records are both relevant and necessary to the litigation.

B. Additional Provisions Affecting Routine Use Disclosures. This system contains Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR Parts 160 and 164, Subparts A and E , 65 Fed. Reg. 82462 (12–28–00)). Disclosures of PHI authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information.''

In addition, our policy will be to prohibit release even of not directly identifiable information, except pursuant to one of the routine uses or if required by law, if we determine there is a possibility that an individual can be identified through implicit deduction based on small cell sizes (instances where the patient population is so small that individuals who are familiar with the enrollees could, because of the small size, use this information to deduce the identity of the beneficiary).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Computer diskette and on magnetic storage media.

RETRIEVABILITY:

Information can be retrieved by the individual identifiable information of the beneficiary.

SAFEGUARDS:

CMS has safeguards in place for authorized users and monitors such users to ensure against excessive or unauthorized use. Personnel having access to the system have been trained in the Privacy Act and information security requirements. Employees who maintain records in this system are instructed not to release data until the intended recipient agrees to implement appropriate management, operational and technical safeguards sufficient to protect the confidentiality, integrity and availability of the information and information systems and to prevent unauthorized access.

This system will conform to all applicable Federal laws and regulations and Federal, HHS, and CMS policies and standards as they relate to information security and data privacy. These laws and regulations include but are not limited to: the Privacy Act of 1974; the Federal Information Security Management Act of 2002; the Computer Fraud and Abuse Act of 1986; the Health Insurance Portability and Accountability Act of 1996; the E-Government Act of 2002, the Clinger-Cohen Act of 1996; the Medicare Modernization Act of 2003, and the corresponding implementing regulations. OMB Circular A–130, Management of Federal Resources, Appendix III, Security of Federal Automated Information Resources also applies. Federal, HHS, and CMS policies and standards include but are not limited to: all pertinent National Institute of Standards and Technology publications; HHS Information Systems Program Handbook and the CMS Information Security Handbook.

RETENTION AND DISPOSAL:

Records are maintained in a secure storage area with identifiers. Disposal occurs 6 years and 3 months from the time the individual accesses the MPDPF.

SYSTEM MANAGER AND ADDRESS:

Director, Beneficiary Information Services Group, Center for Beneficiary Choices, CMS, Mail Stop S1–01–26, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850.

NOTIFICATION PROCEDURE:

For purpose of access, the subject individual should write to the system manager who will require the system name, HICN, and for verification purposes, the subject individual's name (woman's maiden name, if applicable).

RECORD ACCESS PROCEDURE:

For purpose of access, use the same procedures outlined in Notification Procedures above. Requestors should also reasonably specify the record contents being sought. (These procedures are in accordance with Department regulation 45 CFR 5b.5 (a)(2).)

CONTESTING RECORD PROCEDURES:

The subject individual should contact the system manager named above, and reasonably identify the record and specify the information to be contested. State the corrective action sought and the reasons for the correction with supporting justification. (These procedures are in accordance with Department regulation 45 CFR 5b.7.)

RECORD SOURCE CATEGORIES:

Sources of information contained in this records system include data collected from the initial voluntary inquiry made by or on behalf of the individual and validated through the Medicare Beneficiary Database.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 05–22192 Filed 11–7–05; 8:45 am]

BILLING CODE 4120–03–P

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: 013

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: 013'' (Recognition List Number: 013), 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: 013'' to the Division of Small Manufacturers, International and Consumer 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: 013 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, 12720 Twinbrook Pkwy., MD 20857, 301–827–0021.

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 would implement its standard recognition program and provided the initial list of recognized 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), June 18, 2004 (69 FR 34176), and October 4, 2004 (69 FR 59240), FDA modified its initial list of FDA recognized consensus standards. 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: 013

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: 013'' 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			
52	ASTM F1463–93 (1999), Standard Specification for Alarm Signals in Medical Equipment Used in Anesthesia and Respiratory Care	Withdrawn	
B. Biocompatibility			
1	ASTM E1262–88 (2003), Standard Guide for Performance of the Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay	Withdrawn and replaced with newer version	83
2	ASTM E1263–97 (2003), Standard Guide for Conduct of Micronucleus Assays in Mammalian Bone Marrow Erythrocytes	Withdrawn and replaced with newer version	84
3	ASTM E1280–97 (2003), Standard Guide for Performing the Mouse Lymphoma Assay for Mammalian Cell Mutagenicity	Withdrawn and replaced with newer version	85
19	AAMI/ANSI/ISO10993–10: 2002(E), Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization	Withdrawn and replaced with newer version	86
20	AAMI/ANSI/ISO10993–10: 2002(E), Biological Evaluation of Medical Devices—Part 10: Tests for Irritation and Sensitization—Maximization Sensitization Test	Withdrawn and replaced with newer version	87
21	AAMI/ANSI/ISO10993–11:1993, Biological Evaluation of Medical Devices—Part 11: Tests for Systemic Toxicity	Extent of Recognition and Relevant Guidance	
28	AAMI/ANSI/ISO10993–12:2002(E), Biological Evaluation of Medical Devices—Part 12: Sample Preparation and Reference Materials	Withdrawn and replaced with newer version	88
34	ASTM F749–98 (2002)e2, Standard Practice for Evaluating Material Extracts by Intracutaneous Injection in the Rabbit	Withdrawn and replaced with newer version	89

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
37	ASTM E1397–91 (2003), Standard Practice for the In Vitro Rat Hepatocyte DNA Repair Assay	Withdrawn and replaced with newer version	90
38	ASTM E1398–91 (2003), Standard Practice for the In Vivo Rat Hepatocyte DNA Repair Assay	Withdrawn and replaced with newer version	91
39	ASTM F748–04, Standard Practice for Selecting Generic Biological Test Methods for Materials and Devices	Withdrawn and replaced with newer version	92
40	ASTM F763–04, Standard Practice for Short-Term Screening of Implant Materials	Withdrawn and replaced with newer version	93
41	ASTM F981–04, Standard Practice for Assessment of Compatibility of Biomaterials for Surgical Implants with Respect to Effect of Materials on Muscle and Bone	Withdrawn and replaced with newer version	94
42	ASTM F1984–99 (2003), Standard Practice for Testing for Whole Complement Activation in Serum by Solid Materials	Withdrawn and replaced with newer version	95
43	ASTM F1903–98 (2003), Standard Practice for Testing for Biological Responses to Particles In Vitro	Withdrawn and replaced with newer version	96
45	ASTM F1983–99 (2003), Standard Practice for Assessment of Compatibility of Absorbable/Resorbable Biomaterials for Implant Applications	Withdrawn and replaced with newer version	97
51	AAMI/ANSI/ISO10993–1: 2003(E), Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing	Withdrawn and replaced with newer version	98
52	ASTM F1904–98e1 (2003), Standard Practice for Testing for Biological Responses to Particles In Vivo	Withdrawn and replaced with newer version	99
53	ASTM E1372–95 (2003), Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	Withdrawn and replaced with newer version	100
70	ASTM F750–87 (2002)e1, Standard Practice for Evaluating Material Extracts by Systemic Injection in the Mouse	Relevant guidance	
74	USP 28–NF21Biological Tests <87>, Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version	101
75	USP 28–NF21Biological Tests <87>, Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version	102
76	USP 28–NF21Biological Tests <88>, Biological Reactivity Test, In Vivo Procedure—Preparation of Sample	Withdrawn and replaced with newer version	103
77	USP 28–NF21Biological Tests <88>, Biological Reactivity Test, In Vitro, Classification of Plastics—Intracutaneous Test	Withdrawn and replaced with newer version	104
78	USP 28–NF21Biological Tests <88>, Biological Reactivity Test, In Vitro, Classification of Plastics—Systemic Injection Test	Withdrawn and replaced with newer version	105
79	ASTM F619–03, Standard Practice for Extraction of Medical Plastics	Withdrawn and replaced with newer version	106
80	ASTM F1877 (2003)e1, Standard Practice for Characterization of Particles	Withdrawn and replaced with newer version	107
81	ASTM F1905 (2003)e1, Standard Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity	Withdrawn and replaced with newer version	108
B. Cardiovascular/Neurology			
4	ANSI/AAMI SP10:2002—Manual, Electronic, or Automated Sphygmomanometers	Withdrawn and replaced with newer version	53
5	ANSI/AAMI/ISO 7198:1998/2001(R) 2004, Cardiovascular Implants—Tubular vascular prostheses	Withdrawn and replaced with newer version	54

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
14	ASTM F1830:05, Recommended Practice for Selection of Blood for In Vitro Hemolytic Evaluation of Blood Pumps	Withdrawn and replaced with newer version	55
15	ASTM F1841:05, Recommended Practice for Assessment of Hemolysis in Continuous Flow Blood Pumps	Withdrawn and replaced with newer version	56
48	ASTM F2129:04, Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version	57
C. Dental/Ear, Nose, and Throat			
29	IEC 60601–2–18:2000 Amendment 1, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Endoscopic Equipment	Withdrawn and replaced with newer version	122
40	ANSI/ASA S3.6–2004, Specification for Audiometers	Withdrawn and replaced with newer version	123
41	ANSI/ASA S3.22:2003, Specification of Hearing Aid Characteristics	Withdrawn and replaced with newer version	124
61	ISO 1562:2004, Dentistry—Casting gold alloys	Withdrawn and replaced with newer version	125
82	ISO 10477:2004, Dentistry—Polymer-based crown and bridge materials	Withdrawn and replaced with newer version	126
D. General			
16	ASTM D903:1993, Test Methods for Peel or Stripping Strength of Adhesive Bonds	Contact person	
28	IEC 60601–1–2, (Second Edition), Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests	Extent of recognition	
30	AAMI/IEC 60601–1–2, Medical Electrical Equipment—Part 1–2: General Requirements for Safety—Collateral standard: Electromagnetic Compatibility—Requirements and Tests (Edition 2:2001)	Title and extent of recognition	
2	IEC 60601–1, Medical Electrical Equipment—Part 1: General Requirements for Safety	Withdrawn	
4	IEC 60601–1, Medical Electrical Equipment—Part 1: General Requirements for Safety, 1988; Amendment 1, l991–11, Amendment 2, 1995–03	Contact person, devices affected and extent of recognition	
E. General Hospital/General Plastic Surgery			
18	ISO 8537:1991 Sterile Single-Use Syringes, With or Without Needle, for Insulin	Contact person	
38	ASTM F1671–03: Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System.	Withdrawn and replaced with newer version	130
48	ASTM D6499–03 Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber and its Products	Withdrawn and replaced with newer version	131
31 Ophthalmic 89 Radiology	ISO 11810–1:2005: Lasers and Laser-Related Equipment—Test Method and Classification for the Laser-Resistance of Surgical Drapes and/or Patient-Protective Covers—Part 1: Primary Ignition and Penetration	Transferred from Ophthalmic and Radiology	132
97	USP 28: 2005 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version	133

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
98	USP 28<11>: 2005 Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version	134
99	USP 28: 2005 Absorbable Surgical Suture	Withdrawn and replaced with newer version	135
100	USP 28<881>: 2005 Tensile Strength	Withdrawn and replaced with newer version	136
101	USP 28<861>: 2005 Sutures—Diameter	Withdrawn and replaced with newer version	137
102	USP 28<871>: 2005 Sutures Needle Attachment	Withdrawn and replaced with newer version	138
103	USP 28<11>: 2005 Sterile Water for Irrigation	Withdrawn and replaced with newer version	139
104	USP 28<11>: 2005 Heparin Lock Flush Solution	Withdrawn and replaced with newer version	140
105	USP 28<11>: 2005 Sodium Chloride Injection	Withdrawn and replaced with newer version	141
11	ISO 594–1:1986 Conical Fittings With a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment—Part 1: General Requirements	Title and contact person	
13	ISO 595–1:1986 Reusable All-Glass or Metal-and-Glass Syringes for Medical Use—Part 1: Dimensions	Title and contact person	
14	ISO 595–2:1987 Reusable All-Glass or Metal-and-Glass Syringes for Medical Use—Part 2: Design, Performance Requirements and Tests	Title and contact person	
15	ISO 7864:1993 Sterile Hypodermic Needles for Single Use	Contact person	
16	ISO 7886–1:1993 Sterile Hypodermic Syringes for Single Use—Part 1: Syringes for Manual Use	Title and contact person	
62	ISO 8536–6:1995 Infusion Equipment for Medical Use—Part 6: Freeze Drying Closures for Infusion Bottles	Title and contact person	
63	ISO 8536–7–1999: Infusion Equipment for Medical Use—Part 7: Caps Made of Aluminum-Plastics Combinations for Infusion Bottles	Contact Person	
64	ISO 8536–3–1999: Infusion Equipment for Medical Use—Part 3: Aluminum Caps for Infusion Bottles	Title and contact person	
66	ISO 8536–1–2000: Infusion equipment for medical use—Part 1: Infusion glass bottles	Title and Contact Person	
68	ISO 7886–2–1996: Sterile Hypodermic Syringes for Single Use—Part 2: Syringes for Use With Power-Driven Syringe Pumps	Title and contact person	;
69	ISO 9626–1991: Stainless Steel Needle Tubing for the Manufacture of Medical Devices	Title and contact person	
70	ASTM E825–98 (2003) Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature	Contact person	
111	IEC 60601–2–38 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds	Contact person	
119	AAMI BF7: (R2002) Blood Transfusion Micro-Filters	Contact person	
120	ASTM F1054–01: Standard Specification for Conical Fittings	Contact person	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
121	ISO 8536–2–2001: Infusion Equipment for Medical Use—Part 2: Closures for Infusion Bottles	Contact person	
122	ISO 8536–5–2004: Infusion Equipment for Medical Use—Part 5: Burette Infusion Sets for Single Use, Gravity Feed	Title and contact person	
126	ISO 8536–4–2004: Infusion Equipment for Medical Use—Part 4: Infusion Sets for Single Use, Gravity Feed	Contact person	
127	ISO 1135–4–2004: Transfusion Equipment for Medical Use—Part 4: Transfusion Sets for Single Use	Contact person	
129	ISO 594–2:1998 Conical Fittings With a 6% (Luer) Taper for Syringes, Needles, and Certain Other Medical Equipment—Part 2: Lock Fittings	Contact person	
F. In Vitro Diagnostic			
65	CLSI EP5–A2, Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition	Withdrawn and replaced with new version	110
54	CLSI D12–A2, Immunoprecipitin Analyses: Procedures for Evaluating the Performance of Materials—Second Edition; Approved Guideline	Product codes	
G. Materials			
9	ASTM F563–00: Standard Specification for Wrought Cobalt-20 Nickel-20 Chromium-3.5 Molybdenum-3.5 Tungsten-5 Iron Alloy for Surgical Implant Applications (UNS R30563)	Withdrawn	
13	ASTM F648–04: Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Withdrawn and replaced with newer version	106
16	ASTM F746–04: Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	Withdrawn and replaced with newer version	107
25	ASTM F1295–05: Standard Specification for Wrought Titanium–6 Aluminum–7 Niobium Alloy for Surgical Implant Applications (UNS R56700)	Withdrawn and replaced with newer version	108
34	ASTM F1659–95: Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates	Withdrawn	
72	ASTM F2213–04: Standard Test Method for Measurement of Magnetically Induced Torque on Passive Implants in the Magnetic Resonance Environment	Title	
73	ASTM F561–05, Practice for Retrieval and Analysis of Implanted Medical Devices, and Associated Tissues	Withdrawn and replaced with newer version	109
74	ASTM F1377–04: Standard Specification for Cobalt–28 Chromium–6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Withdrawn and replaced with newer version	110
75	ASTM F1160–05: Standard Test Method for Shear and Bending Fatigue Testing of Calcium Phosphate and Metallic Medical and Composite Calcium Phosphate/Metallic Coatings	Withdrawn and replaced with newer version	111
80	ASTM F1088–04a: Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Title	
83	ASTM F1044–05: Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Withdrawn and replaced with newer version	112
84	ASTM F1147–05: Standard Test Method for Tension Testing of Calcium Phosphate and Metal Coatings	Withdrawn and replaced with newer version	113

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
90	ASTM F2255–05: Standard Test Method for Strength Properties of Tissue Adhesives in Lap Shear by Tension Loading	Withdrawn and replaced with newer version	114
91	ASTM F2256–05: Standard Test Method for Strength Properties of Tissue Adhesives in T-Peel by Tension Loading	Withdrawn and replaced with newer version	115
92	ASTM F2258–05: Standard Test Method for Strength Properties of Tissue Adhesives in Tension	Withdrawn and replaced with newer version	116
93	ASTM F86–04: Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants	Withdrawn and replaced with newer version	117
H. OB-GYN/Gastroenterology			
1	AAMI RD5:1992: Hemodialysis systems	Withdrawn	
17	ASTM D3492–03: Standard Specification for Rubber Contraceptives (Male Condoms)	Withdrawn and replaced with newer version	32
24	ASTM F623–99e1: Standard Performance Specification for Foley Catheter	Withdrawn and replaced with newer version	33
26	ISO 4074:2002/Cor.1:2003(E): Natural Latex Rubber Condoms—Requirements and Test Methods, Technical Corrigendum 1	Withdrawn and replaced with newer version	34
27	ASTM D6324–99a (Reapproved 2004): Standard Test Methods for Male Condoms Made From Synthetic Materials	Withdrawn and replaced with newer version	35
I. Ophthalmic			
31	ISO 11810:2002, Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Method for the Laser-Resistance of Surgical Drapes and/or Patient-Protective Covers	Withdrawn newer version recognized under General Hospital/ General Plastic Surgery	
J. Orthopedic			
126	ASTM F366–04: Standard Specification for Fixation Pins and Wires	Withdrawn and replaced with newer version	180
159	ASTM F1717–04: Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Withdrawn and replaced with newer version	181
173	ASTM F1800–04: Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Withdrawn and replaced with newer version	182
K. Radiology			
1	ANSI PH 2.43–1982: Method for Sensitometry/Medical X-Ray Screen-Film	Contact person	
2	ANSI IT 1.48–1997 Photography (Films)—Medical Hard Copy Imaging Film-Dimensions and Specifications	Title and contact person	
5	ANSI PH 2.50–1983: Method/Sensitometry Direct Exposure Medical/Dental	Contact person	
6	IEC 60806 (R1984) Determination of the Maximum Symmetrical Radiation Field From a Rotating Anode X-ray Tube for Medical Diagnosis	Title and contact person	
8	IEC 60336 (R1993) Medical Electrical Equipment—X-ray Tube Assemblies for Medical Diagnosis—Characteristics of Focal Spots	Title	
23	NEMA XR 10–1986 (R2003) Measurement of the Maximum Symmetrical Radiation Field from a Rotating Anode X-Ray Tube Used for Medical Diagnosis	Reaffirmation	

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
34	IEC 60601–2–7–1998 Medical Electrical Equipment—Part 2–7: Particular Requirements for the Safety of High-Voltage Generators of Diagnostic X-ray Generators	Tile and contact person	
37	IEC 60601–2–11–2004 Amendment 1—Medical electrical equipment—Part 2–11: Particular requirements for the Safety of Gamma Beam Therapy Equipment Withdrawn and Replaced With Newer Version	133	
52	UL 544 (1998): Standard for Medical and Dental Equipment—Ed. 4.0	Contact person	
56	IEC 61674–1997 Medical Electrical Equipment—Dosimeters With Ionization Chambers and/or Semi-Conductor Detectors as Used in X-ray Diagnostic Imaging	Withdrawn	
57	IEC 60731–1997 Medical Electrical Equipment—Dosimeters With Ionization Chambers as Used in Radiotherapy	Title and devices affected	
61	UL 122 (1999): Standard for Photographic Equipment—Ed. 4.0	Contact person	
62	UL 187 (1998): Standard for X-Ray Equipment—Ed. 7.0	Contact person	
79	NEMA XR 7–1995 (R2000) High-Voltage X-Ray Cable Assemblies and Receptacles	Title and contact person	
80	NEMA XR 9–1984 (R1994, R2000) Power Supply Guidelines for X-Ray Machines	Contact person	
81	NEMA XR 13–1990 (R1995, R2000) Mechanical Safety Standard for Power Driven Motions of Electromedical Equipment	Contact person	
82	NEMA XR 14–1990 (R1995, R2000) Recommended Practices for Load Bearing Mechanical Assemblies Used in Diagnostic Imaging	Contact Person	
89	ISO 11810:2002 Optics and Optical Instruments—Lasers and Laser-Related Equipment—Test Method for the Laser-Resistance of Surgical Drapes and/or Patient-Protective Covers	Withdrawn Newer version recognized under General Hospital/General Plastic Surgery	
107	ISO 11146–1:2005 Lasers and Laser-Related Equipment—Test Methods for Laser Beam Widths, Divergence Angles and Beam Propagation Ratios—Part 1: Stigmatic and Simple Astigmatic Beams	Withdrawn and replaced with newer version	134
119	NEMA PS 3.1—3.18 Digital Imaging and Communications in Medicine (DICOM) Set	Title	
126	IEC 60601–2–28–1993 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of X-ray Source Assemblies and X-ray Tube Assemblies for Medical Diagnosis—Ed. 1.0	Title and contact person	
127	IEC 60601–2–32–1994 Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Associated Equipment of X-ray Equipment—Ed. 1.0	Title and contact person	
129	NEMA NU 1–2001 (Errata 2004): Performance Measurements of Scintillation Cameras	Title	
131	IEC 61217–2002 Radiotherapy Equipment—Coordinates Movements and Scales Consolidated Ed. 1.1	Title	
132	IEC 60731–2002 Amendment 1—Medical Electrical Equipment—Dosimeters With Ionization Chambers as Used in Radiotherapy	Title and devices affected	
L. Sterility			
48	ANSI/AAMI ST40:2004, Table-Top Dry Heat (Heated Air) Sterilization and Sterility Assurance in Dental and Medical Facilities, 2ed	Withdrawn and replaced with newer version	152

TABLE 1.—Continued

Old Item No.	Standard	Change	Replacement Item No.
52	ANSI/AAMI ST59:1999, Sterilization of Health Care Products—Biological Indicators Part 1: General	Title, relevant guidance, and contact person	
70	ANSI/AAMI/ISO 14161:2000, Sterilization of Health Care Products—Biological Indicators—Guidance for the Selection, Use, and Interpretation of Results, 2ed.	Contact Person	
71	ANSI/AAMI ST8:2001, Hospital Steam Sterilizers	Contact Person	
77	ANSI/AAMI ST24:1999, Automatic, General Purpose Ethylene Oxide Sterilizers and Ethylene Oxide Sterilant Sources Intended for Use in Health Care Facilities, 3ed.	Title and contact person	
116	ANSI/AAMI ST72:2002, Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	Relevant guidance	
117	ANSI/AAMI ST35:2003, Safe Handling and Biological Decontamination of Medical Devices in Health Care Facilities and in Nonclinical Settings	Relevant guidance and contact person	
119	ANSI/AAMI ST55:2003, Table-Top Steam Sterilizers, 2ed.	Correct title and contact person	
124	USP 28:2005, Biological Indicator for Dry Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	153
125	USP 28:2005, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	154
126	USP 28:2005, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	155
127	USP28:2005, <61> Microbial Limits Test	Withdrawn and replaced with newer version	156
128	USP 28:2005, <71>, Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	157
129	USP28:2005, <85>, Biological Tests and Assays, Bacterial Endotoxin Test (LAL)	Withdrawn and replaced with newer version	158
130	USP28:2005 <151>, Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	159
131	USP28:2005 <1211>, Sterilization and Sterility Assurance of Compendial Articles	Withdrawn and replaced with newer version	160
132	USP28:2005 <161>, Transfusion and Infusion Assemblies and Similar Medical Devices	Withdrawn and replaced with newer version	161
133	USP 28:2005, Biological Indicator for Steam Sterilization—Self-Contained	Withdrawn and replaced with newer version	162

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: 013, follows:

Item No.	Title of Standard	Reference No. and Date
A. Anesthesia		
65	Medical Electrical Equipment—Particular Requirements for the Basic Safety and Essential Performance of Respiratory Gas Monitors	ISO 21647:2005
66	Medical Electrical Equipment—Particular Requirements for the Basic Safety and Essential Performance of Pulse Oximeter Equipment for Medical Use	ISO 9919:2005

Item No.	Title of Standard	Reference No. and Date
B. Dental/Ear, Nose, Throat		
127	Root Canal Files, Type H (Hedstrom)	ANSI/ADA Specification No. 58:2004
128	Dentistry—Elastomeric Impression Materials	ISO/4823:2000 Technical Corrigendum 1:2004
129	Dentistry—Elastomeric Impression Materials	ANSI/ADA Specification No. 19:2000 Technical Corrigendum 1:2004
C. General		
34	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))	IEC 60601–1–2:2004
35	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/IEC 60601–1–2:2001
D. General Hospital/General Plastic Surgery		
142	Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Baby Incubators	ANSI/AAMI II36:2004
143	Medical Electrical Equipment—Part 2: Particular Requirements for Safety of Transport Incubators	ANSI/AAMI II51:2004
E. In Vitro Diagnostic		
109	Laboratory Automation: Data Content for Specimen Identification; Approved Standard	CLSI AUTO7–A:2004
111	Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays; Approved Guideline—Fourth Edition	CLSI H21–A4:2003
112	Point-of-Care Monitoring of Anticoagulation Therapy; Approved Guideline	CLSI H49–A:2004
113	Assessing the Quality of Immunoassay Systems: Radioimmunoassays, and Enzyme, Fluorescence, and Luminescence Immunoassays; Approved Guideline	CLSI I/LA23–A:2004
114	Standard Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems	CLSI LIS01–A:2003
115	Standard Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard—Second Edition	CLSI LIS02–A2:2004
116	Standard Guide for Selection of a Clinical Laboratory Information Management System	CLSI LIS03–A:2003
117	Standard Guide for Documentation of Clinical Laboratory Computer Systems	CLSI LIS04–A:2003
118	Standard Specification for Transferring Clinical Observations Between Independent Computer Systems	CLSI LIS05–A:2003
119	Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems	CLSI LIS06–A:2003
120	Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory	CLSI LIS07–A:2003
121	Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems	CLSI LIS08–A:2003
122	Standard Guide for Coordination of Clinical Laboratory Services Within the Electronic Health Record Environment and Networked Architectures	CLSI LIS09–A:2003

Item No.	Title of Standard	Reference No. and Date
123	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine	CLSI MM9–A:2004
F. Materials		
118	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment	ASTM F2503–05
G. OB-GYN/Gastroenterology		
36	Mechanical contraceptives—Reusable Natural and Silicone Rubber Contraceptive Diaphragms—Requirements and Tests	ISO 8009:2004(E)
H. Radiology		
135	Medical electrical equipment—Part 2–5: Particular Requirements for the Safety of Ultrasonic Physiotherapy Equipment Ed. 2.0	IEC 60601–2–5:2000
I. Sterility		
163	Sterilization of Medical Devices—Microbiological methods—Part 3: Guidance on Evaluation and Interpretation of Bioburden Data	ANSI/AAMI/ISO 11737–3:2004
164	Sterilization of Medical Devices—Information To Be Provided by the Manufacturer for the Processing of Resterilizable Medical Devices	ANSI/AAMI ST81:2004
165	Cleanrooms and Associated Controlled Environments—Part 5: Operations	ISO 14644–5:2004
166	Cleanrooms and Associated Controlled Environments—Part 7: Separative Devices (Clean Air Hoods, Gloveboxes, Isolators and Mini-Environments)	ISO 14644–7:2004
J. Tissue Engineering		
6	Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue Engineered Medical Products	ASTM F2450–04
7	Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels	ASTM F2315–03

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

In order to receive ''Guidance on the Recognition and Use of Consensus Standards'' on 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 notice announcing ''Modifications to the List of Recognized Standards, Recognition List Number: 013'' 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. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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: 013. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: October 10, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–22267 Filed 11–7–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0344]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tinnitus Masker Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Tinnitus Masker Devices.'' The draft guidance describes a means by which tinnitus masker devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for the tinnitus masker presently classified into class II (special controls: labeling) to designate a special control for these devices. The draft guidance is neither final, nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by February 6, 2006.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Class II Special Controls Guidance Document: Tinnitus Masker Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this 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*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Teresa Cygnarowicz, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2980.

SUPPLEMENTARY INFORMATION:

I. Background

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for tinnitus masker devices presently classified into class II (special controls: labeling) to designate a special control for the devices. The draft guidance document describes a means by which the device may comply with the requirement of special controls for class II devices. Following the effective date of a final rule based on the proposed rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on tinnitus masker devices. 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 such an approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive ''Class II Special Controls Guidance Document: Tinnitus Masker Devices'' by fax, call the 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 (1555) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so 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 on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E), under OMB control number 0910–0120. The labeling provisions addressed in the draft guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic