community-acquired pneumonia; uncomplicated skin and skin structure infections; uncomplicated and complicated urinary tract infections; pyelonephritis; uncomplicated urethral and cervical gonorrhea; and acute, uncomplicated rectal infections in women.

In January 2003, FDA received revised product labeling relating to several approved supplements for TEQUIN (gatifloxacin). This revised labeling deleted references to TEQUIN injection, 10 milligrams/milliliter (mg/mL) (200 mg), indicating that this product was no longer being marketed; therefore, the product was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book. In response to a citizen petition from Apotex Corp. (Docket No. FDA–2005–P–0369),[2] FDA stated, in the **Federal Register** of February 3, 2006 (71 FR 5858), that TEQUIN injection, 10 mg/mL (200 mg), was not withdrawn for reasons of safety and effectiveness.

On May 1, 2006, Public Citizen Research Group submitted a citizen petition (Docket No. FDA–2006–P–0081),[3] under 21 CFR 10.30, requesting that FDA immediately ban TEQUIN because of the increased risk of dysglycemia (hypoglycemia, low blood sugar, and hyperglycemia, high blood sugar) in humans. Public Citizen states that it reached its conclusion based on: (1) The relatively high numbers and rates of gatifloxacin-associated dysglycemia adverse event reports calculated from data collected by FDA's Adverse Event Reporting System (AERS) and Health Canada's Adverse Drug Reaction Monitoring Program; (2) a study by Park-Wyllie et al., published in March 2006 in the New England Journal of Medicine, that showed that patients (diabetic and nondiabetic) receiving gatifloxacin had approximately 17 times the odds of having a hyperglycemic episode and 4 times the odds of having a hypoglycemic episode compared to those taking macrolide antibiotics; and (3) the relatively high numbers and rates of gatifloxacin-associated dysglycemic events in the manufacturer's safety studies in uninfected patients and other studies in infected patients, including clinical trials, cohort studies, case-control studies, postmarketing surveillance studies, and case reports.

In June 2006, BMS announced that it would no longer market TEQUIN. In light of pending ANDAs and the citizen petition, FDA examined whether all TEQUIN products, including TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), were withdrawn from the market for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records concerning the drug product, analyses of AERS reports, and relevant literature, FDA has determined under § 314.161 that TEQUIN was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will remove all TEQUIN products from the Orange Book (§ 314.162). FDA will not accept or approve ANDAs that refer to these drug products.

Therefore, the agency has determined, under § 314.161, that all dosage forms and strengths of TEQUIN (gatifloxacin) listed in the table of this document were withdrawn from sale for reasons of safety. TEQUIN (gatifloxacin) will be removed from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to any dosage form or strength of TEQUIN (gatifloxacin).

Dated: September 2, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20938 Filed 9–8–08; 8:45 am]

BILLING CODE 4160–01–S

[2] This citizen petition was originally assigned docket number 2005P–0023/CP1. The number was changed to FDA–2005–P–0369 as a result of FDA's transition to its new docketing system (*Regulations.gov*) in January 2008.

[3] This citizen petition was originally assigned docket number 2006P–0178. The number was changed to FDA–2006–P–0081 as a result of FDA's transition to its new docketing system (*Regulations.gov*) in January 2008.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 020

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: 020'' (Recognition List Number: 020), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Effective September 9, 2008. Submit written or electronic comments concerning this document at any time.

ADDRESSES: Submit written requests for single copies of ''Modifications to the List of Recognized Standards, Recognition List Number: 020'' to the Division of Small Manufacturers, International and Consumer Assistance, Center for Devices and Radiological Health (CDRH) (HFZ–220), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 240–276–3151. 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 to *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/cdrhnew.cfm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 020 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–276–8714.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the 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 document described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in

the **Federal Register**, are identified in table 1 of this document.

TABLE 1.—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

October 16, 1998 (63 FR 55617)	October 4, 2004 (69 FR 59240)
July 12, 1999 (64 FR 37546)	May 27, 2005 (70 FR 30756)
November 15, 2000 (65 FR 69022)	November 8, 2005 (70 FR 67713)
May 7, 2001 (66 FR 23032)	March 31, 2006 (71 FR 16313)
January 14, 2002 (67 FR 1774)	June 23, 2006 (71 FR 36121)
October 2, 2002 (67 FR 61893)	November 3, 2006 (71 FR 64718)
April 28, 2003 (68 FR 22391)	May 21, 2007 (72 FR 28500)
March 8, 2004 (69 FR 10712)	September 12, 2007 (72 FR 52142)
June 18, 2004 (69 FR 34176)	December 19, 2007 (72 FR 71924)

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The agency maintains ''hypertext markup language (HTML)'' and ''portable document format (PDF)'' versions of the list of ''FDA Recognized Consensus Standards.'' Both versions are publicly accessible at the agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 020

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. In addition to these changes, FDA has also established a new internal numbering system that assigns unique identification recognition numbers. FDA believes this new numbering system will facilitate the use of FDA Form 3654, ''Standards Data Report for 510(k)s,'' which was implemented in November 2007. 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: 020'' to identify these current modifications.

In table 2 of this document, FDA describes the following modifications: (1) The withdrawal of standards and their replacement by others, (2) the correction of errors made by FDA in listing previously recognized standards, and (3) the changes to the supplementary information sheets of recognized standards that describe revisions to the applicability of the standards.

In section III of this document, FDA lists modifications the agency is making that involve the initial addition of standards not previously recognized by FDA.

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old Recognition No.	Replacement Recognition No.	Standard	Change
A. Anesthesia			
1–11		IEC 60601–3–1:1996–08 Medical Electrical Equipment Part 3–1: Essential Performance Requirements for Transcutaneous Oxygen and Carbon Dioxide Partial Pressure Monitoring Equipment	Withdrawn
1–46		ISO 5367:2000 Breathing Tubes Intended for Use With Anaesthetic Apparatus and Ventilators	Relevant guidance and Extent of recognition
1–51		ASTM F1101–90(1997) Standard Specification for Ventilators Intended for Use During Anesthesia	Withdrawn
1–62		ISO 5356–1:2004 Anaesthetic and Respiratory Equipment—Conical Connectors: Part 1: Cones and Sockets	Relevant guidance
1–66		ISO 9919:2005: Medical Electrical Equipment—Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use	Relevant guidance
1–68		CGA V–5:2005 Diameter-Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)	Relevant guidance
1–72		ISO 10651–5:2006 Lung Ventilators for Medical Use—Particular Requirements for Basic Safety and Essential Performance—Part 5: Gas-powered Emergency Resuscitators	Relevant guidance, Code of Federal Regulations (CFR) Citation and Product Codes
1–73		ISO 10651–4:2002 Lung Ventilators—Part 4: Particular Requirements for Operator Powered Resuscitators	Relevant guidance
B. Biocompatibility			
2–21	2–118	ANSI/AAMI/ISO 10993–11: 2006 Biological Evaluation of Medical Devices—Part 11: Tests for System Toxicity	Withdrawn and replaced with newer version
2–56	2–119	ASTM F813–07 Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
2–63	2–120	ANSI/AAMI/ISO 10993–6: 2007 Biological Evaluation of Medical Devices—Part 6: Tests for Local Effects After Implantation	Withdrawn and replaced with newer version
2–66	2–121	ASTM F2148–07e1 Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA)	Withdrawn and replaced with newer version
2–68	2–122	ASTM F719–81 (2007) e1 Standard Practice for Testing Biomaterials in Rabbits for Primary Skin Irritation	Withdrawn and replaced with newer version
2–69	2–123	ASTM F720–81 (2007) e1 Standard Practice for Testing Guinea Pigs for Contact Allergens: Guinea Pig Maximization Test	Withdrawn and replaced with newer version
2–70	2–124	ASTM F750–87 (2007) e1 Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	Withdrawn and replaced with newer version
2–89	2–125	ASTM F749–98 (2007) e1 Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Withdrawn and replaced with newer version
2–92	2–126	ASTM F748–06 Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Withdrawn and replaced with newer version
2–95		ASTM F1984–99(2003) Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	Relevant guidance
2–109	2–128	USP 31–NF26 Biological Test <87> 2008 Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version
2–110	2–129	USP 31–NF26 Biological Test <88> 2008 Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version
2–111	2–130	USP 31–NF26 Biological Test <88> 2008 Biological Reactivity Test, In Vitro, Procedure—Preparation of Sample	Withdrawn and replaced with newer version
2–112	2–131	USP 31–NF26 Biological Test <88> 2008 Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test	Withdrawn and replaced with newer version
2–113	2–132	USP 31–NF26Biological Test <88> 2008 Biological Reactivity Test, In Vivo—Classification of Plastics—Systemic Injection Test	Withdrawn and replaced with newer version
C. Cardiovascular/Neurology			
3–2		ANSI/AAMI EC53:1995/(R)2001—ECG Cables and Leadwires	Reaffirmation
3–3		ANSI/AAMI NS28:1988/(R)2006—Intracranial Pressure Monitoring Devices	Reaffirmation
3–16	3–60	IEC 60601–2–10: Amendment 1: 2001–09, Medical Electrical Equipment—Part 2–10: Particular Requirements for the Safety of Nerve and Muscle Stimulators	Withdrawn and replaced with newer version
3–18	3–61	IEC 60601–2–27: 2005–08, Second Edition, Medical Electrical Equipment—Part 2–27: Particular Requirements for the Safety, Including Essential Performance, of Electrocardiographic Monitoring Equipment	Withdrawn and replaced with newer version
3–20	3–62	IEC 60601–2–31: 2008–03, Edition 2.0, Medical Electrical Equipment—Part 2–31: Particular Requirements for the Basic Safety and Essential Performance of External Cardiac Pacemakers with Internal Power Source	Withdrawn and replaced with newer version
3–25	3–63	ISO 11318:2002, Second Edition, Cardiac Defibrillators—Connector Assembly DF–1 for Implantable Defibrillators—Dimensions and Test Requirements	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
3–40		ANSI/AAMI SP9:1994, Non-automated Sphygmomanometers	Withdrawn
3–41		ANSI/AAMI EC11:1991/(R)2007—Diagnostic Electrocardiographic Devices	Reaffirmation
3–42		ANSI/AAMI EC13:2002/(R)2007—Cardiac Monitors, Heart Rate Meters, and Alarms	Reaffirmation
3–43	3–65	ANSI/AAMI EC38:2007—Medical Electrical Equipment—Part 2–47: Particular Requirements for the Safety, Including Essential Performance, of Ambulatory Electrocardiographic Systems	Withdrawn and replaced with newer version
3–44		ANSI/AAMI BP22:1994/(R)2006, Blood Pressure Transducers	Reaffirmation
3–45		ANSI/AAMI EC57:1998/(R)2003, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms	Reaffirmation
3–47	3–66	ASTM F2081–06, Standard Guide for Characterization and Presentation of the Dimensional Attributes of Vascular Stents	Withdrawn and replaced with newer version
3–52		ANSI/AAMI EC12:2000/(R)2005, Disposable ECG Electrodes	Reaffirmation
3–57	3–67	ASTM F2129–06, Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version
D. Dental/Ear, Nose, and Throat			
4–43		ANSI/ADA Specification No. 5–Dental Casting Alloys:1997	Type of standard, and Relevant guidance
4–50		ANSI/ADA Specification No. 18–Alginate Impression Materials:1992	Title and Relevant guidance
4–52	4–147	ANSI/ADA Specification No. 27–Resin-Based Filling Materials: 2005	Withdrawn and replaced with newer year
4–62		ISO 1563:1990 Dental Alginate Impression Material	Relevant guidance and Extent of recognition
4–63		ISO 1564:1995 Dental Aqueous Impression Materials Based on Agar	Relevant guidance
4–65	4–151	ISO 3336:1993, Dentistry—Synthetic Polymer Teeth	Withdrawn and replaced with newer version
4–66		ISO 4049:1988, Dentistry—Resin-Based Filling Materials	Withdrawn—newer version previously recognized
4–67		ISO 6871–1:1994, Dental Base Metal Casting Alloys Part 1: Cobalt-based Alloys—TECHNICAL CORRIGENDUM 1:1998	Withdrawn—newer version previously recognized
4–68		ISO 6871–2:1994, Dental Base Metal Casting Alloys Part 2: Nickel-Based Alloys	Withdrawn—newer version previously recognized
4–69		ISO 6872:1995/Amendment 1:1997 Dental Ceramic	Date of standard and Extent of recognition
4–73		ISO 7405:1997 Dentistry—Preclinical Evaluation of Biocompatibility of Medical Devices Used in Dentistry—Test Methods for Dental Materials	Extent of recognition and Contact person
4–75		ISO 7785–1:1997 Dental Handpieces—Part 1: High-Speed Air Turbine Handpieces	Relevant guidance and Extent of recognition

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
4–76		ISO 7785–2:1995 Dental Handpieces—Part 2: Straight and Geared Angle Handpieces	Relevant guidance and Extent of recognition
4–78		ISO 9168:1991 Dental Handpieces—Hose Connectors	Relevant guidance and Extent of recognition
4–83		ISO 11498:1997 Dental Handpieces—Dental Low-Voltage Electrical Motors	Relevant guidance and Extent of recognition
4–84		ISO 13294:1997 Dental Handpieces—Dental Air-Motors	Relevant guidance and Extent of recognition
4–88	4–148	ANSI/ADA Specification No. 78–Endodontic Obturating Cones: 2005	Withdrawn and replaced with newer version
4–89		ANSI/ADA Specification No. 53–Polymer-Based Crowns and Bridge Resins: 1999 (Reaffirmed 2005)	Reaffirmation and Relevant guidance
4–90		ANSI/ASA S3.39:1987 (R2007), Specifications for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	Reaffirmation and Type of standard
4–91		ANSI/ADA Specification No. 80–Dental Materials—Determination of Color Stability: 2001	Relevant guidance
4–92		ANSI/ADA Specification No. 88–Dental Brazing Alloys: 2000 (Reaffirmed 2006)	Reaffirmation and Relevant guidance
4–93	4–159	IEEE ANSI C63.19:2007 Methods of Measurement of Compatibility Between Wireless Communications Devices and Hearing Aids	Withdrawn and replaced with newer version
4–94		ANSI/ADA Specification No. 14—Dental Base Metal Casting Alloys: 1982 (Reaffirmed 1998)	Reaffirmation, Date of standard, Type of standard, Offices, Relevant guidance
4–95		ANSI/ADA Specification No.17:1999, Dental Base Temporary Relining Resin	Withdrawn—newer version previously recognized
4–96		ANSI/ADA Specification No. 30—Dental Zinc Oxide—Eugenol and Zinc Oxide—Non-Eugenol Cements: 2000 (Reaffirmed 2005)	Reaffirmation and Relevant guidance
4–97		ANSI/ADA Specification No. 57—Endodontic Sealing Material: 2000 (Reaffirmed 2006)	Reaffirmation, Offices and Type of standard
4–98		ANSI/ADA Specification No. 96:2000, Dental-Water-Based Cements	Withdrawn—newer version previously recognized
4–99		ISO 4049: 2000 Dentistry—Polymer-based Filling, Restorative and Luting Materials	Relevant guidance, Type of standard and Extent of recognition
4–100	4–133	ISO 6876:2001, Dental Root Canal Sealing Materials	Withdrawn (duplicate)
4–101		ISO 8891:1998, Dental Casting Alloys With Noble Metal Content of At Least 25% but Less Than 75%	Withdrawn—newer version previously recognized
4–102	4–152	ISO 9693:1999, Metal-Ceramic Dental Restorative Systems	Withdrawn and replaced with newer version
4–104	4–149	ANSI/ADA Specification No. 39—Pit and Fissure Sealants: 2006	Withdrawn and replaced with newer version
4–105		ANSI/ADA Specification No. 75—Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials: 1997 (Reaffirmed 2003)	Type of standard and Relevant guidance
4–107		ISO 9917–2:1998 Dental Water-Based Cements—Part 2: Light-Activated Cements	Devices affected, Type of standard, Relevant guidance and Extent of recognition

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
4–109		ISO 13716:1999 Dentistry—Reversible-Irreversible Hydrocolloid Impression Material Systems	Type of standard, Relevant guidance, Extent of recognition and Code of Federal Regulations (CFR) citation
4–110		ANSI/ADA Specification No. 11—Agar Impression Materials: 1997	Type of standard and Relevant guidance
4–111		ANSI/ADA Specification No. 13—Denture Cold-Curing Repair Resins: 1981 (Reaffirmed 2006)	Reaffirmation, Date of standard, Type of standard and Relevant guidance
4–112		ANSI/ADA Specification No. 16—Dental Impression Paste—Zinc Oxide-Eugenol Type: 1961 (Reaffirmed 1999)	Reaffirmation, Date of standard, Type of standard and Relevant guidance
4–113		ANSI/ADA Specification No. 20—Dental Duplicating Material: 1972 (Reaffirmed 1995)	Reaffirmation, Date of standard, Type of standard and Relevant guidance
4–115	4–153	ISO 9917–1:2007 Dentistry—Water-Based Cements—Part 1: Powder/Liquid Acid-Base Cements	Withdrawn and replaced with a newer year
4–117		ANSI/ADA Specification No. 12—Denture Base Polymers: 2002	Type of standard
4–119		ANSI/ADA Specification No. 82—Dental Reversible/Irreversible Hydrocolloid Impression Material Systems: 1998 (Reaffirmed 2003)	Reaffirmation, Date of standard, Type of standard and Relevant guidance
4–120		ISO 10139–2:1999 Dentistry—Soft Lining Materials for Removable Dentures—Part 2: Materials for Long-Term Use	Type of standard, Relevant guidance and Extent of recognition
4–121		ISO 7494–2:2003 Dentistry—Dental Units—Part 2: Water and Air Supply	Type of standard and Extent of recognition
4–125		ISO 1562:2004, Dentistry—Casting Gold Alloys	Withdrawn—newer version previously recognized
4–126		ISO 10477:2004 Dentistry—Polymer-Based Crown and Bridge Materials	Extent of recognition and Relevant guidance
4–127		ANSI/ADA Specification No. 58—Root Canal Files, Type H (Hedstrom): 2004	Type of standard and Extent of recognition
4–128		ISO 4823:2000,, Dentistry—Elastomeric Impression Materials and Technical Corrigendum 1:2004	Withdrawn
4–129	4–150	ANSI/ADA Specification No. 19—Dental Elastomeric Impression Material: 2004	Withdrawn and replaced with newer version
4–130		ANSI/ADA Specification No. 17—Denture Base Temporary Relining Resins: 1983 (Reaffirmed 2006)	Reaffirmation, Processes impacted, Extent of recognition, CFR citations and Relevant guidance
4–131		ISO 3107: 2004 Dentistry—Zinc Oxide/Eugenol and Zinc Oxide/Non-eugenol Cements Technical Corrigendum 1:2006–Third Edition	Processes impacted and Relevant guidance
4–132		ISO 6874:2005 Dentistry—Polymer-Based Pit and Fissure Sealants	Extent of recognition and Relevant guidance
4–133		ISO 6876:2001 Dental Root Canal Sealing Materials	Processes impacted and Extent of recognition
4–134		ISO 7494–1:2004 Dentistry—Dental Units—Part 1: General Requirements and Test Methods	Extent of recognition
4–135		ISO 10139–1:2005 Dentistry—Soft Lining Materials for Removable Dentures—Part 1: Materials for Short-term Use	Relevant guidance and Extent of recognition

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
4–136		ASTM F2504–05 Standard Practice for Describing System Output of Implantable Middle Ear Hearing Devices	Relevant guidance
4–137		ISO 6877:2006 Dentistry—Root-Canal Obturating Points	Extent of recognition
4–139		ANSI/ADA Specification No. 48—Visible Light Curing Units: 2004	Relevant guidance
4–140		ISO 6871–2:1994/Amd 1:2005, Dental Base Metal Casting Alloys—Part 2: Nickel-Based Alloys	Withdrawn—newer version previously recognized
4–141		ISO 6871–1:1994, Dental Base Metal Casting Alloys—Part 1: Cobalt-Based Alloys	Withdrawn—newer version previously recognized
4–142		ISO 6871–1:1994/Amd 1:2005, Dental Base Metal Casting Alloys—Part 1: Cobalt-Based Alloys	Withdrawn—newer version previously recognized
4–143		ANSI/ADA Specification No.96, Dental-Water-Based Cements	Reaffirmation, Type of standard and Relevant guidance
4–145		ISO 22803:2004 Dentistry—Membrane Materials for Guided Tissue Regeneration in Oral and Maxillofacial Surgery—Contents of a Technical File	Relevant guidance and Devices affected
4–146		ISO 22674:2006 Dentistry—Metallic Materials for Fixed and Removable Restorations and Appliances	Devices affected and Processes impacted
E. General			
5–7	12–185	IEC 60601–1–3(1994–07) Medical Electrical Equipment—Part 1: General Requirements for Safety; General Requirements for Radiation Protection in Diagnostic X-Ray Equipment	Transferred
5–8	5–41	IEC 60601–1–4:2000 Medical Electrical Equipment—Part 1–4: General Requirements for Safety—Collateral Standard: Programmable Electrical Medical Systems, Edition 1.1	Withdrawn and replaced with newer version
5–16	5–42	ASTM D903–98(2004) Standard Test Methods for Peel or Stripping Strength of Adhesive Bonds	Withdrawn and replaced with newer version
5–19		ASTM E876/1995 Standard Practice for Use of Statistics in the Evaluation of Spectrometric Data	Withdrawn
5–25	5–43	ANSI/ESD S20.20–2007 Standard for the Development of an Electrostatic Discharge Control Program for Protection of Electrical and Electronic Parts, Assemblies and Equipment (Excluding Electrically Initiated Explosive Devices)	Withdrawn and replaced with newer version
5–28		IEC 60601–1–2, (Second Edition, 2001) Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests	Extent of recognition
5–30		AAMI/ANSI/IEC 60601–1–2 Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests (AAMI/ANSI/IEC 60601–1–2:2001 is the U.S. version of IEC 60601–1–2:2001 with identical requirements for electromagnetic compatibility (EMC) of medical electrical equipment.)	Type of standard and Extent of recognition
5–33	5–44	IEC 60601–1–8:2006 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, Second Edition	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
5–34		IEC 60601–1–2 Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001 with Amendment 1:2004; Edition 2.1 (Edition 2:2001 consolidated with Amendment 1:2004))	Extent of recognition
5–35		AAMI/ANSI/IEC 60601–1–2 Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001 with Amendment 1:2004) (AAMI/ANSI/IEC 60601–1–2:2001 with Amendment 1:2004 is the U.S. version of IEC 60601–1–2:2001 with Amendment 1:2004, with identical requirements for electromagnetic compatibility (EMC) of medical electrical equipment)	Type of standard and Extent of recognition
5–36		ANSI/AAMI/ISO TIR 16142:2006: Technical Information Report: Medical Devices—Guidance on the Selection of Standards in Support of Recognized Essential Principles of Safety and Performance of Medical Devices, Second Edition	CFR Citations, Product codes and Relevant guidance
F. General Hospital/General Plastic Surgery			
6–16		ISO 7886–1:1993 Sterile Hypodermic Syringes for Single Use—Part 1: Syringes for Manual Use	Withdrawn
6–117		ASTM F2172–02: Standard Specification for Blood/Intravenous Fluid/Irrigation Fluid Warmers	Relevant guidance
6–118		ASTM F2196–02 Standard Specification for Circulating Liquid and Forced Air Patient Temperature Management Devices	Relevant guidance, Contact person
6–131	6–203	ASTM D6499–07 Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and Its Products	Withdrawn and replaced with newer version
6–160	6–204	ISO 8537:2007 Sterile Single-Use Syringes, With or Without Needle, for Insulin	Withdrawn and replaced with newer version
6–166	6–215	ASTM F2132–01(2008) Standard Specification for Puncture Resistance of Materials Used in Containers for Discarded Medical Needles and Other Sharps	Withdrawn and replaced with newer version
6–167		ASTM D6319–00a(2005) Standard Specification for Nitrile Examination Gloves for Medical Application	Relevant guidance
6–188	6–205	USP 31:2008 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version
6–189	6–206	USP 31<11>2008 Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version
6–190	6–207	USP 31:2008 Absorbable Surgical Suture	Withdrawn and replaced with newer version
6–191	6–208	USP 31<881>:2008 Tensile Strength	Withdrawn and replaced with newer version
6–192	6–209	USP 31<861>:2008 Sutures—Diameter	Withdrawn and replaced with newer version
6–193	6–210	USP 31<871>:2008 Sutures Needle Attachment	Withdrawn and replaced with newer version
6–194	6–211	USP 31<11>: 2008 Sterile Water for Irrigation	Withdrawn and replaced with newer version
6–195	6–212	USP 31<11>: 2008 Heparin Lock Flush Solution	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
6–196	6–213	USP 31<11>: 2008 Sodium Chloride Injection	Withdrawn and replaced with newer version
6–198		ASTM F2100–07 Standard Specification for Performance of Materials Used in Medical Face Masks	Relevant guidance
6–201		ISO 8536–4:2007 Infusion Equipment for Medical Use—Part 4: Infusion Sets for Single Use, Gravity Feed	Relevant guidance
G. In Vitro Diagnostic			
7–6	7–131	CLSI ILA18–A2 Specifications for Immunological Testing for Infectious Diseases	Withdrawn and replaced with newer version
7–11	7–132	CLSI MM03–A2 Molecular Diagnostic Methods for Infectious Diseases	Withdrawn and replaced with newer version
7–12		CLSI/NCCLS C12–A Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis; Approved Standard (1994)	Withdrawn
7–13		CLSI/NCCLS C21–A Performance Characteristics for Devices Measuring PO2 and PCO2 in Blood Samples; Approved Standard (1992)	Withdrawn
7–15		CLSI/NCCLS C25–A Fractional Oxyhemoglobin, Oxygen Content and Saturation, and Related Quantities in Blood: Terminology, Measurement, and Reporting; Approved Guideline (1997)	Withdrawn
7–16		CLSI/NCCLS C27–A Blood Gas Preanalytical Considerations: Specimen Collection, Calibration, and Controls; Approved Guideline (1993)	Withdrawn
7–18	7–133	CLSI C30–A2, Point-of Care Blood Glucose Testing in Acute and Chronic Care Facilities	Withdrawn and replaced with newer version
7–21		CLSI C42–A, Erythrocyte Protoporphyrin Testing; Approved Guideline (1996)	Contact person
7–22	7–134	CLSI GP20–A2 Fine-Needle Aspiration Biopsy (FNAB) Techniques	Withdrawn and replaced with newer versions
7–25		NCCLS H8–A2 Detection of Abnormal Hemoglobin Using Cellulose Acetate Electrophoresis—Second Edition; Approved Standard (1994)	Withdrawn
7–26		NCCLS H9–A Chromatographic (Microcolumn) Determination of Hemoglobin A2; Approved Standard (1989)	Withdrawn
7–27		NCCLS H10–A2 Solubility Test to Confirm the Presence of Sickling Hemoglobins—Second Edition; Approved Standard (1995)	Withdrawn
7–29		NCCLS H14–A2 Devices for Collection of Skin Puncture Blood Specimens—Second Edition; Approved Guideline (1990)	Withdrawn
7–34	7–135	CLSI H44–A2 Methods for Reticulocyte Counting (Flow Cytometry and Supravital Dyes)	Withdrawn and replaced with newer version
7–35		CLSI H47–A One-Stage Prothrombin Time (PT) Test and Activated Partial Thromboplastin Time (APTT) Test; Approved Guideline (1996)	Contact person
7–36	7–136	CLSI ILA02–A2 Quality Assurance of Laboratory Tests for Autoantibodies to Nuclear Antigens	Withdrawn and replaced with newer version
7–37		CLSI ILA06–A Detection and Quantitation of Rubella IgG Antibody	Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
7–38		CLSI/NCCLS I/LA10–A Choriogonadotropin Testing: Nomenclature, Reference Preparations, Assay Performance, and Clinical Application; Approved Guideline (1996)	Withdrawn
7–39		CLSI/NCCLS I/LA17–A Assessing the Quality of Systems for Alpha-Fetoprotein (AFP) Assays Used in Prenatal Screening and Diagnosis of Neural Tube Defects; Approved Guideline (1997)	Withdrawn
7–40		NCCLS I/LA18–A Specifications for Immunological Testing for Infectious Diseases; Approved Guideline (1994)	Withdrawn
7–41		CLSI ILA19–A Primary Reference Preparations Used to Standardize Calibration of Immunochemical Assays for Serum Prostate Specific Antigen (PSA); Approved Guideline (1997)	Contact person
7–42		CLSI ILA20–A Evaluation Methods and Analytical Performance Characteristics of Immunological Assays for Human Immunoglobulin E (IgE) Antibodies of Defined Allergen Specificities; Approved Guideline (1997)	Contact person
7–43	7–137	CLSI LA04–A5 Blood Collection on Filter Paper for Newborn Screening Programs	Withdrawn and replaced with newer version
7–46	7–138	CLSI M27–A2, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts	Withdrawn and replaced with newer version
7–49		CLSI H26–A Performance Goals for the Internal Quality Control of Multichannel Hematology Analyzers; Approved Standard	Contact person
7–50		NCCLS D11–A2 Glossary and Guidance for Immunodiagnostic Procedures, Reagents, and Reference Materials—Second Edition, Approved Guideline	Withdrawn
7–51	7–139	CLSI GP27–A2 Using Proficiency Testing to Improve the Clinical Laboratory	Withdrawn and replaced with newer version
7–52		CLSI / NCCLS NRSCL 8–A Terminology and Definitions for use in NCCLS Documents; Approved Standard	Withdrawn
7–53	7–140	CLSI GP22–A2 Continuous Quality Improvement	Withdrawn and replaced with newer version
7–55	7–141	CLSI H18–A3 Procedures for the Handling and Processing of Blood Specimens	Withdrawn and replaced with newer version
7–58	7–142	CLSI H11–A4 Procedures for the Collection of Arterial Blood Specimens	Withdrawn and replaced with newer version
7–59	13–9	CLSI / NCCLS AUTO2–A Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard	Transferred
7–60	13–10	NCCLS AUTO1–A Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard	Transferred
7–61	13–11	NCCLS AUTO3–A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard	Transferred
7–62	13–12	NCCLS AUTO4–A Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard	Transferred
7–63	13–13	NCCLS AUTO5–A Laboratory Automation: Electromechanical Interfaces; Approved Standard	Transferred
7–64	13–14	NCCLS POCT1–A Point-of-Care Connectivity; Approved Standard	Transferred

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
7–67	7–143	CLSI EP14–A2 Evaluation of Matrix Effects	Withdrawn and replaced with newer version
7–68	13–15	NCCLS GP19–A2 Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition	Transferred
7–70	7–144	CLSI H4–A5 Procedures and Devices for the Collection of Diagnostic Blood Specimens by Skin Puncture	Withdrawn and replaced with newer version
7–72	7–145	CLSI H42–A2 Enumeration of Immunologically Defined Cell Populations by Flow Cytometry	Withdrawn and replaced with newer version
7–74	7–146	NCCLS M6–A2 Protocols for Evaluating Dehydrated Mueller-Hinton Agar	Withdrawn and replaced with newer version
7–77	7–147	CLSI M22–A3 Quality Control for Commercially Prepared Microbiological Culture Media	Withdrawn and replaced with newer version
7–79	7–148	CLSI M28–A2 Procedures for the Recovery and Identification of Parasites From the Intestinal Tract	Withdrawn and replaced with newer version
7–80		CLSI MM01–A2 Molecular Diagnostic Methods for Genetic Diseases	Withdrawn
7–83		NCCLS C46–A Blood Gas and pH Analysis and Related Measurements; Approved Guideline	Withdrawn
7–85	7–149	CLSI C24–A3 Statistical Quality Control for Quantitative Measurement Procedures	Withdrawn and replaced with newer version
7–90	7–150	CLSI H43–A2 Clinical Flow Cytometric Analysis of Neoplastic Hematolymphoid Cells	Withdrawn and replaced with newer version
7–93		NCCLS EP10–A2, Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline	Withdrawn
7–94	7–152	CLSI EP12–A2 User Protocol for Evaluation of Qualitative Test Performance	Withdrawn and replaced with newer version
7–95	7–153	CLSI EP15–A2 User Verification of Performance for Precision and Trueness	Withdrawn and replaced with newer version
7–98	7–154	CLSI MM02–A2 Immunoglobin and T-Cell Receptor Gene Rearrangement Assays	Withdrawn and replaced with newer version
7–99		CLSI MM5–A Nucleic Acid Amplification Assays for Molecular Hematopathology	Contact person
7–103	7–155	CLSI H03–A6 Procedures for the Collection of Diagnostic Blood Specimens by Venipunture	Withdrawn and replaced with newer version
7–106	7–156	CLSI M02–A9 Performance Standards for Antimicrobial Disk Susceptibility Tests	Withdrawn and replaced with newer version
7–107	7–157	CLSI M11–A7 Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria	Withdrawn and replaced with newer version
7–108	7–158	CLSI M7–A7 Methods for Antimicrobial Susceptibility Tests of Anaerobic Bacteria	Withdrawn and replaced with newer version
7–109		CLSI AUTO7–A Laboratory Automation: Data Content for Specimen Identification; Approved Standard	Withdrawn
7–111	7–159	CLSI H21–A5 Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays and Molecular Hemostasis Assays	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
7–114	13–16	CLSI LIS01–A Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems	Transferred
7–115	13–17	CLSI LIS02–A2 Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard-Second Edition	Transferred
7–116	13–18	CLSI LIS03–A Standard Guide for Selection of a Clinical Laboratory Information Management System	Transferred
7–117	13–19	CLSI LIS04–A Standard Guide for Documentation of Clinical Laboratory Computer Systems	Transferred
7–118	13–20	CLSI LIS05–A, Standard Specification for Transferring Clinical Observations Between Independent Computer Systems	Transferred
7–119	13–21	CLSI LIS06–A Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems	Transferred
7–120	13–22	CLSI LIS07–A Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory	Transferred
7–121	13–23	CLSI LIS08–A Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems	Transferred
7–122	13–24	CLSI LIS09–A Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures	Transferred
7–125		CLSI/NCCLS M28–A2 Volume 25, No. 16 Procedures for the Recovery and Identification of Parasites From the Intestinal Tract; Approved Guideline	Withdrawn
H. Materials			
8–32		ASTM F1586–02: Standard Specification for Wrought Nitrogen Strengthened 21 Chromium–10 Nickel–3 Manganese–2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675)	Contact person
8–44		ASTM F0136–02a: Standard Specification for Wrought Titanium–6 Aluminum–4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Contact person
8–46	8–154	ASTM F0621–08: Standard Specification for Stainless Steel Forgings for Surgical Implants	Withdrawn and replaced with newer year version
8–50		ASTM F1091–02: Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy Surgical Fixation Wire (UNS R30605)	Contact person
8–52		ASTM F1350–02: Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	Contact person
8–53		ASTM F1472–02a: Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	Contact person
8–54	8–155	ASTM F1580–07 Standard Specification for Titanium and Titanium–6 Aluminum–4 Vanadium Alloy Powders for Coatings of Surgical Implants	Withdrawn and replaced with newer year version
8–57		ISO 5832–2:1999, Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	Contact person
8–58		ISO 5832–3:1996, Implants for Surgery—Metallic Materials—Part 3: Wrought Titanium 6–Aluminium 4–Vanadium Alloy	Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
8–59		ISO 5832–4:1996, Implants for Surgery—Metallic Materials—Part 4: Cobalt-Chromium-Molybdenum Casting Alloy	Contact person
8–61		ISO 5832–6:1997, Implants for Surgery—Metallic Materials—Part 6: Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy	Contact person
8–63		ISO 5832–11:1994, Implants for Surgery—Metallic Materials—Part 11: Wrought Titanium 6–Aluminium 7–Niobium Alloy	Contact person
8–76		ASTM F138–03: Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Contact person
8–77	8–156	ASTM F0139–08, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer year version
8–79		ASTM F0961–03, Standard Specification for Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Forgings for Surgical Implants [UNS R30035]	Contact person
8–81		ASTM F1609–03 Standard Specification for Calcium Phosphate Coatings for Implantable Materials	Contact person
11–81	8–157	ISO 9583:1993 Implants for Surgery—Non-Destructive Testing—Liquid Penetrant Inspection of Metallic Surgical Implants	Transferred
8–82	8–158	ASTM F1713–08 Standard Specification for Wrought Titanium–13 Niobium–13 Zirconium Alloy for Surgical Implant Applications (UNS R58130)	Withdrawn and replaced with newer year version
11–82	8–159	ISO 9584:1993 Implants for Surgery—Non-Destructive Testing—Radiographic Examination of Cast Metallic Surgical Implants	Transferred
8–86		ASTM F1926–03 Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings	Relevant guidance
8–88		ASTM F2024–00 Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	Relevant guidance
8–98	8–162	ASTM F451–99a(2007)e1 Standard Specification for Acrylic Bone Cement	Withdrawn and replaced with newer year version
8–104		ASTM F1108–04 Standard Specification for Titanium–6Aluminum–4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	Contact person
8–108		ASTM F1295–05 Standard Specification for Wrought Titanium–6 Aluminum–7 Niobium Alloy for Surgical Implant Applications (UNS R56700)	Contact person
8–110		ASTM F1377–04 Standard Specification for Cobalt–28 Chromium–6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Contact person
8–112		ASTM F1044–05 Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Relevant guidance
8–113		ASTM F1147–05 Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Relevant guidance
8–119		ASTM F688–05 Standard Specification for Wrought Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035)	Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
8–120	8–160	ASTM F0560–07 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Withdrawn and replaced with newer year version
8–123		ISO 5832–5:2005 Implants for Surgery—Metallic Materials—Part 5: Wrought Cobalt-Chromium-Tungsten-Nickel Alloy	Contact person
8–127		ISO 5834–2:2006 Implants for Surgery—Ultra-high-molecular-weight polyethylene—Part 2: Moulded Forms	Relevant guidance
8–129		ASTM F67–06 Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50400, UNS R50550, UNS R50700)	Contact person
8–130		ASTM F620–06 Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants	Contact person
8–131		ASTM F799–06 Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	Contact person
8–132		ASTM F1088–04ae1 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Contact person
8–137		ASTM F0075–07 Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	Contact person
8–138		ASTM F0745–07 Standard Specification for 18 Chromium–12.5 Nickel–2.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	Contact person
8–139		ASTM F1314–07 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)	Contact person
8–142		ASTM F1978–00(2007)e2 Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the Taber Abraser	Relevant guidance
8–144		ASTM F0754–00 Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube and Rod Shapes	Contact person
8–145		ASTM F0090–07 Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	Contact person
8–147		ASTM F0562–07 Standard Specification for Wrought 35Cobalt–35Nickel–20Chromium–10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	Contact person
8–149		ISO 5832–1:2007 Implants for Surgery—Metallic Materials—Part 1: Wrought Stainless Steel	Contact person
8–150		ISO 5832–9:2007 Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel	Contact person
8–151		ISO 5832–12:2007 Implants for Surgery—Metallic Materials—Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy	Contact person
8–152		ASTM F1537–07 Standard Specification for Wrought Cobalt–28Chromium–6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)	Contact person

I. OB-GYN/Gastroenterology

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
9–4		IEC 60601–2–16 (1998) Medical Electrical Equipment—Part 2–16: Particular Requirements for the Safety of Haemodialysis, Haemodiafiltration and Haemofiltration Equipment	Relevant guidance and Contact person
9–6		IEC 60601–2–36 (1997) Medical Electrical Equipment—Part 2–36: Particular Requirements for the Safety of Equipment for Extracorporeally Induced Lithotripsy	Title, Relevant guidance, CFR Citation, and Product Codes
9–7		IEC 61846 (1998) Ultrasonics—Pressure Pulse Lithotripters—Characteristics of Fields	Relevant guidance, CFR Citation, and Product Codes
9–21		ISO 8600–4:1997 Optics and Optical Instruments—Medical Endoscopes and Certain Accessories—Part 4: Determination of Maximum Width of Insertion Portion	Relevant guidance
9–23		ASTM F1518–00 Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera	Relevant guidance, CDRH Office and Division associated with recognized standard
9–25		AAMI / ANSI HF18:2001 Electrosurgical Devices	Withdrawn
9–28	9–47	ANSI/AAMI RD16:2007 Cardiovascular Implants and Artificial Organs—Hemodialyzers, Hemodiafilters, Hemofilters, and Hemoconcentrators	Withdrawn and replaced with newer version
9–29	9–48	AAMI / ANSI RD17 :2007 Cardiovascular Implants and artificial organs—Extracorporeal Blood Circuit for Hemodialyzers, Hemodiafilters, and Hemofilters	Withdrawn and replaced with newer version
9–32		ASTM D3492–03 Standard Specification for Rubber Contraceptives (Male Condoms)	Relevant guidance
9–34		ISO 4074:2002/Cor.1:2003(E) Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 1	Relevant guidance
9–37		ISO 8600–1:2005 Optics and Photonics—Medical Endoscopes and Endotherapy Devices—Part 1: General Requirements ISO 8600–1:2005	Relevant guidance
9–38		ISO 8600–3:1997 Amendment 1 2003, Optics and Optical Instruments—Medical Endoscopes and Endoscopic Accessories Part 3: Determination of Field of View and Direction of View of Endoscopes with Optics	Relevant guidance
9–39		ISO 8600–5:2005 Optics and Photonics—Medical Endoscopes and Endotherapy Devices—Part 5: Determination of Optical Resolution of Rigid Endoscopes with Optics	Relevant guidance
9–40		ISO 8600–6:2005 Optics and Photonics—Medical Endoscopes and Endotherapy Devices—Part 6: Vocabulary	Relevant guidance
9–41		ASTM D6324–05 Standard Test Methods for Male Condoms Made from Synthetic Materials	Relevant guidance
9–42		IEC 60601–2–18 (1996) Amendment 1 2000 Medical electrical equipment—Part 2: Particular Requirements for the Safety of Endoscopic Equipment	Relevant guidance
9–43		ISO 16038:2005 Rubber Condoms—Guidance on the Use of ISO 4074 in the Quality Management of Natural Rubber Latex Condoms	Relevant guidance
J. Ophthalmic			
10–21		ISO 11979–2:1999 Ophthalmic Implants—Intraocular Lenses—Part 2: Optical Properties and Test Methods	Withdrawn

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
10–23		ISO 11981:1999 Ophthalmic Optics—Contact Lenses and Contact Lens Care Products—Determination of Physical Compatibility of Contact Lens Care Products With Contact Lenses	Withdrawn
10–42		ISO 11979–2:1999/Corrigendum1:2003 Ophthalmic Implants—Intraocular Lenses—Part 2: Optical Properties and Test Methods	Extent of recognition and Process impacted
10–44		ISO 11981:1999/Corrigendum1:2005 Ophthalmic Optics—Contact Lenses and Contact Lens Car Products—Determination of Physical Compatibility of Contact Lens Care Products with Contact Lenses	Relevant guidance and Process impacted
K. Orthopedic			
11–73		ISO 5838–1:1995 Implants for Surgery—Skeletal Pins and Wires—Part 1: Material and Mechanical Requirements	Type of standard and Contact person
11–74		ISO 5838–2:1991 Implants for Surgery—Skeletal Pins and Wires—Part 2: Steinmann Skeletal Pins—Dimensions	Type of standard and Contact person
11–75		ISO 5838–3:1993 Implants for Surgery—Skeletal Pins and Wires—Part 3: Kirschner Skeletal Wires	Type of standard and Contact person
11–79		ISO 7206–8:1995 Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion	Type of standard, CFR Citation, Product codes and Relevant guidance
11–80		ISO 8828:1988 Implants for Surgery—Guidance on Care and Handling of Orthopaedic Implants	Contact person Processes Impacted
11–81	8–157	ISO 9583:1993 Implants for Surgery—Non-Destructive Testing—Liquid Penetrant Inspection of Metallic Surgical Implants	Transferred
11–82	8–159	ISO 9584:1993 Implants for Surgery—Non-Destructive Testing—Radiographic Examination of Cast Metallic Surgical Implants	Transferred
11–155		ISO 7207–2:1998 Implants for Surgery—Components for Partial and Total Knee Joint Prostheses—Part 2: Articulating Surfaces Made of Metal, Ceramic and Plastics Materials	Type of standard and Relevant guidance
11–164	11–203	ASTM F1541–02(2007) Standard Specification and Test Methods for External Skeletal Fixation Devices	Withdrawn and replaced with newer version
11–166	11–204	ASTM F0897–02(2007) Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	Withdrawn and replaced with newer version
11–168		ASTM F1781–03 Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Type of standard
11–171		ASTM F1814–97a(2003) Standard Guide for Evaluating Modular Hip and Knee Joint Components	Type of standard and Relevant guidance
11–172		ASTM F1798–97(2003) Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Type of standard and Relevant guidance
11–175		ASTM F1582–98(2003) Standard Terminology Relating to Spinal Implants	Type of standard, CFR Citation, Product codes and Relevant guidance
11–177	11–205	ASTM F1264–03(2007) Standard Specification and Test Methods for Intramedullary Fixation Devices	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
11–178		ASTM F1440–92(2002) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion	Processes impacted, Type of standard, CFR Citation, Product codes and Relevant guidance
11–179		ASTM F2068–03 Standard Specification for Femoral Prostheses—Metallic Implants	Processes impacted, Type of standard, CFR Citation, Product codes and Relevant guidance
11–180		ASTM F0366–04 Standard Specification for Fixation Pins and Wires	Type of standard and Contact person
11–181		ASTM F1717–04 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Type of standard and Relevant guidance
11–182	11–206	ASTM F1800–07 Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Withdrawn and replaced with newer version
11–183		ASTM F1875–98(2004) Standard Practice for Fretting Corrosion Testing of Modular Implant Interfaces: Hip Femoral Head-Bore and Cone Taper Interface	Type of standard, CFR Citations, Product codes and Relevant guidance
11–184		ISO 8827:1988 Implants for surgery—Staples with Parallel Legs for Orthopaedic Use—General Requirements	Type of standard and Contact person
11–185		ASTM F2267–04 Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device Under Static Axial Compression	CFR Citations, Product codes and Relevant guidance
11–186		ASTM F2077–03 Test Methods for Intervertebral Body Fusion Devices	Type of standard, CFR Citations, Product codes and Relevant guidance
11–187	11–207	ASTM F2193–02(2007) Standard Specifications and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System	Withdrawn and replaced with newer version
11–188		ISO 14243–1:2002 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	Type of standard, CFR Citations and Product codes
11–189		ISO 14243–2:2000 Implants for Surgery—Wear of Total Knee-Joint Prostheses—Part 2: Methods of Measurement	Type of standard, Extent of recognition, CFR Citations and Product codes
11–190		ISO 14243–3:2004 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	Type of standard, CFR Citations and Product codes
11–191		ISO 14879–1:2000 Implants for Surgery—Total Knee-Joint Prostheses—Part 1: Determination of Endurance Properties of Knee Tibial Trays	Type of standard
11–192		ASTM F1223–05 Standard Test Method for Determination of Total Knee Replacement Constraint	Type of standard CFR Citations and Product codes
11–194	11–208	ISO 14630:2008 Non-Active Surgical Implants—General Requirements—3d Edition	Withdrawn and replaced with newer version
11–195		ASTM F1612–95(2005) Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components with Torsion	Type of standard, CFR Citations, Product codes and Relevant guidance
11–196		ASTM F1672–95(2005) Standard Specification for Resurfacing Patellar Prosthesis	Type of standard and Relevant guidance

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
11–197		ASTM F0983–86(2005) Standard Practice for Permanent Marking of Orthopaedic Implant Components	Contact person and Processes impacted
11–198		ASTM F0382–99(2003)e1 Standard Specification and Test Method for Metallic Bone Plates	Type of standard and Contact person
11–199		ASTM F0565–04 Standard Practice for Care and Handling of Orthopedic Implants and Instruments	Contact person and Processes impacted
11–200	11–209	ASTM F2083–07 Standard Specification for Total Knee Prosthesis	Withdrawn and replaced with newer version
11–201		ASTM F0564–02(2006) Standard Specification and Test Methods for Metallic Bone Staples	Contact person
11–202	11–210	ASTM F0543–07 Standard Specification and Test Methods for Metallic Medical Bone Screws	Withdrawn and replaced with newer version
L. Physical Medicine			
16–19		ISO 7176–4:1997 Wheelchairs—Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range	Contact person and Type of standard
16–20		ISO 7176–5:1986 Wheelchairs—Part 5: Determination of Overall Dimensions, Mass and Turning Space	Contact person and Type of standard
16–23		ISO 7176–10:1988 Wheelchairs—Part 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs	Contact person and Type of standard
16–24		ISO 7176–11:1992 Wheelchairs—Part 11: Test Dummies	Contact person and Type of standard
16–25		ISO 7176–13:1989 Wheelchairs—Part 13: Determination of Coefficient of Friction of Test Surfaces	Contact person and Type of standard
16–26		ISO 7176–14:1997 Wheelchairs—Part 14: Power and Control Systems for Electric Wheelchairs—Requirements and Test Methods	Contact person and Type of standard
16–27		ISO 7176–15:1996 Wheelchairs—Part 15: Requirements for Information Disclosure, Documentation and Labeling	Contact person and Type of standard
16–28		ISO 7176–16: 1997 Wheelchairs—Part 16: Resistance to Ignition of Upholstered Parts—Requirements and Test Methods	Contact person and Type of standard
16–29		ISO 7176–6:2001 Wheelchairs—Part 6: Determination of Maximum Speed, Acceleration and Deceleration of Electric Wheelchairs	Contact person and Type of standard
16–30		ISO 7176–9:2001 Wheelchairs—Part 9: Climatic Tests for Electric Wheelchairs	Contact person and Type of standard
16–31		ANSI/RESNA WC/Volume 1–1998 Section 1: Determination of Static Stability	Contact person and Type of standard
16–32		ANSI/RESNA WC/Volume 2–1998 Section 2: Determination of Dynamic Stability of Electric Wheelchairs	Contact person and Type of standard
16–33		ANSI/RESNA WC/Volume 2–1998 Section 3: Test Methods and Requirements for the Effectiveness of Brakes	Contact person and Type of standard
16–34		ANSI/RESNA WC/Volume 2–1998 Section 4: Determination of Energy Consumption of Electric Wheelchairs	Contact person and Type of standard
16–35		ANSI/RESNA WC/Volume 1–1998 Section 5: Determination of Overall Dimensions, Mass, and Turning Space—Wheelchair	Contact person and Type of standard

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
16–36		ANSI/RESNA WC/Volume 2–1998 Section 6: Determination of Maximum Speed, Acceleration, and Retardation of Electric Wheelchairs	Contact person and Type of standard
16–37		ANSI/RESNA WC/Volume 1–1998 Section 7: Wheelchairs - Determination of Seating and Wheel Dimensions	Contact person and Type of standard
16–38		ANSI/RESNA WC/Volume 1–1998 Section 8: Wheelchairs—Static, Impact and Fatigue Strength Tests	Contact person and Type of standard
16–39		ANSI/RESNA WC/Volume 2 - 1998 Section 9: Climatic Tests for Electric Wheelchairs	Contact person and Type of standard
16–40		ANSI/RESNA WC/Volume 2 - 1998 Section 10: Determination of the Obstacle-Climbing Ability of Electric Wheelchairs	Contact person and Type of standard
16–41		ANSI/RESNA WC/Volume 1 - 1998 Section 11: Wheelchairs—Test Dummies	Contact person and Type of standard
16–42		ANSI/RESNA WC/Volume 1 - 1998 Section 13: Determination of Coefficient of Friction of Test Surfaces	Contact person and Type of standard
16–43		ANSI/RESNA WC/Volume 2 - 1998 Section 14: Wheelchairs—Testing of Power and Control Systems for Electric Wheelchairs	Contact person and Type of standard
16–44		ANSI/RESNA WC/Volume 1 - 1998 Section 15: Wheelchairs—Requirements for Information Disclosures, Documentation and Labeling	Contact person and Type of standard
16–45		ANSI/RESNA WC/Volume 1 - 1998 Section 16: Wheelchairs—Determination of Flammability	Title change, Contact person and Type of standard
16–46		ANSI/RESNA WC/Volume 1 - 1998 Section 20: Wheelchairs—Determination of the Performance of Stand-Up Wheelchairs	Contact person and Type of standard
16–47		ANSI/RESNA WC/Volume 1 - 1998 Section 22: Wheelchairs—Set Up Procedures	Contact person and Type of standard
16–48		ANSI/RESNA WC/Volume 1 - 1998 Section 93: Maximum Overall Dimensions	Contact person and Type of standard
16–49		ANSI/RESNA WC/Volume 1 - 1998 Section 0: Nomenclature, Terms, and Definitions	Contact person and Type of standard
16–50		ISO 7176–3:2003 Wheelchairs—Part 3: Determination of Effectiveness of Brakes	Contact person and Type of standard
16–158		ISO 7176–1:1999 Wheelchairs—Part 1: Determination of Static Stability	Contact person and Type of standard
16–159		ISO 7176–2:2001 Wheelchairs—Part 2: Determination of Dynamic Stability of Electric Wheelchairs	Contact person and Type of standard
M. Radiology			
12–17		NEMA MS 8–1993 (2000), Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems	Relevant guidance and Contact person
12–61	12–177	UL 122 (2007): Standard for Photographic Equipment—Ed. 5.0	Withdrawn and replaced with newer version
12–64	12–178	IEC 60601–2–45 Ed. 2.0, (2006) Medical Electrical Equipment—Part 2–45: Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices	Withdrawn and replaced with newer version

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
12–69		NEMA MS 6–1991 (R2000) Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images	Relevant guidance, Contact person and CFR Citations
12–95		NEMA MS 2–2003 Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images	Relevant guidance and Contact person
12–96		NEMA MS 3–2003 Determination of Image Uniformity in Diagnostic Magnetic Resonance Images	Relevant guidance and Contact person
12–97		NEMA MS–1–2001 Determination of Signal-to-Noise Ratio (SNR) in Diagnostic Magnetic Resonance Imaging	Relevant guidance, Contact person and CFR Citations
12–103	12–179	ANSI / IESNA RP–27.3–2007 Recommended Practice for Photobiological Safety for Lamps—Risk Group Classification and Labeling	Withdrawn and replaced with newer version
12–120		IEC 60601–2–44 (2002–11): Medical Electrical Equipment—Part 2–44: Particular Requirements for the Safety of X-ray Equipment for Computed Tomography—Ed. 2.1	Relevant guidance and CFR Citations
12–123	12–180	IEC 61689:2007 Ultrasonics—Physiotherapy Systems—Field Specifications and Methods of Measurement in the Frequency Range 0,5 MHz to 5 MHz Ed. 2.0	Withdrawn and replaced with newer version
12–125		NEMA MS 5–2003 Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging	Relevant guidance and Contact person
12–129	12–181	NU 1–2007 Performance Measurements of Gamma Cameras	Withdrawn and replaced with newer version
12–131	12–184	IEC 61217 2002 Consolidated Ed. 1.1, 2007 Amendment 2 Ed. 1.0 Radiotherapy Equipment—Coordinates, Movements, and Scales	Withdrawn and replaced with newer version
12–150		IEC / ISO 10918–1:1994 Technical Corrigendum 1:2005 Information Technology—Digital Compression and Coding of Continuous-Tone Still Images—Part 1: Requirements	Relevant guidance, Contact person, CFR Citations, Product code, and Devices affected
12–151		NEMA MS 4 (2006) Acoustic Noise Measurement Procedure for Diagnosing Magnetic Resonance Imaging Devices	Relevant guidance, Contact person and CFR Citations
12–158		NEMA MS 10–2006 Determination of Local Specific Absorption Rate (SAR) in Diagnostic Magnetic Resonance Imaging	Relevant guidance, Contact person and CFR Citations
12–159		NEMA MS 11–2006 Determination of Gradient-Induced Electric Fields in Diagnostic Magnetic Resonance Imaging	Relevant guidance, Contact person and CFR Citations
12–160		NEMA MS 12–2006 Quantification and Mapping of Geometric Distortion for Special Applications	Relevant guidance, Contact person and CFR Citations
12–161		IEC 60601–2–33 (2006), Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis	Relevant guidance and Contact person
12–164	12–182	IEC 60601–2–37:2007 Medical Electrical Equipment—Part 2–37: Particular Requirements for the Basic Safety and Essential Performance of Ultrasonic Medical Diagnostic and Monitoring Equipment	Withdrawn and replaced with newer version
12–165		NEMA XR 22–2006 "Quality Control Manual" Template for Manufacturers of Displays and Workstations Labeled for Final Interpretation in Full-Field Digital Mammography	Relevant guidance
12–166		NEMA XR 23–2006 "Quality Control Manual" Template for Manufacturers of Hardcopy Output Devices Labeled for Final Interpretation in Full-Field Digital Mammography	Relevant guidance
12–168		IEC 60825–1 Ed. 2.0 (2007) Safety of Laser Products—Part 1: Equipment Classification, and Requirements	Contact person and Processes impacted

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
12–169		IEC 60601–2–22 Ed. 3.0 (2007) Medical Electrical Equipment—Part 2–22: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment	Contact person, Processes impacted and Title
12–170	12–183	NEMA PS 3.1 - 3.18 (2008) Digital Imaging and Communications in Medicine (DICOM) Set	Withdrawn and replaced with newer versions
5–7	12–185	IEC 60601–1–3 2008 Edition 2.0 Medical Electrical Equipment—Part 1–3:General Requirements for Basic Safety and Essential Performance—Collateral Standard: Radiation Protection in Diagnostic X-ray Equipment	Transferred
N. Software/Informatics			
13–4		ANSI/UL 1998, Software in Programmable Components	CFR Citations, Product codes, Relevant guidance and Extent of recognition
13–5		IEEE 1074:1997, Standard for Developing Software Life Cycle Processes	Withdrawn
13–8		IEC 62304 Ed. 1.0, Medical Device Software—Software Life Cycle Processes	CFR Citations, Product codes, Relevant guidance, and Extent of recognition
7–59	13–9	CLSI AUTO2–A2 Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard	Transferred
7–60	13–10	CLSI AUTO1–A Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard	Transferred
7–61	13–11	CLSI AUTO3–A Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard	Transferred
7–62	13–12	CLSI AUTO4–A Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard	Transferred
7–63	13–13	CLSI AUTO5–A Laboratory Automation: Electromechanical Interfaces; Approved Standard	Transferred
7–64	13–14	CLSI POCT1–A2 Point-of-Care Connectivity; Approved Standard	Transferred
7–68	13–15	CLSI GP19–A2 Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition	Transferred
7–114	13–16	CLSI LIS01–A Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems	Transferred
7–115	13–17	CLSI LIS02–A2 Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard-Second Edition	Transferred
7–116	13–18	CLSI LIS03–A Standard Guide for Selection of a Clinical Laboratory Information Management System	Transferred
7–117	13–19	CLSI LIS04–A Standard Guide for Documentation of Clinical Laboratory Computer Systems	Transferred
7–118	13–20	CLSI LIS05–A Standard Specification for Transferring Clinical Observations Between Independent Computer Systems	Transferred
7–119	13–21	CLSI LIS06–A Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems	Transferred

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
7–120	13–22	CLSI LIS07–A Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory	Transferred
7–121	13–23	CLSI LIS08–A Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems	Transferred
7–122	13–24	CLSI LIS09–A Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures	Transferred
O. Sterility			
14–24		AAMI/ANSI/ISO 11134:1993 Sterilization of Health Care Products—Requirements for Validation and Routine Control-Industrial Moist Heat Sterilization	Withdrawn
14–53		AAMI/ANSI ST66:1996 Sterilization of Health Care Products—Chemical Indicators—Part 2: Indicators for Air Removal Test Sheets and Packs	Withdrawn
14–54		AAMI/ANSI/ISO 11737–2:1998 Sterilization of Medical Devices—Microbiological Methods—Part 2: Tests of Sterility Performed in the Validation of a Sterilization Process	CFR Citations, Product codes and Devices affected
14–55		AAMI/ANSI/ISO 14160:1998 Sterilization of Single-Use Medical Devices Incorporating Materials of Animal Origin—Validation and Routine Control of Sterilization by Liquid Chemical Sterilants	Relevant guidance
14–60		ASTM F1327:1998 Standard Terminology Relating to Barrier Materials for Medical Packaging	Withdrawn
14–63		ASTM F1886: 1998 (2004) Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	CFR Citations and Product codes
14–64		ASTM F1929:1998 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	CFR Citations and Product codes
14–70		AAMI/ANSI/ISO 14161:2000 Sterilization of Health Care Products—Biological Indicators—Guidance for the Selection, Use and Interpretation of Results, 2ed.	CFR Citations, Product codes and Devices affected
14–76		AAMI/ANSI/ISO 10993–7:1995 (R) 2001 Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	CFR Citations, Product codes and Contact person
14–88		AAMI/ANSI/ISO 14937:2000 Sterilization of Health Care Products—General Requirements for Characterization of a Sterilizing Agent and the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	CFR Citations and Product codes
14–90	14–256	ASTM F2095–07 Standard Test Methods for Pressure Decay Leak Test for Nonporous Flexible Packages With and Without Restraining Plates	Withdrawn and replaced with newer version
14–116		AAMI ST72:2002 Bacterial endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	CFR Citations, Product codes, Type of standard, Guidance and Extent of recognition
14–120		ASTM D3078:2002 Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	CFR Citations, Product codes and Type of standard
14–123		ASTM F2096–04 Standard Test Method for Detecting Gross Leaks in Medical Packaging by Internal Pressurization (Bubble Test)	CFR Citations, Product codes, CDRH Office and Division associated with recognized standard

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
14–135		AAMI/ANSI ST63:2002 Sterilization of Health Care Products—Requirements for the Development, Validation and Routine Control of an Industrial Sterilization Process for Medical Devices—Dry Heat	CFR Citations, Product codes and Type of standard
14–136		AAMI/ANSI ST67:2003 Sterilization of Health Care Products—Requirements for Products Labeled 'Sterile' 1st Edition	CFR Citations, Product codes and Guidance
14–138		ISO 13408–2:2003 Aseptic Processing of Health Care Products—Part 2: Filtration	CFR Citations, Product codes, Type of standard and Guidance
14–139		ISO 14644–1:1999 Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness	CFR Citations, Product codes and Type of standard
14–140		ISO 14644–2:2000 Cleanrooms and Associated Controlled Environments—Part 2: Specification for Testing and Monitoring to Prove Continued Compliance With ISO 14644–1	CFR Citations, Product codes and Type of standard
14–141		ISO 14644–4:2001 Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction and Startup	CFR Citations, Product codes and Type of standard
14–142		ISO 14698–1:2003 Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 1: General Principles and Methods	CFR Citations, Product codes and Type of standard
14–143		ISO 14698–2:2003 Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 2: Evaluation and Interpretation of Biocontamination Data	CFR Citations, Product codes and Type of standard
14–148		ASTM F2250–03 Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	CFR Citations, Product codes and Type of standard
14–149		ASTM F2251–03e1 Standard Test Method for Thickness Measurement of Flexible Packaging Material	CFR Citations, Product codes and Type of standard
14–150		ASTM F2252–03 Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	CFR Citations, Product codes and Type of standard
14–164		AAMI/ANSI ST81:2004 Sterilization of Medical Devices—Information to be Provided by the Manufacturer for the Processing of Resterilizable Devices	CFR Citations, Product codes, and Devices affected
14–165		ISO 14644–5:2004 Cleanrooms and Associated Controlled Environments—Part 5: Operations	CFR Citations, Product codes and Type of standard
14–166		ISO 14644–7:2004 Cleanrooms and Associated Controlled Environments—Part 7: Separative Devices (Clean Air Hoods, Gloveboxes, Isolators and Mini-Environments)	CFR Citations, Product codes and Type of standard
14–168	14–245	ASTM F2338–07 Standard Test Method for Nondestructive Detection of Leaks in Packages by Vacuum Decay Method	Withdrawn and replaced with newer version
14–169		ASTM F2391–05 Standard Test Method for Measuring Package and Seal Integrity Using Helium as Tracer Gas	CFR Citations, Product codes and Type of standard
14–170		ASTM F2475–05 Standard Guide for Biocompatibility Evaluation of Medical Device Packaging Materials	CFR Citations, Product codes and Type of standard
14–191		ISO 13408–4:2005 Aseptic Processing of Health care Products—Part 4: Clean-in-Place Technologies	CFR Citations, Product codes, Type of standard and Relevant guidance
14–193		AAMI/ANSI/ISO 11607–1:2006 Packaging for terminally Sterilized Medical Devices—Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems, 3d ed.	CFR Citations, Product codes, Devices affected and Relevant guidance

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
14–194		AAMI/ANSI/ISO 11607–2:2006 Packaging for Terminally Sterilized Medical Devices—Part 2: Validation Requirements for Forming, Sealing and Assembly Processes, 1st ed.	CFR Citations, Product codes, Devices affected and Relevant guidance
14–197		ASTM F1608:00(2004) Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	CFR Citations and Product codes
14–199		ASTM D4169–05 Standard Practice for Performance Testing of Shipping Containers and Systems	Related CFR Citations and Product codes
14–202	14–246	USP 31:2008 Biological Indicator for Dry-Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14–203	14–247	USP 31:2008 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier.	Withdrawn and replaced with newer version
14–204	14–248	USP 31:2008 Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version
14–205	14–249	USP 31:2008 <61> Microbial Limits Test	Withdrawn and replaced with newer version
14–206	14–250	USP 31:2008 <71> Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version
14–207	14–251	USP 31:2008 <85> Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version
14–208	14–252	USP 31:2008 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version
14–209	14–253	USP 31:2008 <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version
14–210	14–254	USP 31:2008 Biological Indicator for Steam Sterilization—Self Contained	Withdrawn and replaced with newer version
14–220		AAMI/ANSI ST79:2006 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities	Type of Standard
14–221		AAMI/ANSI/ISO TIR 11139:2006 Sterilization of Health Care Products—Vocabulary	CFR Citations, Product codes, Title, Devices affected, and Type of standard
14–222		AAMI/ANSI/ISO 18472:2006 Sterilization of Health Care Products—Biological and Chemical Indicators—Test Equipment	Type of standard
14–223		ANSI/AAMI/ISO 11138–1:2006 Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	Type of standard, Guidance and Extent of recognition
14–224		AAMI/ANSI/ISO 11137–1:2006 Sterilization of Health Care Products—Radiation—Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	CFR Citations, Product codes, and Type of standard
14–225		AAMI/ANSI/ISO 11137–2:2006 Sterilization of Health Care Products—Radiation—Part 2: Establishing the Sterilization Dose	CFR Citations, Product codes and Type of standard
14–226		AAMI/ANSI/ISO 11137–3:2006 Sterilization of Health Care Products—Radiation—Part 3: Guidance on Dosimetric Aspects	CFR Citations, Product codes and Type of standard

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
14–227		AAMI/ANSI/ISO 11737–1:2006 Sterilization of Medical Devices-Microbiological Methods-Part 1: Determination of the Population of Microorganisms on Products, 2d, ed.	CFR Citations, Product codes, Devices affected, CDRH Office and Division associated with recognized standard
14–228		ANSI/AAMI/ISO 11135–1:2007 Sterilization of Health Care Products—Ethylene Oxide—Part 1: Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	CFR Citations, Product codes, Devices affected, and Type of standard
14–229		ASTM F1980–07 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices	CFR Citations and Product codes
14–230		ASTM F2203–02(2007) Standard Test Method for Linear Measurement Using Precision Steel Rule	CFR Citations, Product codes and Type of standard
14–231		ASTM F2217–02(2007) Standard Practice for Coating/Adhesive Weight Determination	CFR Citations, Product codes and Type of standard
14–232		ASTM F2227–02(2007) Standard Test Method for Non-Destructive Detection of Leaks in Non-Sealed and Empty Medical Packaging Trays by CO2 Tracer Gas Method	CFR Citations, Product codes and Type of standard
14–233		ASTM F2228–02(2007) Standard Test Method for Non-Destructive Detection of Leaks in Medical Packaging Which Incorporates Porous Barrier Material by CO2 Tracer Gas Method	CFR Citations, Product codes and Type of standard
14–234		ASTM F2097–07 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	CFR Citations, Product codes and Type of standard
14–235		ASTM F1140–07 Standard Test Methods for Internal Pressurization Failure Resistance of Unrestrained Packages	CFR Citations, Product codes and Type of standard
14–236		ASTM F2054–07 Standard Test Method for Burst Testing of Flexible Package Seals Using Internal Air Pressurization Within Restraining Plates	CFR Citations, Product codes and Type of standard
14–237		ASTM F88–07 Standard Test Method for Seal Strength of Flexible Barrier Materials	CFR Citations, Product codes and Type of standard
14–239		ISO 13408–3:2006 Aseptic Processing of Health Care Products—Part 3: Lyophilization	CFR Citations and Product codes
14–240		ISO 13408–5:2006 Aseptic Processing of Health Care Products—Part 5: Sterilization-in-Place	CFR Citations and Product codes
14–241		ISO 13408–6:2005 Aseptic Processing of Health Care Products—Part 6: Isolator Systems	CFR Citations and Product codes
14–242		ISO 14644–3:2005 Cleanrooms and Associated Controlled Environments—Part 3: Test Methods	CFR Citations and Product codes
14–243		ISO 14644–6:2007 Cleanrooms and Associated Controlled Environments—Part 6: Vocabulary	CFR Citations and Product codes
14–244		ISO 14644–8:2006 Cleanrooms and Associated Controlled Environments—Part 8: Classification of Airborne Molecular Contamination	CFR Citations and Product codes
P. Tissue Engineering			
15–12		ASTM F2103–01(2007)e1 Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Standard	Change
15–5		ASTM F2347–03, Standard Guide for Characterization and Testing of Hyaluronan as Starting Materials Intended for Use in Biomedical and Tissue Engineered Medical Product Applications	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–6		ASTM F2450–04, Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–7		ASTM F2315–03, Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–8		ASTM F2064–00(2006), Standard Guide for Characterization and Testing of Alginates as Starting Materials Intended for use in Biomedical and Tissue-Engineered Medical Products Application	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–9		ASTM F2311–06, Standard Guide for Classification of Therapeutic Skin Substitutes	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–10		ASTM F2451–05, Standard Guide for in vivo Assessment of Implantable Devices Intended to Repair or Regenerate Articular Cartilage	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard
15–11		ASTM F2212–02(2007)e1, Standard Guide for Characterization of Type I Collagen as a Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products	CFR Citations and Product codes, Relevant guidance, Type of standard and CDRH Office and Division associated with recognized standard

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 020.

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of Standard	Reference No. and Date
A. Biocompatibility		
2–127	Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Delayed-Type Hypersensitivity—Amendment 1	ANSI/AAMI BE 78:2002/A1:2006
B. Cardiovascular/Neurology		
3–70	Manual, Electronic or Automated Sphygmomanometers	ANSI/AAMI SP10:2002/A1:2003—Amendment 1 to ANSI/AAMI SP10:2002
3–71	Manual, Electronic and Automated Sphygmomanometers	ANSI/AAMI SP10:2002/A2:2006—Amendment 2 to ANSI/AAMI SP10:2002
C. Dental/ Ear, Nose, and Throat		
4–151	Dentistry—Artificial Teeth for Dental Prostheses	ISO 22112:2005

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of Standard	Reference No. and Date
4–152	Metal-Ceramic Dental Restorative Systems	ISO 9693:1999/Amendment 1:2005
4–154	Dentistry—Elastometric Impression Materials-Third Edition	ISO 4823:2000
4–155	Dentistry—Elastomeric Impression Materials Technical Corrigendum 1–Third Edition	ISO 4823:2000 Technical Corrigendum 1:2004
4–156	Dentistry—Elastomeric Impression Materials Amendment 1–Third Edition	ISO 4823:2000 Amendment 1:2007
4–157	Dentistry—Zinc Oxide/Eugenol and Zinc Oxide/Non-eugenol Cements-Third Edition	ISO 3107: 2004
4–158	Dentistry—Soft Lining Materials for Removable Dentures—Part 1: Materials for Short-Term Use Technical Corrigendum 1	ISO 10139–1:2005 Technical Corrigendum 1:2006
D. General Hospital/ General Plastic Surgery		
6–214	Standard Test Method for Human Repeat Insult Patch Testing of Medical Gloves	ASTM D6355–07
E. In Vitro Diagnostic		
7–160	Abbreviated Identification of Bacteria and Yeast; Approved Guideline	CLSI M35–A,
7–161	Laboratory Detection and Identification of Mycobacteria; Proposed Guideline.	CLSI M48–P
7–162	Point-of-Care Monitoring of Anticoagulant Therapy; Approved Guideline	CLSI H49–A
7–163	Body Fluid Analysis for Cellular Composition	CLSI H56–A
7–164	Microwave Device Use in the Histology Laboratory; Approved Guideline	CLSI GP28–A
7–165	Reference Leukocyte (WBC) Differential Count (Proportional) and Evaluation of Instrumental Methods; Approved Standard-Second Edition	CLSI H20–A2
7–166	Fine Needle Aspiration Biopsy (FNAB) Techniques; Approved Guideline—Second Edition	CLSI GP20–A2
7–167	Nongynecologic Cytologic Specimens: Collection and Cytopreparatory Techniques; Approved Guideline	CLSI GP23–A
7–168	Reference Method for Broth Dilution Antifungal Susceptibility Testing of Filamentous Fungi; Approved Standard	CLSI M38–A
F. Materials		
8–161	Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials	ASTM F2516–07
G. OB-GYN/Gastroenterology		
9–46	Medical Electrical Equipment—Part 2–2: Particular Requirements for the Safety of High Frequency Surgical Equipment	ANSI/AAMI 60601–2–2:2006
9–49	Concentrates for Hemodialysis	AAMI / ANSI RD61:2006
9–50	Dialysate for Hemodialysis	ANSI/AAMI RD52:2004
9–51	Cardiovascular Implants and Artificial Organs—Haemodialysers, Haemodiafilters, Haemofilters and Haemoconcentrators	ISO 8637:2004
9–52	Cardiovascular Implants and Artificial Organs—Extracorporeal Blood Circuit for Haemodialysers, Haemodiafilters and Haemofilters	ISO 8638:2004
9–53	Standard Practice for Reprocessing of Reusable, Heat-Stable Endoscopic Accessory Instruments (EAI) Used with Flexible Endoscopes	ASTM F1992–99(2007)
9–54	Standard Specification for Rubber Contraceptives—Vaginal Diaphragms	ASTM D6976–08
H. Ophthalmic		
10–56	Ophthalmics Multifocal Intraocular Lenses	ANSI Z80.12–2007

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of Standard	Reference No. and Date
10–57	Phakic Intraocular Lenses	ANSI Z80.13–2007
I. Physical Medicine		
16–161	Safety Standard for Platform Lifts and Stairway Chairlifts	ASME A18.1–2005
J. Sterility		
14–255	Standard Terminology Relating to Flexible Barrier Packaging	ASTM F17–07a

IV. List of Recognized Standards

FDA maintains the agency's current list of FDA recognized consensus standards in a searchable database that may be accessed directly at FDA's Internet site at *http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm*. FDA will incorporate the modifications and minor revisions described in this notice into the database and, upon publication in the **Federal Register**, this recognition of consensus standards will be effective. FDA will announce additional modifications and minor revisions to the list of recognized consensus standards, as needed, in the **Federal Register** once a year, or more often, if necessary.

V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under the new provision of section 514 of the act by submitting such recommendations, with reasons for the recommendation, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). To be properly considered such recommendations should contain, at a minimum, the following information: (1) Title of the standard, (2) any reference number and date, (3) name and address of the national or international standards development organization, (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply, and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

Persons interested in obtaining a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions [including lists of approved applications and manufacturers' addresses], small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available at *http://www.regulations.gov*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/cdrh/fedregin.html*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) written or electronic comments regarding this document. Two copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. 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: 020. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: August 27, 2008.

Daniel G. Schultz,

Director, Center for Devices and Radiological Health.

[FR Doc. E8–20939 Filed 9–8–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0043]
[FDA No. 225–08–8001]

Memorandum of Understanding Between the Food and Drug Administration and the University of Pennsylvania

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is providing notice of a memorandum of understanding (MOU) between FDA and the University of Pennsylvania (Penn). The purpose of this MOU is to establish terms of collaboration between FDA and Penn focused primarily but not exclusively, in the areas of translational therapeutics, diagnostics, bioinformatics, new clinical trial models, drug/device co-development, and pharmacoepidemiology. Beyond the collaborations in the traditional academic programs for training, research, and outreach, this MOU will also include collaborations with Penn extended partnerships such as the Institute for Translational Medicine and Therapeutics which includes the Children's Hospital of Philadelphia, the Wistar Institute, and the University of Sciences in Philadelphia.

DATES: The agreement became effective on July 24, 2008.

FOR FURTHER INFORMATION CONTACT:

For FDA: Wendy R. Sanhai, Office of the Commissioner, Office of Scientific and Medical Programs (HF–18), Food and Drug