Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, 1350 Piccard Dr., Rockville, MD 20850–4307, Manufacturers Assistance: 800–638–2041 or 301–443–6597; or the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Submit telephone requests to 800–835–4709 or 301–827–1800. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Joseph Salewski, Center for Drug Evaluation and Research (HFD–45), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0020; or

Patricia Holobaugh, Center for Biologics Evaluation and Research (HFM–664), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–6347; or

John Murray, Jr., Center for Devices and Radiological Health (HFZ–340), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4646, ext. 107; or

John Welsh, Center for Food Safety and Applied Nutrition (HFS–205), Food and Drug Administration, 1110 Vermont Ave., NW, Washington, DC 20005, 202–418–3057; or

Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20835, 301–827–0312; or

James McCormack, Office of Enforcement (HFC–230), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20857, 301–827–0425; or

Patricia Beers Block, Good Clinical Practice Programs (HF–34), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3340.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Computerized Systems Used in Clinical Trials.'' This document provides guidance about computerized systems that are used to create, modify, maintain, archive, retrieve, or transmit clinical data required to be maintained and/or submitted to FDA. These data form the basis for the agency's decisions regarding the safety and effectiveness of new human and animal drugs, biological products, medical devices, and certain food and color additives. As such, these data have broad public health significance and are expected to be of the highest quality and integrity.

This draft guidance, when finalized, will supercede the guidance of the same name issued in April 1999. This draft guidance is being revised to make it consistent with agency policy as reflected in the guidance for industry on ''Part 11, Electronic Records; Electronic Signatures—Scope and Application,'' which issued in August 2003. It also reflects policy consistent with regard to the agency's international harmonization efforts.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on computerized systems used in clinical trials. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if the approach satisfies the requirements of the applicable statute and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of any 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet at *http://www.fda.gov/cder/guidance/index.htm, http://www.fda.gov/cber/guidelines.htm, http://www.fda.gov/cvm/guidance/guidance.html*, and *http://www.fda.gov/oc/gcp/draft.html*.

Dated: September 28, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22204 Filed 9–29–04; 1:51 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0226]

Food and Drug Administration Modernization Act of 1997; Modifications to the List of Recognized Standards, Recognition List Number: 011

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: 011'' (Recognition List Number: 011), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

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

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of ''Modifications to the List of Recognized Standards, Recognition List Number: 011'' to the Division of Small Manufacturers Assistance, Center for Devices and Radiological Health (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 301–443–8818. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by e-mail: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/cdrh/fedregin.html*. 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: 011 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, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext.156.

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 notice described how FDA will implement its standard recognition program and provided the initial list of FDA recognized consensus standards.

In **Federal Register** notices published on October 16, 1998 (63 FR 55617), July 12, 1999 (64 FR 37546), November 15, 2000 (65 FR 69022), May 7, 2001 (66 FR 23032), January 14, 2002 (67 FR 1774), October 2, 2002 (67 FR 61893), April 28, 2003 (68 FR 22391), March 8, 2004 (69 FR 10712), and June 18, 2004 (69 FR 34176), FDA modified its initial list of FDA recognized consensus standards. These notices described 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 Recognition List Number: 011

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the agency will recognize for use in satisfying premarket reviews and other requirements for devices. FDA will incorporate these modifications in the list of FDA recognized consensus standards in the agency's searchable database. FDA will use the term ''Recognition List Number: 011'' to identify these current modifications.

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

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

TABLE 1.

Old Item No.	Standard	Change	Replacement Item No.
A. Anesthesia			
1	ASTM F920–93 (1999), Standard Specification for Minimum Performance and Safety Requirements for Resuscitators Intended for Use With Humans	Withdrawn and replaced with newer version	50
2	ASTM F1100–90 (1997), Standard Specification for Ventilators Intended for Use in Critical Care	Withdrawn and replaced with newer version	51
5	ASTM F1463–93 (1999), Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	Withdrawn and replaced with newer version	52
6	ASTM F1464–93 (1999), Standard Specification for Oxygen Concentrators for Domiciliary Use	Withdrawn and replaced with newer version	53
8	PVHO–1–2002, Safety Standard for Pressure Vessels for Human Occupancy	Withdrawn and replaced with newer version	54
23	ASTM F1054–01, Standard Specification for Conical Fittings	Withdrawn and replaced with newer version	55
24	ASTM F1456–01, Standard Specification for Minimum Performance and Safety Requirements for Capnometers	Withdrawn and replaced with newer version	59
25	ASTM F1462–93, Specification for Oxygen Analyzers	Withdrawn	
34	ASTM PS127: 2000, Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	Withdrawn	
40	CGA V–7.1: 1997 (reaffirmed 2003), Standard Method for Determining Cylinder Valve Outlet Connections for Medical Gases	Withdrawn and replaced with newer version	56
45	ASTM 1101–90 (2003) e1, Standard Specification for Ventilators Intended for Use During Anesthesia	Withdrawn and replaced with newer version	57
B. Cardiovascular/Neurology			

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
1	ANSI/AAMI EC12: 2000, Disposable Electrocardiogram (ECG) Electrodes	Withdrawn and replaced with newer version	52
4	AAMI SP10: 1992, Electronic or Automated Sphygmomanometers	Change in processes affected and contact person	
44	ANSI/AAMI BP22: 1994 (R2001), Blood Pressure Transducers	Change in processes affected and contact person	
C. Dental/Ear, Nose, and Throat			
22	ASTM/F1377–92, Standard Specification for Cobalt-Chromium-Molybdenum Powder for Coating of Orthopaedic Implants	Transfer to materials	
42	ANSI/ADA Specification No. 3: 1994, Dental Impression Compound	Withdrawn	
43	ANSI/ADA Specification No. 5: 1997, Dental Casting Alloys	Change date of standard	
44	ANSI/ADA Specification No. 11: 1997, Agar Impression Material	Withdrawn and replaced with newer version	110
45	ANSI/ADA Specification No. 13: 1999, Dental Cold-Curing Repair Resin	Withdrawn and replaced with newer version	111
48	ANSI/ADA Specification No. 16: 1999, Dental Impression Paste Zinc Oxide-Eugenol Materials	Withdrawn and replaced with newer version	112
51	ANSI/ADA Specification No. 20: 1995, Dental Duplicating Material	Withdrawn and replaced with newer version	113
55	ANSI/ADA Specification No. 48: 1989, Ultraviolet Activator and Disclosing Lights	Withdrawn and replaced with newer version	114
67	ISO 6871–1: 1994, Dental Base Metal Casting Alloys—Part 1: Cobalt-Based Alloys—Technical Corrigendum 1: 1998	Title correction	
80	ISO 9917–1: 2003, Dental Water Based Cements—Part 1: Powder/Liquid Acid-Base Cements—first edition	Withdrawn and replaced with newer version	115
81	ISO 10139–1: 1999, Dentistry—Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	Withdrawn and replaced with newer version	116
90	ANSI/ASA S3.39: 1987 (R2002), Specification for Instruments to Measure Aural Acoustic Impedance and Admittance (Aural Acoustic Immittance)	Change date of standard	
103	ANSI/ADA Specification No. 12: 2002, Denture Base Polymers	Withdrawn and replaced with newer version	117
105	ANSI/ADA Specification No. 75: 1997 (R2003), Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	Title correction	
106	ANSI/ADA Specification No. 82: 2003, Dental Reversible/Irreversible Hydrocolloid Impression Material System	Withdrawn and replaced with newer version	119
108	ISO 10139–2: 1999, Dentistry—Soft Lining Materials for Removable Dentures—Part 2: Materials for Long-Term Use	Withdrawn and replaced with newer version	120
D. General			
10	AAMI/ISO 14971–1, Medical Devices—Risk Management—Part 1: Application of Risk Analysis	Withdrawn	
21	CEN EN 1441: 1997, Medical Devices—Risk Management	Withdrawn	
E. In Vitro Diagnostic			
23	NCCLS H1–A5, Tubes and Additives for Venous Blood Specimen Collection; Approved Standard	Withdrawn and replaced with newer version	102

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
69	NCCLS H3–A5, Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture; Approved Standard	Withdrawn and replaced with newer version	103
24	NCCLS H7–A3, Procedure for Determining Packed Cell Volume by the Microhematocrit Method; Approved Standard—third edition	Withdrawn and replaced with newer version	104
33	NCCLS H30–A2, Procedure for the Determination of Fibrinogen in Plasma; Approved Guideline—second edition	Withdrawn and replaced with newer version	105
57	NCCLS M2–A8, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard—eighth edition	Withdrawn and replaced with newer version	106
75	NCCLS M11–A6, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically, Approved Standard—sixth edition	Withdrawn and replaced with newer version	107
56	NCCLS M7–A6, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard—sixth edition	Withdrawn and replaced with newer version	108
F. Materials			
5	ASTM F138–03, Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Withdrawn and replaced with newer version	76
6	ASTM F139–03, 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 version	77
7	ASTM F560–04, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Withdrawn and replaced with newer version	78
13	ASTM F648–00e1, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Change date of standard	
16	ASTM F746–87 (1999), Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	Change in processes affected	
19	ASTM F961–03, Standard Specification for Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	Withdrawn and replaced with newer version	79
21	ASTM F1088–04, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Withdrawn and replaced with newer version	80
33	ASTM F1609–03, Standard Specification for Calcium Phosphate for Coatings for Implantable Materials	Withdrawn and replaced with newer version	81
34	ASTM F1659–95, Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates	Change in processes affected	
35	ASTM F1713–03, Standard Specification for Wrought Titanium-13 Niobium-13 Zirconium Alloy for Surgical Implant Applications	Withdrawn and replaced with newer version	82
40	ASTM F2063–00, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	Change in extent of recognition, contact person, and processes affected	
42	ASTM F2119–01, Standard Test Method for Evaluation of MR Image Artifacts From Passive Implants	Change in processes affected	
48	ASTM F899–02, Standard Specification for Stainless Steel for Surgical Instruments	Change in processes affected	
70	ASTM F2052–02, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment	Withdrawn	
72	ASTM F2213–04, Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	Change in processes affected	
Ortho #91	ASTM F561–97 (2003), Practice for Retrieval and Analysis of Implanted Medical Devices and Associated Tissues	Transferred to materials	73

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
Ortho #93	ASTM 601–03, Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Transferred to materials	94
Ortho #107	ASTM F1147–99, Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coating	Transferred to materials	84
Ortho/PM #113 Dental # 22	ASTM F1377–98a, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Transferred to materials	74
Ortho #124	ASTM F86–01, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Transferred to materials	93
Ortho #131	ASTM F1044–99, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Transferred to materials	83
Ortho #152	ASTM F1160–00e1, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Transferred to materials	75
Ortho #160	ASTM F629–02, Standard Practice for Radiography of Cast Metallic Surgical Implants	Transferred to materials	95
G. OB–GYN/Gastroenterology			
16	AAMI/ANSI ID54: 1996 (R)2001, Enteral Feeding Set Adapters and Connectors	Withdrawn and replaced with newer version	31
H. Orthopaedic			
58	ASTM F1781–03, Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Withdrawn and replaced with newer version	168
91	ASTM F561–97, Practice for Retrieval and Analysis of Implanted Medical Devices and Associated Tissues	Transferred to materials	73
93	ASTM F601–98, Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants	Transferred to materials	94
107	ASTM F1147–99, Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Transferred to materials	84
111	ASTM F1814–97a (2003), Standard Guide for Evaluating Modular Hip and Knee Joint Components	Withdrawn and replaced with newer version	171
113	ASTM F1377–98a, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Transferred to materials	74
114	ASTM F1798–97 (2003), Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Withdrawn and replaced with newer version	172
115	ASTM F1800–97 (2003), Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Withdrawn and replaced with newer version	173
120	ASTM F382–99 (2003), Standard Specification and Test Method for Metallic Bone Plates	Withdrawn and replaced with newer version	174
124	ASTM F86–01, Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Transferred to materials	93
131	ASTM F1044–99, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Transferred to materials	83
140	ASTM F1582–98 (2003), Standard Terminology Relating to Spinal Implants	Withdrawn and replaced with newer version	175
145	ASTM F565–00 (2003), Standard Practice for Care and Handling of Orthopedic Implants and Instruments	Withdrawn and replaced with newer version	176

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
152	ASTM F1160–00e1, Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Transferred to materials	75
160	ASTM F629–02, Standard Practice for Radiography of Cast Metallic Surgical Implants	Transferred to materials	95
161	ASTM F1264–03, Standard Specification and Test Methods for Intramedullary Fixation Devices	Withdrawn and replaced with newer version	177
165	ISO 7206–4: 2002, Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties of Stemmed Femoral Components	Withdrawn	
I. Physical Medicine			
1	ANSI/RESNA WC/volume—1998, Section 1: Determination of Static Stability	Withdrawn and replaced with newer version	31
2	ANSI/RESNA WC/volume 2—1998, Section 2: Determination of Dynamic Stability of Electric Wheelchairs	Withdrawn and replaced with newer version	32
3	ANSI/RESNA WC/volume 2—1998, Section 3: Test Methods and Requirements for the Effectiveness of Brakes	Withdrawn and replaced with newer version	33
4	ANSI/RESNA WC/volume 2—1998, Section 4: Determination of Energy Consumption of Electric Wheelchairs and Scooters—Theoretical Range	Withdrawn and replaced with newer version	34
5	ANSI/RESNA WC/volume 1—1998, Section 5: Determination of Overall Dimensions, Mass, and Turning Space	Withdrawn and replaced with newer version	35
6	ANSI/RESNA WC/volume 2—1998, Section 6: Determination of Maximum Speed, Acceleration, and Retardation of Electric Wheelchairs	Withdrawn and replaced with newer version	36
7	ANSI/RESNA WC/volume 1—1998, Section 7: Method of Measurement of Seating and Wheel Dimensions	Withdrawn and replaced with newer version	37
8	ANSI/RESNA WC/volume 1—1998, Section 8: Requirements and Test Methods for Static, Impact, and Fatigue Strengths	Withdrawn and replaced with newer version	38
9	ANSI/RESNA WC/volume 2—1998, Section 9: Climatic Tests for Electric Wheelchairs	Withdrawn and replaced with newer version	39
10	ANSI/RESNA WC/volume 2—1998, Section 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs	Withdrawn and replaced with newer version	40
11	ANSI/RESNA WC/volume 1—1998, Section 11: Test Dummies	Withdrawn and replaced with newer version	41
12	ANSI/RESNA WC/volume 1—1998, Section 13: Determination of Coefficient of Friction of Test Surfaces	Withdrawn and replaced with newer version	42
13	ANSI/RESNA WC/volume 2—1998, Section 14: Power and Control Systems for Electric Wheelchairs—Requirements and Test Methods	Withdrawn and replaced with newer version	43
14	ANSI/RESNA WC/volume 1—1998, Section 15: Requirements for Information Disclosure, Documentation, and Labeling	Withdrawn and replaced with newer version	44
15	ANSI/RESNA WC/volume 1—1998, Section 16: Resistance to Ignition of Upholstered Parts—Requirements and Test Methods	Withdrawn and replaced with newer version	45
18	ISO 7176–3: 2003, Wheelchairs—Part 3: Determination of Effectiveness of Brakes	Withdrawn and replaced with newer version	50
J. Radiology			
39	IEC 60601–2–17, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Remote-Controlled Automatically-Drive Gamma-Ray Afterloading Equipment (1989) Amendment No. 1 to IEC 601–2–17 (1996)	Withdrawn	
71	NEMA UD 2–2004, Revision 3: Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Withdrawn and replaced with newer version	105

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
72	NEMA UD 3–2004, Revision 2: Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	Withdrawn and replaced with newer version	100
78	NEMA PS 3, Set: Digital Imaging and Communications in Medicine (DICOM) Set	Withdrawn and replaced with newer version	119
86	IEC 60601–2–33 (2002–05), Medical Electrical Equipment—Part 2–33: Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis	Withdrawn and replaced with newer version	104
88	IEC 60601–2–17 (2004–01), Medical Electrical Equipment—Part 2–17: Particular Requirements for the Safety of Automatically-Controlled Brachytherapy Afterloading Equipment	Withdrawn and replaced with newer version	118
94	IEC 60731 Amendment 1 (2002–06), Medical Electrical Equipment—Dosimeters With Ionization Chambers as Used in Radiotherapy	Withdrawn and replaced with newer version	98
K. Sterility			
16	ANSI/AAMI ST35: 2003, Safe Handling and Biological Decontamination of Reusable Medical Devices in Health Care Facilities and in Nonclinical Settings	Withdrawn and replaced with newer version	117
17	ANSI/AAMI ST44: 1992, BIER/EO Gas Vessels	Withdrawn	
18	ANSI/AAMI ST45: 1992, BIER/Steam Vessels	Withdrawn	
20	ANSI/AAMI ST50: 2004, Dry Heat (Heated Air) Sterilizers	Withdrawn and replaced with newer version	118
21	ANSI/AAMI ST55: 2003, Table-Top Steam Sterilizers	Withdrawn and replaced with newer version	119
48	ANSI/AAMI ST40: 1992/(R)1998, Table-Top Dry Heat (Heated Air) Sterilizers and Sterility Assurance in Dental and Medical Facilities	Change in relevant guidance and contact person	
50	ANSI/AAMI ST42: 1998, Steam Sterilization and Sterility Assurance Using Table-Top Sterilizers in Office-Based, Ambulatory-Care Medical, Surgical, and Dental Facilities	Contact person	
52	ANSI/AAMI ST59: 1999, Sterilization of Health Care Products—Biological Indicators—Part 1: General Requirements	Change in relevant guidance	
53	ANSI/AAMI ST66: 1999, Sterilization of Health Care Products—Chemical Indicators—Part 2: Class 2 Indicators for Air Removal Test Sheets and Packs	Contact person	
56	ASTM D3078: 2002, Standard Test Method for Determination of Leaks in Flexible Packaging by Bubble Emission	Withdrawn and replaced with newer version	120
57	ASTM D4169: 2004, Standard Practice for Performance Testing of Shipping Containers and Systems	Withdrawn and replaced with newer version	121
58	ASTM F88: 2000, Standard Test Method for Seal Strength of Flexible Barrier Materials	Withdrawn and replaced with newer version	122
63	ASTM F1886: 1998 (2004), Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	Reaffirmation	
64	ASTM F1929: 1998 (2004), Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	Reaffirmation	
72	ANSI/AAMI ST33: 1996, Guidelines for the Selection and Use of Reusable Rigid Sterilization Container Systems for Ethylene Oxide Sterilization and Steam Sterilization in Health Care Facilities	Contact person	
74	ANSI/AAMI ST60: 1996, Sterilization of Health Care Products—Chemical Indicators—Part 1: General Requirements	Contact person	
75	ANSI/AAMI/ISO 11137: 1994, Sterilization of Health Care Products—Requirements for Validation and Routine Control—Radiation Sterilization and ANSI/AAMI/ISO 11137: 1994/Amendment 1: 2002	Change in title, relevant guidance, and contact person	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
91	ASTM F2096: 2004, Standard Test Method for Detecting Gross Leaks in Porous Medical Packaging by Internal Pressurization (Bubble Test)	Withdrawn and replaced with newer version	123
103	AAMI/ANSI/ISO 11607: 2000, Packaging for Terminally Sterilized Medical Devices	Change in relevant guidance	
105	ANSI/AAMI ST46: 2002, Steam Sterilization and Sterility Assurance in Health Care Facilities	Contact person	
106	USP 27: 2004, Biological Indicator for Dry Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	124
107	USP 27: 2004, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	125
108	USP 27: 2004, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	126
109	USP 27: 2004, <61> Microbial Limits Test	Withdrawn and replaced with newer version	127
110	USP 27: 2004, <71> Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	128
111	USP 27: 2004, <85> Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version	129
112	USP 27: 2004, <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	130
113	USP 27: 2004, <1211> Sterilization and Sterility Assurance of Compendial Articles	Withdrawn and replaced with newer version	131
114	USP 27: 2004, <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version	132
115	USP 27: 2004, Biological Indicator for Steam Sterilization—Self-Contained	Withdrawn and replaced with newer version	133
116	ANSI/AAMI ST72: 2002, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Change in relevant guidance	

III. Listing of New Entries

The listing of new entries and consensus standards added as modifications to the list of recognized standards, under Recognition List Number: 011, follows:

TABLE 2.

Item No.	Title of Standard	Reference No. and Date
A. Anesthesia		
58	Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Regulators Used for Medical and Emergency Applications	ASTM G175–03
B. Dental/ENT		
121	Dentistry—Dental Units—Part 2: Water and Air Supply	ISO 7494–2: 2003
C. General Hospital/General Plastic Surgery		
112	Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilitates	ANSI/AAMI PB70: 2003
113	Standard Specification for Performance of Materials Used in Medical Face Masks	ASTM F2100–04
D. Materials		

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
85	Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants	ASTM F1854–01
86	Standard Test Method for Evaluation of the Environmental Stability of Calcium Phosphate Coatings	ASTM F1926–03
87	Standard Test Method for Measuring Abrasion Resistance of Metallic Thermal Spray Coatings by Using the TaberT Abraser	ASTM F1978–00e1
88	Standard Practice for X-Ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	ASTM F2024–00
89	Standard Specification for High-Purity Dense Yttria Tetragonal Zirconium Oxide Polycrystal (Y–TZP) for Surgical Implant Applications	ASTM F1873–98
90	Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading	ASTM F2255–03
91	Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	ASTM F2256–03
92	Standard Test Method for Strength Properties of Tissue Adhesives in Tension	ASTM F2258–03
96	Standard Test Method for In Vitro Degradation Testing of Poly (L-lactic Acid) Resin and Fabricated Form for Surgical Implants	ASTM 1635–95 (2000)
97	Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	ASTM F2129–04
98	Standard Specification for Acrylic Bone Cement	ASTM F451–99ae1
99	Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis	ASTM F2004–03
100	Standard Terminology for Nickel-Titanium Shape Memory Alloys	ASTM F2005–00
101	Test Method for Constant Amplitude of Force Controlled Fatigue Testing of Acrylic Bone Cement Materials	ASTM F2118–03
102	Standard Test Method for Determination of Transformation Temperature of Nickel-Titanium Shape Memory Alloys by Bend and Free Recovery	ASTM F2082–03
E. OB–GYN/Gastroenterology		
30	Water Treatment Equipment for Hemodialysis Applications	ANSI/AAMI RD62: 2001
F. Ophthalmic		
33	Contact Lens Care Products—Vocabulary, Performance Specifications, and Test Methodology	ANSI Z80.18
G. Orthopaedic		
178	Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components Without Torsion	ASTM F1440–92 (2002)
179	Standard Specification for Femoral Prostheses—Metallic Implants	ASTM F2068–03
H. Physical Medicine		
46	Determination of Performance of Stand-Up Type Wheelchairs	ANSI/RESNA WC/volume 1—1998, section 20
47	Set Up Procedures	ANSI/RESNA WC/volume 1—1998, section 22
48	Maximum Overall Dimensions	ANSI/RESNA WC/volume 1—1998, section 93
49	Nomenclature, Terms, and Definitions	ANSI/RESNA WC/volume 1—1998, section 0
I. Radiology		

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
101	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—General Requirements	ANSI/ESNA RP–27.1.96
102	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Measurement Techniques	ANSI/ESNA RP–27.2.00
103	Recommended Practice for Photobiological Safety for Lamps and Lamp Systems—Risk Group Classification and Labeling	ANSI/ESNA RP–27.3.96
106	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Lifetime of Lasers	ISO 17526: 2003
107	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Beam Widths, Divergence Angle, and Beam Propagation Factor	ISO 11146: 1999
108	Lasers and Laser-Related Equipment—Determination of Laser-Induced Damage Threshold of Optical Surfaces—Part 1: 1-on-1 Test	ISO 11254–1: 2000
109	Lasers and Laser-Related Equipment—Determination of Laser-Induced Damage Threshold of Optical Surfaces—Part 2: S-on-1 Test	ISO 11254–2: 2001
110	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Method for Absorptance of Optical Laser Components (revision of ISO 11551: 1997)	ISO 11551: 2003
111	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Methods for Laser Beam Power, Energy, and Temporal Characteristics (revision of ISO 11554: 1998)	ISO 11554: 2003
112	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Beam Positional Stability (revision of ISO 11670: 1999)	ISO 11670: 2003
113	Lasers and Laser-Related Equipment—Test Methods for Laser Beam Parameters—Polarization (revision of ISO 12005: 1999)	ISO 12005: 2003
114	Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Methods for Laser Beam Power (Energy) Density Distribution	ISO 13694: 2000
115	Optics and Photonics—Lasers and Laser-Related Equipment—Test Methods for the Spectral Characteristics of Lasers	ISO 13695: 2004
116	Optics and Optical Instruments—Test Methods for Radiation Scattered by Optical Components	ISO 13696: 2002
117	Lasers and Laser-Related Equipment—Test Methods for Determination of the Shape of a Laser Beam Wavefront—Part 1: Terminology and Fundamental Aspects	ISO 15367–1: 2003
120	Particular Requirements for the Safety of X-Ray Equipment for Computed Tomography	IEC 60601–2–44 (ed. 2.1)
J. Sterility		
134	Resistometers Used for Characterizing the Performance of Biological and Chemical Indicators	ANSI/AAMI ST44: 2002
135	Sterilization of Health Care Products—Requirements for the Development, Validation, and Routine Control of an Industrial Sterilization Process for Medical Devices—Dry Heat	ANSI/AAMI ST63: 2002
136	Sterilization of Health Care Products—Requirements for Products Labeled ''Sterile''	ANSI/AAMI ST67: 2003
137	Sterilization of Health Care Products—Vocabulary	ANSI/AAMI/ISO TIR 11139: 2002
138	Aseptic Processing of Health Care Products—Part 2: Filtration	ISO 13408–2: 2003
139	Cleanrooms and Associated Controlled Environments—Part 1: Classification of Air Cleanliness	ISO 14644–1: 1999
140	Cleanrooms and Associated Controlled Environments—Part 2: Specifications for Testing and Monitoring to Prove Continued Compliance With ISO 14644–1	ISO 14644–2: 2000
141	Cleanrooms and Associated Controlled Environments—Part 4: Design, Construction, and Start-Up	ISO 14644–4: 2001
142	Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 1: General Principles and Methods	ISO 14698–1: 2003
143	Cleanrooms and Associated Controlled Environments—Biocontamination Control—Part 2: Evaluation and Interpretation of Biocontamination Data	ISO 14698–2: 2003

TABLE 2.—Continued

Item No.	Title of Standard	Reference No. and Date
K. Tissue Engineering		
5	Standard Guide for Characterization and Testing of Hyaluronan as Starting Material Intended for Use in Biomedical and Tissue Engineered Medical Product Applications	ASTM F2347–2003

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 document 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

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' via your fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 321 followed by the pound sign. Follow the remaining voice prompts to complete your request.

You may also obtain a copy of ''Guidance on the Recognition and Use of Consensus Standards'' by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this document announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 011,'' will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/cdrh*.

You may access ''Guidance on the Recognition and Use of Consensus Standards,'' and the searchable database for FDA recognized consensus standards, through the hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*.

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: 011. These modifications to the list or recognized standards are effective upon publication of this document in the **Federal Register**.

Dated: September 21, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0117]

Guidance for Industry, Food and Drug Administration Staff, and Third Parties; Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is revising the criteria the agency will use to accredit persons for the purpose of conducting inspections of eligible device manufacturers under the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), which established an ''inspection by accredited persons'' program. FDA is also announcing the availability of a revised guidance document that will provide information for those interested in participating in this program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.'' This revised guidance document is immediately in effect, but it remains subject to comment in accordance with the agency's good guidance practices. FDA is taking these actions to implement recent technical amendments to MDUFMA.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Implementation of the Inspection by