL CORRIGENDUM 1(2004)].	Withdrawn and replaced with newer version including amendment and technical corrigendum.
4–155		ISO 4823: Technical Corrigendum 1 Published 2004–07–15—Dentistry—Elastometric impression materials—Third Edition.	Withdrawn. See 4–210.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
4–156		ISO 4823 Third edition 2000–12–15 Amendment 1 2007–07–01 Dentistry—Elastometric impression materials—Third Edition.	Withdrawn. See 4–210.
4–157		ISO 3107 Third edition 2004–10–01 Dentistry—Zinc oxide/Eugenol and zinc oxide/non-eugenol cements—Third edition.	Withdrawn. See 4–198.
4–159	4–211	ANSI/IEEE C63.19:2007 American National Standard Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids.	Withdrawn and replaced with newer version.
4–170	4–212	ANSI/ASA S3.36–2012 American National Standard Specification for a Manikin for Simulated in situ Airborne Acoustic Measurements.	Withdrawn and replaced with newer version.
4–178		ISO 6872 Third edition 2008–09–01 Dentistry—Ceramic materials ..	Extent of recognition.
4–179		ISO 7405 Second edition 2008–12–15 Dentistry—Evaluation of biocompatibility of medical devices used in dentistry.	Extent of recognition.
4–180		ISO 9168 Third edition 2009–07–15 Dentistry—Hose connectors for air driven dental handpieces.	Extent of recognition.
4–181		ISO 4049 Fourth edition 2009–10–01 Dentistry—Polymer-based restorative materials.	Extent of recognition.
4–182		ISO 10139–2 Second edition 2009–08–01 Dentistry—Soft lining materials for removable dentures—Part 2: Materials for long-term use.	Extent of recognition.
4–188		ISO 9917–2 Second edition 2010–04–15 Dentistry—Water-based cements—Part 2: Resin-modified cements.	Extent of recognition.
4–189		ISO 10139–1:2005 TECHNICAL CORRIGENDUM 1 2006–03–01 Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use.	Withdrawn. See 4–213.
4–195		ISO 14801 Second edition 2007–11–15 Dentistry—Implants-Dynamic fatigue test for endosseous dental implants.	Extent of recognition.
4–196		ANSI/ADA Specification No.69:2010/ISO 6872:2008 Dental Ceramic.	Extent of recognition.
4–198		ISO 3107 Fourth edition 2011–03–01 Dentistry—Zinc oxide/eugenol and zinc oxide/non-eugenol cements.	Extent of recognition.
4–199		ISO 6876 Third edition 2012–06–01 Dentistry—Root Canal Sealing Materials.	Extent of recognition.
4–200		ISO 24234 First edition 2004–10–15 Dentistry—Mercury and alloys for dental amalgam AMENDMENT 1.	Withdrawn. See 4–209.
4–201		ISO 9693–2012 Dentistry—Compatibility testing—Metal-ceramic systems.	Extent of recognition.
4–205		ISO 14457 First edition 2012–09–15 Dentistry—Handpieces and motors.	Withdrawn. See 4–206.
		E. General	
5–22		ISO 2768–1 First edition 1989–11–15 General tolerances—Part 1: Tolerances for linear and angular dimensions without individual tolerance indications.	Extent of recognition.
5–23		ISO 2768–2 First edition 1989–11–15 General Tolerances—Part 2: Geometrical tolerances for features without individual tolerance indications.	Extent of recognition.
5–36		ISO/TR 16142 Second edition 2006–01–15 Medical devices—Guidance on the selection of standards in support of recognized essential principles of safety and performance of medical devices.	Extent of recognition.
5–37	5–81	ISO 2859–1 Second edition 1999–11–15 Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection [Including: TECHNICAL CORRIGENDUM 1 (2001)].	Withdrawn and replaced with newer version including technical corrigendum.
5–43		ANSI/ESD S20.20–2007 For the Development of an Electrostatic Discharge Control Program for Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices).	Extent of recognition.
5–45	5–79	ASTM D7386–12 Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems.	Withdrawn and replaced with new version.
5–46		ISO 2859–1:1999/Cor 1:2001 Sampling procedures for inspection by attributes—Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.	Withdrawn. See 5–81.
5–47		ISO 10012 First edition 2003–01–15 Measurement management systems—Requirements for measurement processes and measuring equipment.	Extent of recognition.
5–50		IEC 62366 Edition 1.0 2007–10 Medical devices—Application of usability engineering to medical devices.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
5–51	5–80	ASTM D–4332–13 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing.	Withdrawn and replaced with new version.
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.	Relevant guidance.
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 relevant guidance.
5–57		ANSI/AAMI HE75:2009 Human factors engineering—Design of medical devices.	Extent of recognition.
5–58	5–82	IEC 60601–1–11 Edition 1.0:2010 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)].	Withdrawn and replaced with newer version including technical corrigendum.
5–62		ANSI/ASQ Z1.4–2008 Sampling Procedures and Tables for Inspection by Attributes.	Extent of recognition.
5–66		IEC 60601–1–10 Edition 1.0: 2007–11 Medical electrical equipment—Part 1–10: General requirements for basic safety and essential performance—Collateral Standard: Requirements for the development of physiologic closed-loop controllers.	Extent of recognition.
5–67		ANSI/AAMI/IEC 62366:2007/(R)2013 Medical devices—Application of usability engineering to medical devices.	Reaffirmation and extent of recognition.
5–69		IEC 60601–1–11 (First edition 2010) April 2011 Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment CORRIGENDUM 1.	Withdrawn. See 5–82.
		F. General Hospital/General Plastic Surgery	
6–13		ISO 595–1 First edition 1986–12–15 Reusable all-glass or metal-and-glass syringes for medical use—Part 1: Dimensions.	Withdrawn.
6–14		ISO 595–2 First edition 1987–12–15 Reusable all-glass or metal-and-glass syringes for medical use—Part 2: Design, performance requirements and tests.	Withdrawn.
6–117		ASTM F2172–02 (Reapproved 2011) Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers.	Extent of recognition.
6–142		ANSI/AAMI II36:2004 Medical electrical equipment—Part 2: Particular requirements for safety of baby incubators.	Withdrawn. See 6–230.
6–143		ANSI/AAMI II51:2004 Medical electrical equipment—Part 2: Particular requirements for safety of transport incubators.	Withdrawn. See 6–231.
6–150		ASTM D7161–05 (Reapproved 2010) Standard Practice for Determination of Real Time Expiration Dating of Mature Medical Gloves Stored Under Typical Warehouse Conditions.	Withdrawn.
6–161	6–301	ISO 10555–1 Second edition 2013–06–15 Corrected version 2013–07–01 Intravascular catheters—Sterile and single-use catheters—Part 1: General requirements.	Withdrawn and replaced with newer version.
6–163		ISO 9626 First edition 1991–09–01 AMENDMENT 1 2001–06–01 Stainless steel needle tubing for the manufacture of medical devices.	Withdrawn. See 6–302.
6–164	6–303	ISO 10555–5 Second edition 2013–06–15 Intravascular catheters—Sterile and single-use catheters—Part 5: Over-needle peripheral catheters.	Withdrawn and replaced with newer version.
6–170	6–304	ISO 7886–1 First edition 1993–10–01 Sterile hypodermic syringes for single use—Part 1: Syringes for manual use [Including: TECHNICAL CORRIGENDUM 1 Published 1995–11–01].	Withdrawn and replaced with newer version including technical corrigendum.
6–171	6–305	ISO 10555–3 Second edition 2013–06–15 Intravascular catheters—Sterile and single-use catheters—Part 3: Central venous catheters.	Withdrawn and replaced with newer version.
6–176		ASTM D7103–06 (Reapproved 2013) Standard Guide for Assessment of Medical Gloves.	Extent of recognition.
6–187	6–306	ASTM F1671/F1671M–13 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.	Withdrawn and replaced with newer version.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
6–233		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.	Withdrawn. See 6–321.
6–236	6–307	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 [Including: CORRIGENDUM 1 (April 2009)].	Withdrawn and replaced with newer version including technical corrigendum.
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 CORRIGENDUM 1.	Withdrawn. See 6–307.
6–238	6–308	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: CORRIGENDUM 1 (March 2012)].	Withdrawn and replaced with newer version including technical corrigendum.
6–245		ISO 8536–4 Fifth edition 2010–10–01 Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed.	Withdrawn. See 6–318.
6–253		ISO 10535 Second edition 2006–12–15 Hoists for the transfer of disabled persons—Requirements and test methods.	Extent of recognition.
6–264		ISO 10555–1 First edition 1995–06–15 AMENDMENT 1 1999–07–15 Sterile, single-use intravascular catheters—Part 1: General requirements.	Withdrawn. See 6–301.
6–265		ISO 10555–1 First edition 1995–06–5 AMENDMENT 2 2004–05–15 Sterile, single-use intravascular catheters—Part 1: General requirements.	Withdrawn. See 6–301.
6–266		ISO 10555–5 First edition 1996–06–15 AMENDMENT 1 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters.	Withdrawn. See 6–303.
6–267		ISO 10555–5 1996 TECHNICAL CORRIGENDUM 1 Published 2002–06–15 Sterile, single-use intravascular catheters—Part 5: Over-needle peripheral catheters.	Withdrawn. See 6–303.
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.	Extent of recognition.
6–279		IEC 60601–2–19 (Second Edition 2009) Medical electrical equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators CORRIGENDUM 1.	Withdrawn. See 6–319.
6–280		IEC 60601–2–20 (Second edition 2009) Medical electrical equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators CORRIGENDUM 1.	Withdrawn. See 6–320.
6–281		IEC 80601–2–35 (Second edition 2009) 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.	Withdrawn. See 6–308.
6–283	6–309	USP 36–NF31:2013 Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–284	6–310	USP 36–NF31:2013 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–285	6–311	USP 36–NF31:2013 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–286	3–312	USP 36–NF31:2013 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–287	6–313	USP 36–NF31:2013 <861> Sutures—Diameter	Withdrawn and replaced with newer version.
6–288	6–314	USP 36–NF 31:2013 <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–289	6–315	USP 36–NF31:2013 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–290	6–316	USP 36–NF31:2013 Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
6–291	6–317	USP 36–NF31:2013 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
6–292		ISO 7886–1:1993 TECHNICAL CORRIGENDUM 1 Published 1995–11–01 Sterile hypodermic syringes for single-use—Part 1: Syringes for manual use.	Withdrawn. See 6–304.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
6–298	6–319	IEC 60601–2–19 Edition 2.0 2009–02 Medical electrical equipment—Part 2–19: Particular requirements for the basic safety and essential performance of infant incubators [Including: CORRIGENDUM 1 (2012)].	Withdrawn and replaced with newer version including technical corrigendum.
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 transport incubators.	Withdrawn. See 6–320.
		G. In Vitro Diagnostics	
7–100		ISO 15197 First edition 2003–05–01 In Vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.	Withdrawn.
7–137	7–244	CLSI NBS01–A6 Blood Collection on Filter Paper for Newborn Screening Programs; Approved Standard—Sixth Edition.	Withdrawn and replaced with newer version.
7–239		CLSI EP32–R (Formerly X05–R) Metrological Traceability and Its Implementation; A Report.	Designation number.
7–226		CLSI QMS01–A4 (Formerly GP26–A4) Quality Management System: A Model for Laboratory Services; Approved Guideline—Fourth Edition.	Designation number.
7–224		CLSI EP28–A3c (Formerly C28–A3c) Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline—Third Edition.	Designation number.
7–223		CLSI QSM06–A3 (Formerly GP22–A3) Quality Management System: Continual Improvement; Approved Guideline—Third Edition.	Designation number.
7–92	7–245	CLSI EP09–A3 Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Third Edition.	Withdrawn and replaced with newer version.
7–210		CLSI H26–A2 Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard—Second Edition.	Extent of recognition.
7–152		CLSI EP12–A2 User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition.	Extent of recognition.
7–174		CLSI EP21–A Estimation of Total Analytical Error for Clinical Laboratory Methods; Approved Guideline.	Extent of recognition.
7–178		CLSI M22–A3 Quality Control for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition.	Extent of recognition.
7–193		CLSI EP06–A Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.	Extent of recognition.
7–220		CLSI H59–A Quantitative D-dimer for the Exclusion of Venous Thromboembolic Disease; Approved Guideline.	Extent of recognition.
		H. Materials	
8–67	8–344	ISO 7153–1 Second edition 1991–04–01 Surgical instruments—Metallic materials—Part 1: Stainless steel [Including: AMENDMENT 1(1999)].	Withdrawn and replaced with newer version including amendment.
8–138		ASTM F745–07 Standard Specification for 18 Chromium-12.5 Nickel-2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications.	Withdrawn.
8–139	8–345	ASTM F1314–13 Standard Specification for Wrought Nitrogen Strengthened 22 Chromium-13 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910).	Withdrawn and replaced with newer version.
8–140	8–346	ASTM F1813–13 Standard Specification for Wrought Titanium-12 Molybdenum-6 Zirconium-2 Iron Alloy for Surgical Implant (UNS R58120).	Withdrawn and replaced with newer version.
8–141	8–347	ASTM F2146–13 Standard Specification for Wrought Titanium-3 Aluminum-2.5 Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320).	Withdrawn and replaced with newer version.
8–169	8–348	ASTM F138–13 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybendum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673).	Withdrawn and replaced with newer version.
8–176	8–349	ASTM F2503–13 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.
8–149	8–350	ISO 5832–1 Fourth edition 2007–06–15 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel [Including: TECHNICAL CORRIGENDUM 1(2008)].	Withdrawn and replaced with newer version including technical corrigendum.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–196		ISO 5832–1: 2007 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel TECHNICAL CORRIGENDUM 1.	Withdrawn. See 8–350.
8–151	8–351	ISO 5832–12 Second edition 2007–05–01 Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy [Including: TECHNICAL CORRIGENDUM 1 2008].	Withdrawn and replaced with newer version including technical corrigendum.
8–197		ISO 5832–12:2007 TECHNICAL CORRIGENDUM 1 2008–09–05, Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy TECHNICAL CORRIGENDUM 1.	Withdrawn. See 8–351.
8–211	8–352	ISO 5834–1 Third edition 2005–06–01 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form [Including: TECHNICAL CORRIGENDUM 1 2007].	Withdrawn and replaced with newer version including technical corrigendum.
8–212		ISO 5834–1:2005 Technical Corrigendum 1 Published 2007–05–01 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form TECHNICAL CORRIGENDUM 1.	Withdrawn. See 8–352.
8–228	8–353	ASTM F86–13 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	Withdrawn and replaced with newer version.
8–175	8–354	ASTM F1377–13 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075).	Withdrawn and replaced with newer version.
8–163	8–355	ASTM F1586/F 1586M–13$^{\varepsilon 1}$ Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar for Surgical Implants (UNS S31675).	Withdrawn and replaced with newer version.
8–129	8–356	ASTM F67–13 Standard Specification for Unalloyed Titanium, for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700).	Withdrawn and replaced with newer version.
8–208	8–357	ASTM F648–13 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.	Withdrawn and replaced with newer version.
8–103		ASTM F1801–97 (Reapproved 2009)$^{\varepsilon 1}$ Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials.	Extent of recognition.
8–107		ASTM F746–04 (Reapproved 2009)$^{\varepsilon 1}$ Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.	Extent of recognition.
8–111		ASTM F1160–05 (Reapproved 2011)$^{\varepsilon 1}$ Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings.	Extent of recognition.
8–112		ASTM F1044–05 (Reapproved 2011)$^{\varepsilon 1}$ Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings.	Extent of recognition.
8–113		ASTM F1147–05 (Reapproved 2011) Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings.	Extent of recognition.
8–114		ASTM F2255 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading.	Extent of recognition.
8–115		ASTM F2256–05 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading.	Extent of recognition.
8–116		ASTM F2258–05 (Reapproved 2010) Standard Test Method for Strength Properties of Tissue Adhesives in Tension.	Extent of recognition.
8–121		ASTM F2005–05 (Reapproved 2010) Standard Terminology for Nickel-Titanium Shape Memory Alloys.	Extent of recognition.
8–123		ISO 5832–5 Third edition 2005–10–15 Implants for surgery—Metallic materials—Part 5: Wrought cobalt-chromium-tungsten-nickel alloy.	Extent of recognition.
8–124		ASTM F2052–06$^{\varepsilon}$ Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	Extent of recognition.
8–125		ASTM F2004–05 (Reapproved 2010) Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis.	Extent of recognition.
8–126	8–370	ASTM F561–13 Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids.	Withdrawn and replaced with newer version.
8–128		ASTM F2213–06 (Reapproved 2011) Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment.	Extent of recognition.
8–132		ASTM F1088–04a (Reapproved 2010) Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–134		ASTM F2082–06 Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery.	Extent of recognition.
8–135		ASTM F2392–04 (Reapproved 2010) Standard Test Method for Burst Strength of Surgical Sealants.	Extent of recognition.
8–136		ASTM F2458–05 (Reapproved 2010) Standard Test Method for Wound Closure Strength of Tissue Adhesives and Sealants.	Extent of recognition.
8–150		ISO 5832–9 Second edition 2007–06–15 Implants for surgery—Metallic materials—Part 9: Wrought high nitrogen stainless steel.	Extent of recognition.
8–157		ISO 9583 First edition 1993–10–15 Implants for surgery—Non-destructive testing—Liquid penetrant inspection of metallic surgical implants.	Extent of recognition.
8–159		ISO 9584 First edition 1993–10–15 Implants for surgery—Non-destructive testing—Radiographic examination of cast metallic surgical implants.	Extent of recognition.
8–165		ASTM F1058–08$^{\varepsilon 1}$ Standard Specification for Wrought 40 Cobalt-20 Chromium-16 Iron-15 Nickel-7 Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008).	Extent of recognition.
8–167		ASTM F1350–08 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).	Extent of recognition.
8–168		ASTM F1472–08$^{\varepsilon 1}$ Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium Alloy for Surgical Implant Applications (UNS R56400).	Extent of recognition.
8–170		ASTM F961–08 Standard Specification for 35 Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035).	Extent of recognition.
8–171		ASTM F1609–08 Standard Specification for Calcium Phosphate Coatings for Implantable Materials.	Extent of recognition.
8–173		ASTM F601–03 (Reapproved 2008) Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants.	Extent of recognition.
8–177		ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Extent of recognition.
8–179		ASTM F754–08 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Sheet, Tube, and Rod Shapes Fabricated from Granular Molding Powders.	Extent of recognition.
8–183		ASTM F560–08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400).	Extent of recognition.
8–184		ASTM F2516–07$^{\varepsilon 2}$ Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials.	Extent of recognition.
8–185		ASTM F451–08 Standard Specification for Acrylic Bone Cement	Extent of recognition.
8–187		ISO 13779–1 Second edition 2008–10–01 Implants for surgery—Hydroxyapatite—Part 1: Ceramic hydroxyapatite.	Extent of recognition.
8–188		ISO 13779–2 Second edition 2008–10–01 Implants for surgery—Hydroxyapatite—Part 2: Coatings of hydroxyapatite.	Extent of recognition.
8–189		ASTM F 1108–04 (Reapproved 2009) Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406).	Extent of recognition.
8–190		ASTM F 90–09 Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Applications (UNS R30605).	Extent of recognition.
8–192		ASTM F1854–09 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants.	Extent of recognition.
8–193		ASTM F2754/F 2754M–09 Standard Test Method for Measurement of Camber, Cast, Helix and Direction of Helix of Coiled Wire.	Extent of recognition.
8–194		ISO 6474–1 First edition 2010–02–15 Implants for surgery—Ceramic materials—Part 1: Ceramic materials based on high purity alumina.	Extent of recognition.
8–195		ASTM F2024–10 Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings.	Extent of recognition.
8–199		ASTM F2633–07 Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants.	Extent of recognition.
8–204		ASTM F2118–10 Standard Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials.	Extent of recognition.
8–205		ASTM F1635–11 Standard Test Method for In Vitro Degradation Testing of Hydrolytically Degradable Polymer Resins and Fabricated Forms for Surgical Implants.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–206		ASTM F688–10 Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Extent of recognition.
8–207		ASTM F1926/F1926M–10 Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Granules, Fabricated Forms, and Coatings.	Extent of recognition.
8–213		ISO 5834–3 First edition 2005–07–15 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 3: Accelerated ageing methods.	Extent of recognition.
8–214		ISO 5834–4 First edition 2005–05–01 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 4: Oxidation index measurement method.	Extent of recognition.
8–215		ISO 5834–5 First edition 2005–06–01 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 5: Morphology assessment method.	Extent of recognition.
8–216		ASTM F1295–11 Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications (UNS R56700).	Extent of recognition.
8–217		ASTM F620–11 Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants.	Extent of recognition.
8–218		ASTM F799–11 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539).	Extent of recognition.
8–220		ASTM F629–11 Standard Practice for Radiography of Cast Metallic Surgical Implants.	Extent of recognition.
8–221		ASTM F2066–11 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150).	Extent of recognition.
8–224		ASTM F2102–06$^{\varepsilon 1}$ Standard Guide for Evaluating the Extent of Oxidation in Ultra-High-Molecular-Weight Polyethylene Fabricated Forms Intended for Surgical Implants.	Extent of recognition.
8–225		ASTM F2003–02 (Reapproved 2008) Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	Extent of recognition.
8–226		ASTM F603–12 Standard Specification for High-Purity Dense Aluminum Oxide for Medical Application.	Extent of recognition.
8–229		ASTM F75–12 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Extent of recognition.
8–330		ASTM F1978–12 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser.	Extent of recognition.
8–331		ASTM F1580–12 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Extent of recognition.
8–333		ASTM F2393–12 Standard Specification for High-Purity Dense Magnesia Partially Stabilized Zirconia (Mg-PSZ) for Surgical Implant Applications.	Extent of recognition.
8–334		ASTM F2459–12 Standard Test Method for Extracting Residue from Metallic Medical Components and Quantifying via Gravimetric Analysis.	Extent of recognition.
		I. Nanotechnology	
18–1		ASTM E2490–09 Standard Guide for Measurement of Particle Size Distribution of Nanomaterials in Suspension by Photon Correlation Spectroscopy (PCS).	Extent of recognition.
18–2		ASTM E2535–07 (Reapproved 2013) Standard Guide for Handling Unbound Engineered Nanoscale Particles in Occupational Settings.	Reaffirmation and extent of recognition.
		J. Neurology	
17–3	17–12	ISO 7197 Third edition 2006–06–01 Neurosurgical Implants—Sterile, single-use hydrocephalus shunts and components [Including TECHNICAL CORRIGENDUM 1 (2007)].	Withdrawn and replaced with newer version including technical corrigendum.
17–7		ISO 7197: 2006 Neurosurgical implants—Sterile, single-use hydrocephalus shunts and components TECHNICAL CORRIGENDUM 1.	Withdrawn. See 17–12.
17–1		ANSI/AAMI NS28:1988/(R) 2010 Intracranial pressure monitoring devices.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
17–4		ASTM F647–94 (Reapproved 2006) Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	Extent of recognition.
17–9		ASTM F2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Extent of recognition.
		K. OB–GYN/Gastroenterology/Urology	
9–34	9–82	ISO 4074 First edition 2002–02–15 Corrected version 2002–12–01 Natural latex rubber condoms—Requirements and test methods [Including TECHNICAL CORRIGENDUM 1 (2002), TECHNICAL CORRIGENDUM 2 (2002)].	Withdrawn and replaced with newer version including technical corrigendum.
9–57		ISO 4074:2002 TECHNICAL CORRIGENDUM 2, Natural latex rubber condoms—Requirements and test methods TECHNICAL CORRIGENDUM 2.	Withdrawn. See 9–82.
9–75	9–84	ISO 8600–3 First edition 1997–07–01 Optics and Optical instruments—Medical endoscopes and endoscopic accessories—Part 3: Determination of field of view and direction of view of endoscopes with optics [Including AMENDMENT 1 (2003)].	Withdrawn and replaced with newer version including amendment.
9–36	9–90	ISO 8009 First edition 2004–10–01 Mechanical contraceptives—Reusable natural and silicone rubber contraceptive diaphragms—Requirements and tests [Including AMENDMENT 1(2012)].	Withdrawn and replaced with newer version including amendment.
9–37	9–83	ISO 8600–1 Third edition 2013–03–01 Endoscopes—Medical endoscopes and endotherapy devices—Part 1: General requirements.	Withdrawn and replaced with newer version.
9–38		ISO 8600–3 First edition 1997–07–01 AMENDMENT 1, Optics and optical instruments—Medical endoscopes and endoscopic accessories Part 3: Determination of field of view and direction of view of endoscopes with optics.	Withdrawn. See 9–84.
9–44		ASTM F623–99 (Reapproved 2006) Standard Performance Specification for Foley Catheter.	Extent of recognition.
9–54	9–85	ASTM D6976–13 Standard Specification for Rubber Contraceptives—Vaginal Diaphragms.	Withdrawn and replaced with a newer version.
9–56		ASTM D3492–08 Standard Specification for Rubber Contraceptives (Male Condoms).	Extent of recognition.
9–65	9–91	ANSI/AAMI/ISO 8637:2010 Cardiovascular implants and extracorporeal systems—Hemodialyzers, hemodiafilters, hemofilters, and hemoconcentrators [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
9–66		ANSI/AAMI/ISO 8638:2010 Cardiovascular implants and Extracorporeal blood circuit for hemodialyzers, hemodiafilters, and hemofilters.	Extent of recognition.
9–67		ASTM D7661–10 Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms.	Extent of recognition.
9–68		ISO 23409 First edition 2011–02–15 Male Condoms—Requirements and test methods for condoms made from synthetic materials.	Extent of recognition.
9–73		ANSI/AAMI/ISO 13958:2009 Concentrates for hemodialysis and related therapies.	Extent of recognition.
9–74		ISO 13958 Second edition 2009–04–15 Concentrates for haemodialysis and related therapies.	Extent of recognition.
9–79		ISO 26722 First edition 2009–04–15 Water treatment equipment for haemodialysis applications and related therapies.	Extent of recognition.
		L. Ophthalmic	
10–41	10–81	ISO 11979–7 Second edition 2006–05–01 Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations [Including Amendment 1:2012].	Withdrawn and replaced with newer version including amendment.
10–75		ISO 11979–7/Amendment 1:2012 Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations.	Withdrawn. See 10–81.
10–42	10–82	ISO 11979–2 First edition 1999–12–15 Ophthalmic implants—Intraocular lenses—Part 2: Optical properties and test methods [Including TECHNICAL CORRIGENDUM 1 (2003)].	Withdrawn and replaced with newer version including technical corrigendum.
10–53	10–83	ISO 18369–1 First edition 2006–08–15 Ophthalmic optics—Contact lenses—Part 1: Vocabulary, classification system and recommendations for labeling specifications [Including AMENDMENT 1 2009].	Withdrawn and replaced with newer version including amendment.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
10–61		ISO 18369–1:2006 Ophthalmic optics—Contact lenses Part 1: Vocabulary, classification system and recommendations for labeling specifications. ISO 18369–1 First edition 2006–08–05 AMENDMENT 1 2009–02–15.	Withdrawn. See 10–83.
10–58	10–84	ANSI Z80.11–2012 American National Standard for Ophthalmics—Laser Systems for Corneal Reshaping.	Withdrawn and replaced with newer version.
10–59	10–85	ISO 11980 Third edition 2012–11–15 Corrected version 2013–12–01 Ophthalmic optics—Contact lenses and contact lens care products—Guidance for clinical investigations.	Withdrawn and replaced with newer version.
10–71	10–86	ISO 14729 First edition 2001–04–15 Ophthalmic optics—Contact lens care products—Microbiological requirements and test methods for products and regimens for hygienic management of contact lenses [Including: AMENDMENT 1 2010].	Withdrawn and replaced with newer version including amendment.
10–43		ISO 11979–8 Second edition 2006–07–01 Ophthalmic implants—Intraocular lenses—Part 8: Fundamental requirements.	Extent of recognition.
10–54		ISO 18369–4 First edition 2006–08–15 Ophthalmic optics—contact lenses—Part 4: Physicochemical properties of contact lens materials.	Extent of recognition.
10–55		ISO 11979–6 Second edition 2007–07–15 Ophthalmic implants—Intraocular lenses—Part 6: Shelf-life and transport stability.	Extent of recognition.
10–56		ANSI Z80.12–2007 (R2012) American National Standard for Ophthalmics—Multifocal Intraocular Lenses.	Reaffirmation and extent of recognition.
10–57		ANSI Z80.13–2007 (R2012) American National Standard for Ophthalmics—Phakic Intraocular Lenses.	Reaffirmation and extent of recognition.
10–60		ISO 11981 Second edition 2009–07–01 Ophthalmic optics—Contact lenses and contact lens care products—Determination of physical compatibility of contact lens care products with contact lenses.	Extent of recognition.
10–62		ANSI Z80.10–2009 Ophthalmic Instruments—Tonometers	Extent of recognition.
10–64	10–89	ANSI Z80.7–2013 Ophthalmics—Intraocular Lenses	Withdrawn and replaced with newer version.
10–68		ISO 13212 Second edition 2011–05–15 Ophthalmic optics—Contact lens care products—Guidelines for determination of shelf-life.	Extent of recognition.
10–69		ANSI Z80.18–2010 American National Standard for Ophthalmics—Contact Lens Care Products—Vocabulary, Performance Specifications and Test Methodology.	Extent of recognition.
10–74		ISO 10940 Second edition 2009–08–01 Ophthalmic instruments—Fundus Cameras.	Extent of recognition.
		M. Orthopedic	
11–190	11–256	ISO 14243–3 First edition 2004–09–15 Implants for surgery—Wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test [Including: TECHNICAL CORRIGENDUM 1(2006)].	Withdrawn and replaced with newer version including technical corrigendum.
11–218		ISO 14243–3:2004 TECHNICAL CORRIGENDUM 1 Implants for surgery—Wear of total knee-joint prostheses—Part 3: Loading and displacement parameters for wear-testing machines with displacement control and corresponding environmental conditions for test.	Withdrawn. See 11–256.
11–210	11–257	ASTM F543–13 Standard Specification and Test Methods for Metallic Medical Bone Screws.	Withdrawn and replaced with a newer version.
11–212		ASTM F1440–92 (Reapproved 2008) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion.	Withdrawn.
11–241		ASTM F543–07 Standard Specification and Test Methods for Metallic Medical Bone Screws.	Withdrawn duplicate. See 11–257.
11–244	11–258	ASTM F2083–12 Standard Specification for Knee Replacement Prosthesis.	Withdrawn and replaced with a newer version.
11–74		ISO 5838–2 First edition 1991–01–15 Implants for surgery—Skeletal pins and wires—Part 2: Steinmann skeletal pins—Dimensions.	Extent of recognition.
11–75		ISO 5838–3 First edition 1993–09–15 Implants for surgery—Skeletal pins and wires—Part 3: Kirschner skeletal wires.	Extent of recognition.
11–80		ISO 8828 First edition 1988–10–15 Implants for surgery—Guidance on care and handling of orthopaedic implants.	Extent of recognition.
11–83		ISO 13402 First edition 1995–08–01 Surgical and dental hand instruments—Determination of resistance against autoclaving, corrosion and thermal exposure.	Extent of recognition.
11–168		ASTM F1781–03 (Reapproved 2009) Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
11–171		ASTM F1814–97a (Reapproved 2009) Standard Guide for Evaluating Modular Hip and Knee Joint Components.	Extent of recognition.
11–183		ASTM F1875–98 (Reapproved 2009) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-bore and Cone Taper Interface.	Extent of recognition.
11–184		ISO 8827 First edition 1988–10–15 Implants for surgery—Staples with parallel legs for orthopaedic use—General requirements.	Extent of recognition.
11–185		ASTM F2267–04 (Reapproved 2011) Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression.	Extent of recognition.
11–191		ISO 14879–1 First edition 2000–06–01 Implants for surgery—Total knee-joint prostheses—Part 1: Determination of endurance properties of knee tibial trays.	Extent of recognition.
11–196		ASTM F1672–95 (Reapproved 2011) Standard Specification for Resurfacing Patellar Prosthesis.	Extent of recognition.
11–197		ASTM F983–86 (Reapproved 2013) Standard Practice for Permanent Marking of Orthopaedic Implant Components.	Reaffirmation and extent of recognition.
11–199		ASTM F565–04 (Reapproved 2013) Standard Practice for Care and Handling of Orthopedic Implants and Instruments.	Reaffirmation and extent of recognition.
11–203		ASTM F1541–02 (Reapproved 2011) [1] Standard Specification and Test Methods for External Skeletal Fixation Devices.	Extent of recognition.
11–207		ASTM F2193–02 (Reapproved 2007) Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System.	Extent of recognition.
11–211		ASTM F1798–97 (Reapproved 2008) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.	Extent of recognition.
11–214		ASTM F382–99 (Reapproved 2008) [1] Standard Specification and Test Method for Metallic Bone Plates.	Extent of recognition.
11–216		ASTM F1264–03 (Reapproved 2012) Standard Specification and Test Methods for Intramedullary Fixation Devices.	Extent of recognition.
11–220		ASTM F2068–09 Standard Specification for Femoral Prostheses—Metallic Implants.	Extent of recognition.
11–222		ISO 14243–1 Second edition 2009–11–15 Implants for surgery—Wear of total knee-joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test.	Extent of recognition.
11–223		ISO 14243–2 Second edition 2009–11–15 Implants for surgery—Wear of total knee-joint prostheses—Part 2: Methods of measurement.	Extent of recognition.
11–224		ASTM F2706–08 Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model.	Extent of recognition.
11–225		ISO 7206–4 Third edition 2010–06–15 Implants for surgery—Partial and total hip-joint prostheses—Part 4: Determination of endurance properties and performance of stemmed femoral components.	Extent of recognition.
11–226		ASTM F1089–10 Standard Test Method for Corrosion of Surgical Instruments.	Extent of recognition.
11–227		ASTM F366–10 Standard Specification for Fixation Pins and Wires ..	Extent of recognition.
11–228		ASTM F564–10 Standard Specification and Test Methods for Metallic Bone Staples.	Extent of recognition
11–231		ISO 7207–2 Second edition 2011–07–01 Implants for surgery—Components for partial and total knee joint prostheses—Part 2: Articulating surfaces made of metal, ceramic and plastics materials.	Extent of recognition.
11–232		ISO 7207–1 Third edition 2007–02–01 Implants for surgery—Components for partial and total knee joint prostheses—Part 1: Classification, definitions and designation of dimensions.	Extent of recognition.
11–234		ASTM F732–00 (Reapproved 2011) Standard Test Method for Wear Testing of Polymeric Materials Used in Total Joint Prostheses.	Extent of recognition.
11–235		ASTM F2077–11 Test Methods for Intervertebral Body Fusion Devices.	Extent of recognition.
11–237		ISO 7206–6 First edition 1992–03–15 Implants for surgery—Partial and total hip joint prostheses—Part 6: Determination of endurance properties of head and neck region of stemmed femoral components.	Extent of recognition.
11–238		ASTM F2033–12 Standard Specification for Total Hip Joint Prosthesis and Hip Endoprosthesis Bearing Surfaces Made of Metallic, Ceramic, and Polymeric Materials.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
11–239		ASTM F 2345–03 (Reapproved 2013) Standard Test Methods for Determination of Static and Cyclic Fatigue Strength of Ceramic Modular Femoral Heads.	Extent of recognition. Reaffirmation.
11–240		ASTM F382–99 (Reapproved 2008) [1] Standard Specification and Test Method for Metallic Bone Plates.	Extent of recognition.
11–243		ASTM F2346–05 (Reapproved 2011) Standard Test Methods for Static and Dynamic Characterization of Spinal Artificial Discs.	Extent of recognition.
11–245		ASTM F384–12 Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices.	Extent of recognition.
11–247		ASTM F2789–10 Standard Guide for Mechanical and Functional Characterization of Nucleus Devices.	Extent of recognition.
11–248		ISO 14242–1 Second edition 2012–01–15 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.	Extent of recognition.
11–249		ISO 14242–2 First edition 2000–09–15 Implants for surgery—Wear of total hip-joint prostheses—Part 2: Methods of measurement.	Extent of recognition.
11–250		ISO 14242–3 First edition 2009–03–15 Implants for surgery—Wear of total hip-joint prostheses—Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test.	Extent of recognition.
		N. Physical Medicine	
16–25		ISO 7176–13 First edition 1989–08–01 Wheelchairs—Part 13: Determination of coefficient of friction of test surfaces.	Extent of recognition.
16–27		ISO 7176–15 First edition 1996–11–15 Wheelchairs—Part 15: Requirements for information disclosure, documentation and labeling.	Extent of recognition.
16–29		ISO 7176–6 Second edition 2001–10–01 Wheelchairs—Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs.	Extent of recognition.
16–158		ISO 7176–1 Second edition 1999–10–01 Wheelchairs—Part 1: Determination of static stability.	Extent of recognition.
16–159		ISO 7176–2 Second edition 2001–06–15 Wheelchairs—Part 2: Determination of dynamic stability of electric wheelchairs.	Extent of recognition.
16–162		ISO 7176–4 Third edition 2008–10–01 Wheelchairs—Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range.	Extent of recognition.
16–163		ISO 7176–5 Second edition 2008–06–01 Wheelchairs—Part 5: Determination of overall dimensions, mass and manoeuvring space.	Extent of recognition.
16–164		ISO 7176–10 Second edition 2008–11–01 Wheelchairs—Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.	Extent of recognition.
16–165		ISO 7176–14 Second edition 2008–02–15 Wheelchairs—Part 14: Power and control systems for electrically powered wheelchairs and scooters—Requirements and test methods.	Extent of recognition.
16–166		ISO 7176–21 Second edition 2009–04–01 Wheelchairs—Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	Extent of recognition.
16–167		ISO 7176–9: Third edition 2009–11–15 Wheelchairs—Part 9: Climatic tests for electric wheelchairs.	Extent of recognition.
16–168		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability.	Extent of recognition.
16–169		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs.	Extent of recognition.
16–170		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 3: Determination of effectiveness of brakes.	Extent of recognition.
16–171		ANSI/RESNA WC–2:2009 Section 4: Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range.	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
16–172		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space.	Extent of recognition.
16–173		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed, acceleration and deceleration of electrically powered wheelchairs.	Extent of recognition.
16–174		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of Measurement of Seating and Wheel Dimensions.	Extent of recognition.
16–175		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths.	Extent of recognition.
16–176		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs.	Extent of recognition.
16–177		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.	Extent of recognition.
16–178		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test dummies.	Extent of recognition.
16–179		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces.	Extent of recognition.
16–180		ANSI/RESNA WC–2:2009 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs—Requirements and test methods.	Extent of recognition.
16–181		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling.	Extent of recognition.
16–182		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of upholstered parts—Requirements and test methods.	Extent of recognition.
16–183		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 20: Determination of the performance of stand-up type wheelchairs.	Extent of recognition
16–184		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 22: Set-up procedures.	Extent of recognition.
16–185		ANSI/RESNA WC–2:2009,American National Standard for Wheelchairs—Volume 2, Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters.	Extent of recognition.
16–187		ANSI/RESNA WC–1:2009 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary.	Extent of recognition.
		O. Radiology	
12–53	12–257	ISO 2919 Third edition 2012–02–15 Radiological protection—Sealed radioactive sources—General requirements and classification.	Withdrawn and replaced with newer version.
12–59		IEC 61168 First edition 1993–12 Radiotherapy simulators—Functional performance characteristics.	Extent of recognition.
12–66		AIUM MUS, Medical Ultrasound Safety	Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
12–139		AIUM AOMS–2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.	Extent of recognition.
12–140		AIUM RTD2–2004 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 2.	Withdrawn. See 12–209 and 12–258.
12–145	12–259	IEC 61674 Edition 2.0 2012–11 Medical electrical equipment—Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging.	Withdrawn and replaced with newer version.
12–149	12–260	IEC 60336 Fourth edition 2005–04 Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots [Including: Technical Corrigendum 1 (2006)].	Withdrawn and replaced with newer version including technical corrigendum.
12–150		ISO/IEC 10918–1:1994 TECHNICAL CORRIGENDUM 1:2005 Information technology—Digital compression and coding of continuous-tone still image—Part 1: Requirements and guidelines.	Withdrawn. See 12–261.
12–156		ISO 11670:2003 TECHNICAL CORRIGENDUM 1:2004 Lasers and laser-related equipment—Test methods for laser beam parameters—Beam positional stability.	Withdrawn. See 12–262.
12–157		ISO 13694:2000 TECHNICAL CORRIGENDUM 1:2005 Optics and optical instruments—Lasers and laser-related equipment—Test methods for laser beam power (energy) density distribution.	Withdrawn. See 12–263.
12–159	12–264	NEMA MS 11–2010 Determination of Gradient-Induced Electric Fields In Diagnostic Magnetic Resonance Imaging.	Withdrawn and replaced with newer version.
12–167	12–265	NEMA NU 2–2012 Performance Measurements of Positron Emission Tomographs (PETs).	Withdrawn and replaced with newer version.
12–179		ANSI/IESNA RP–27.3–2007, Recommended Practice for Photobiological Safety for Lamps—Risk Group Classification and Labeling.	Extent of recognition.
12–180	12–266	IEC 61689 Edition 3.0 2013–02 Ultrasonic-Physiotherapy systems—Field specifications and methods of measurement in the frequency range 0. 5 MHz to 5 MHz.	Withdrawn and replaced with newer version.
12–190	12–267	IEC 61217 Edition 2.0 2011–12 Radiotherapy equipment—Coordinates, movements and scales.	Withdrawn and replaced with newer version.
12–194		ANSI/HPS N43.6–2007, Sealed Radioactive Sources—Classification	Extent of recognition.
12–207	12–271	IEC 60601–2–33 Edition 3.1 2013–04 Medical electrical equipment—Part 2–33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.	Withdrawn and replaced with newer version.
12–208	12–268	IEC 60601–2–22 Edition 3.1 2012–10 Medical electrical equipment—Part 2–22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.	Withdrawn and replaced with newer version.
12–210	12–269	IEC 60601–1–3 Edition 2.1 2013–04 Medical electrical equipment—Part 1–3: General requirements for basic safety and essential performance—Collateral Standard: Radiation protection in diagnostic X-ray equipment.	Withdrawn and replaced with newer version.
12–219		IEC 60336 (2005) Medical electrical equipment—X-ray tube assemblies for medical diagnosis—Characteristics of focal spots.	Withdrawn. See 12–260.
12–222	12–270	IEC 61223–3–5 First edition 2004–08 Evaluation and routine testing in medical imaging departments—Part 3–5: Acceptance tests—Imaging performance of computed tomography X-ray equipment [Including: TECHNICAL CORRIGENDUM 1 (2006)].	Withdrawn and replaced with newer version including technical corrigendum.
12–223		IEC 61223–3–5 (First edition 2004) Evaluation and routine testing in medical imaging departments—Part 3–5: Acceptance tests—Imaging performance of computed tomography X-ray equipment CORRIGENDUM 1.	Withdrawn. See 12–270.
12–227		IEC 61391–1 First edition 2006–07 Ultrasonics—Pulse-echo scanners—Part 1: Techniques for calibrating spatial measurement systems and measurement of system point-spread function response.	Extent of recognition.
12–228		IEC 61391–2 Edition 1.0 2010–01 Ultrasonics—Pulse-echo scanners—Part 2: Measurement of maximum depth of penetration and local dynamic range.	Extent of recognition.
12–233	12–262	ISO 11670 Second edition 2003–04–01 Lasers and laser-related equipment—Test methods for laser beam parameters—Beam positional stability [Including: TECHNICAL CORRIGENDUM 1 (2004)].	Withdrawn and replaced with newer version including technical corrigendum.
12–237	12–258	IEC 62359 Edition 2.0 2010–10 Ultrasonics—Field characterization—Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields [Including TECHNICAL CORRIGENDUM 1 (2011)].	Withdrawn and replaced with newer version including technical corrigendum.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
12–243	12–263	ISO 13694 First edition 2000–04–01 Optics and optical instruments—Lasers and laser-related equipment—Test methods for laser beam power [energy] density distribution [Including: TECHNICAL CORRIGENDUM 1 (2005)].	Withdrawn and replaced with newer version including technical corrigendum.
12–244		IEC 62359 (Second edition 2010) March 2011 Ultrasonics—Field characterization—Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields CORRIGENDUM 1.	Withdrawn. See 12–258.
12–247		ISO 11990–1 First edition 2011–08–01, Lasers and laser-related equipment—Determination of laser resistance of tracheal tubes—Part 1: Tracheal tube shaft.	Extent of recognition.
		P. Software/Informatics	
13–4		ANSI/UL 1998 Standards for Safety Software in Programmable Components, Second Edition. [This Standard contains revisions through and including October 28, 2008.]	Extent of recognition.
		Q. Sterility	
14–143	14–395	ISO 14698–2 First edition 2003–09–15 Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data. [Including: TECHNICAL CORRIGENDUM 1 Published 2004–11–01].	Withdrawn and replaced with newer version including technical corrigendum.
14–193		ANSI/AAMI/ISO 11607–1:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Extent of recognition and relevant guidance.
14–194		ANSI/AAMI/ISO 11607–2:2006/(R)2010 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes.	Extent of recognition and relevant guidance.
14–195		ANSI/AAMI/ISO 11140–1:2005(R)2010 Sterilization of health care products—Chemical indicators—Part 1: General requirements.	Extent of recognition.
14–201	14–396	ANSI/AAMI ST77:2013 Containment devices for reusable medical device sterilization.	Withdrawn and replaced with newer version.
14–214	14–397	AOAC 6.2.04:2013 Official Method 955.15 Testing Disinfectants Against Staphylococcus aureus, Use-Dilution Method.	Withdrawn and replaced with newer version.
14–218	14–398	AOAC 6.3.05:2013 Official Method 966.04 Sporicidal Activity of Disinfectants Method I.	Withdrawn and replaced with newer version.
14–219	14–399	AOAC 6.3.06:2012 Official Method 965.12 Tuberculocidal Activity of Disinfectants.	Withdrawn and replaced with newer version.
14–230	14–400	ASTM F2203–13 Standard Test Method for Linear Measurement Using Precision Steel Rule.	Withdrawn and replaced with newer version.
14–231	14–401	ASTM F2217/F2217M–13 Standard Practice for Coating/Adhesive Weight Determination.	Withdrawn and replaced with newer version.
14–235	14–402	ASTM F1140/F1140M–13 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages.	Withdrawn and replaced with newer version.
14–236	14–403	ASTM F2054/F2054M–13 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates.	Withdrawn and replaced with newer version.
14–241	14–424	ISO 13408–6 First edition 2005–06–15 Aseptic processing of health care products—Part 6: Isolator systems [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
14–258	14–404	ASTM F2250–13 Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials.	Withdrawn and replaced with newer version.
14–260	14–405	ASTM F2252/F2252M–13$^{\varepsilon 1}$ Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape.	Withdrawn and replaced with newer version.
14–264	14–406	ANSI/AAMI ST8:2013 Hospital steam sterilizers	Withdrawn and replaced with newer version.
14–274		ANSI/AAMI/ISO 15882:2008 Sterilization of health care products—Chemical indicators—Guidance for selection, use, and interpretation of results.	Extent of recognition and relevant guidance.
14–285		ANSI/AAMI/ISO 14161:2009 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Extent of recognition.
14–289		ISO 14698–2:2003 TECHNICAL CORRIGENDUM Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data.	Withdrawn. See 14–395.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–296		ANSI/AAMI/ISO 11138–1:2006/(R)2010, Sterilization of health care products—Biological indicators—Part 1: General requirements.	Relevant guidance.
14–300		ASTM D4169–09 Standard Practice for Performance Testing of Shipping Containers and Systems.	Extent of recognition.
14–326	14–407	ISO 11737–1 Second edition 2006–04–01, Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products [Including: TECHNICAL CORRIGENDUM 1 Published 2007–05–15].	Withdrawn and replaced with newer version including technical corrigendum.
14–328	14–428	ISO 11137–1 First edition 2006–04–15 Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
14–334		ISO 15882 Second edition 2008–09–01 Sterilization of health care products—Chemical indicators—Guidance for selection, use and interpretation of results.	Extent of recognition, title.
14–335	14–408	ISO 10993–7 Second edition 2008–10–15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals [Including: TECHNICAL CORRIGENDUM 1 Published 2009–11–15].	Withdrawn and replaced with newer version including technical corrigendum.
14–336		ISO 14161 Second edition 2009–09–15 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Extent of recognition.
14–338		ISO 11138–1 Second edition 2006–07–01, Sterilization of health care products—Biological indicators—Part 1: General requirements.	Relevant guidance.
14–352	14–425	ANSI/AAMI/ISO 13408–6:2005 Aseptic processing of health care products—Part 6: Isolator systems [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
14–353		ISO 11140–1 Second edition 2005–07–15 Sterilization of health care products—Chemical indicators—Part 1: General requirements.	Extent of recognition.
14–355		ISO 11607–1 First edition 2006–04–15 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Extent of recognition and relevant guidance.
14–356		ISO 11607–2 First edition 2006–04–15 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes.	Extent of recognition.
14–357		ISO 11737–1:2006 TECHNICAL CORRIGENDUM 1 Published 2007–05–15 Sterilization of medical devices—Microbiological methods—Part 1: Determination of a population of microorganisms on products.	Withdrawn. See 14–407.
14–360		ANSI/AAMI ST72:2011, Bacterial endotoxins—Test methods, routine monitoring, and alternatives to batch testing.	Relevant guidance.
14–362	14–412	AOAC 6.2.01:2013 Official Method 955.14, Testing Disinfectants Against Salmonella choleraesuis, Use-Dilution Method.	Withdrawn and replaced with newer version.
14–363	14–413	AOAC 6.2.06:2013 Official Method 964.02, Testing Disinfectants Against Pseudomonas aeruginosa, Use-Dilution Method.	Withdrawn and replaced with newer version.
14–365	14–409	ISO 11137–2 Third edition 2013–06–01 Sterilization of health care products—Radiation—Part 2: Establishing the sterilization dose.	Withdrawn and replaced with newer version.
14–366	14–414	USP 36–NF31:2013 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–367	14–415	USP 36–NF31:2013 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–368	14–416	USP 36–NF31:2013 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–369	14–417	USP 36–NF31:2013 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version.
14–370	14–418	USP 36–NF31:2013 <161> Transfusion and Infusion Assemblies and Similar Medical Devices.	Withdrawn and replaced with newer version.
14–371	14–419	USP 36–NF31:2013 Biological Indicator for Steam Sterilization, Self-Contained.	Withdrawn and replaced with newer version.
14–372	14–420	USP 36–NF31:2013 Biological Indicator for Dry-Heat Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–373	14–421	USP 36–NF31:2013 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–374	14–422	USP 36–NF31:2013 Biological Indicator for Steam Sterilization, Paper Carrier.	Withdrawn and replaced with newer version.
14–375	14–423	USP 36–NF31:2013 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–380	14–410	ASTM F17–13 Standard Terminology Relating to Flexible Barrier Packaging.	Withdrawn and replaced with newer version.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–384		ISO 10993–7:2008 TECHNICAL CORRIGENDUM 1, Published 2009–11–15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals.	Withdrawn. See 14–408.
14–385	14–426	ANSI/AAMI/ISO 13408–1:2008 (R2011) Aseptic processing of health care products—Part 1: General requirements [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
14–386	14–427	ISO 13408–1 Second edition 2008–06–15 Aseptic processing of health care products—Part 1: General requirements [Including AMENDMENT 1 (2013)].	Withdrawn and replaced with newer version including amendment.
14–393	14–411	ISO/ASTM 51818 Third edition 2013–06–01 Practice for dosimetry in an electron beam facility for radiation processing at energies between 80 and 300 keV.	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 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: 034.

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

Recognition No.	Title of standard [1]	Reference No. and date
	A. Anesthesia	
1–96	Medical electrical equipment—Part 2–55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.	ISO 80601–2–55 First edition 2011–12–15.
	B. Cardiovascular	
3–121	Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses [Including: Amendment 1 (2005)].	ISO 25539–1 First edition 2003–03–01.
	C. General	
5–83	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 60601–1–11:2010, MOD).	ANSI/AAMI HA60601–1–1:2011.
5–84	Design of training and instructional materials for medical devices used in non-clinical environments.	AAMI TIR49:2013.
5–85	Medical electrical equipment—Part 1–6: General requirements for basic safety and essential performance—Collateral standard: Usability.	IEC 60601–1–6 Edition 3.0 2010–01.
5–86	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.	IEC 60601–1–8 Edition 2.0 2006–10.
	D. General Hospital/General Plastic Surgery	
6–302	Stainless steel needle tubing for the manufacture of medical devices [Including: AMENDMENT 1 2001–06–01].	ISO 9626 First edition 1991–09–01.
6–318	Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed [Including: AMENDMENT 1 2013–03–01].	ISO 8536–4 Fifth edition 2010–10–01.
6–320	Medical electrical equipment—Part 2–20: Particular requirements for the basic safety and essential performance of infant transport incubators [Including: CORRIGENDUM 1 (February 2012) and CORRIGENDUM 2 (February 2013)].	IEC 60601–2–20 Edition 2.0 2009–02.
6–321	Medical electrical equipment—Part 2–52: Particular requirements for basic safety and essential performance of medical beds [Including: CORRIGENDUM 1 (September 2010)].	IEC 60601–2–52 Edition 1.0 2009–12.
6–322	Intravascular catheters—Sterile and single-use catheters—Part 4: Balloon dilatation catheters.	ISO 10555–4 Second edition 2013–06–15.
	E. Material	
8–358	Standard Specification for Polyoxymethylene (Acetal) for Medical Applications	ASTM F1855–00 (Reapproved 2011).
8–359	Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials.	ASTM F2038–00 (Reapproved 2011).

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

Recognition No.	Title of standard [1]	Reference No. and date
8–360	Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II—Cross-Linking and Fabrication.	ASTM F2042–00 (Reapproved 2011).
8–361	Standard Specification for Selection of Porous Polyethylene for Use in Surgical Implants.	ASTM F755–99 (Reapproved 2011).
8–362	Standard Specification for Metal Injection Molded Unalloyed Titanium Components for Surgical Implant Applications.	ASTM F2989–13.
8–363	Standard Test Method for Tensile Properties of Plastics	ASTM D638–10.
8–364	Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement.	ASTM D792–08.
8–365	Standard Test Method for Density of Plastics by the Density-Gradient Technique	ASTM D1505–10.
8–366	Ultra-high-molecular-weight polyethylene (PE–UHMW) moulding and extrusion materials—Part 2: Preparation of test specimens and determination of properties.	ISO 11542–2 First edition 1998–11–15.
8–367	Standard Test Method for Measurement of Fatigue Crack Growth Rates	ASTM E647–13$^{\varepsilon 1}$.
8–368	Standard Test Method for Measurement of Enthalpy of Fusion, Percent Crystallinity, and Melting Point of Ultra-High-Molecular Weight Polyethylene by Means of Differential Scanning Calorimetry.	ASTM F2625–10.
8–369	Standard Practice for Accelerated Aging of Ultra-High Molecular Weight Polyethylene after Gamma Irradiation in Air.	ASTM F2003–02 (Reapproved 2008).
	F. OB–GYN/Gastroenterology/Urology	
9–86	Rubber condoms for clinical trials—Measurement of physical properties Including [AMENDMENT 1 2011–02–15)].	ISO 16037 First Edition 2002–05–15.
9–87	Female condoms—Requirements and test methods	ISO 25841 First Edition 2011–07–15.
9–88	Prophylactic dams—Requirements and test methods	ISO 29942 First Edition 2011–07–01.
9–89	Cardiovascular implants and extracorporeal blood circuit for haemodialysers, haemodiafilters, and haemofilters.	ISO 8638 Third edition 2010–07–01.
9–92	Cardiovascular implants and extracorporeal systems—Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators Including [AMENDMENT 1 2013–04–01)].	ISO 8637 Third edition 2010–07–01.
	G. Ophthalmics	
10–87	Standard Test Method for Tensile Properties of Thin Plastic Sheeting	ASTM D882–12.
10–88	Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	ASTM D790–10.
	H. Orthopedics	
11–259	Standard Specification For Total Elbow Prostheses	ASTM F2887–12.
11–260	Standard Guide for Presentation of End User Labeling Information for Orthopedic Implants Used in Joint Arthroplasty.	ASTM F2943–13.
11–261	Standard Specification for Shoulder Prostheses	ASTM F1378–12
11–262	Standard Specification for Acetabular Prostheses	ASTM F2091–01 (Reapproved 2012).
11–263	Standard Test Methods for Dynamic Evaluation of Glenoid Loosening or Disassociation.	ASTM F2028–08 (Reapproved 2012) [1].
11–264	Standard Test Method for Determining the Forces for Disassembly of Modular Acetabular Devices.	ASTM F1820–13.
11–265	Standard Practice for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prosthesis.	ASTM F2580–13.
11–266	Standard Specification for Total Ankle Replacement Prosthesis	ASTM F2665–09.
11–267	Standard Test Method for Determining the Axial Disassembly Force of Taper Connections of Modular Prostheses.	ASTM F2009–00 (Reapproved 2011).
11–268	Standard Test Method for Static Evaluation of Glenoid Locking Mechanism in Shear.	ASTM F1829–98 (Reapproved 2009).
11–269	Standard Guide for Functional, Kinematic, and Wear Assessment of Total Disc Prostheses.	ASTM F2423–11.
11–270	Standard Specification and Test Methods for Absorbable Plates and Screws for Internal Fixation Implants.	ASTM F2502–11.
11–271	Standard Specification for Metallic Implantable Strands and Cables	ASTM F2180–02 (Reapproved 2011).
11–272	Standard Guide for Gravimetric Wear Assessment of Prosthetic Hip Designs in Simulator Devices.	ASTM F1714–96 (Reapproved 2013).
11–273	Implants for surgery—Wear of total intervertebral spinal disc prostheses—Part 1 Loading and displacement parameters for wear testing and corresponding environmental conditions for test.	ISO 18192–1 Second edition 2011–03–01.
11–274	Implants for surgery—Wear of total intervertebral spinal disc prostheses—Part 2: Nucleus replacements.	ISO 18192–2 First edition 2010–06–15.
11–275	Standard Test Method for Evaluating Trans-Vinylene Yield in Irradiated Ultra-High Molecular Weight Polyethylene Fabricated Forms Intended for Surgical Implants by Infrared Spectroscopy.	ASTM F2381–10.

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

Recognition No.	Title of standard [1]	Reference No. and date
	I. Radiology	
12–261	Information technology—Digital compression and coding of continuous-tone still images: Requirements and guidelines [Including: TECHNICAL CORRIGENDUM 1 (2005)].	ISO/IEC 10918–1 First edition 1994–02–15.
	J. Software/Informatics	
13–63	Application of risk management for IT-networks incorporating medical devices—Part 2–4: Application guidance—General implementation guidance for healthcare delivery organizations.	IEC/TR 80001–2–4 Edition 1.0 2012–11.
13–64	Application of risk management for IT-networks incorporating medical devices—Part 2–4: General implementation guidance for healthcare delivery organizations.	ANSI/AAMI/IEC TIR80001–2–4:2012.
	K. Sterility	
14–429	Practice for use of a radiochromic film dosimetry system	ISO/ASTM 51275 Third edition 2013–06–01.
14–430	Practice for use of an alanine-EPR dosimetry system	ISO/ASTM 51607 Third edition 2013–06–01.
14–431	Guide for estimating uncertainties in dosimetry for radiation processing	ISO/ASTM 51707 Second edition 2005–05–15.

[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, 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) The title of the standard, (2) any reference number and date, (3) the 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: 034'' 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: 034. These modifications to the list of recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: January 23, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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