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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1997D–0530]

Food and Drug Adminstration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 009

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 of the List of Recognized Standards, Recognition List Number: 009" (Recognition List Number: 009), 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 "Modification to the List of Recognized Standards, Recognition List Number: 009" 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 to recommend

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: 009 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health (CDRH) (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4766, ext.156.

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 guidance entitled "Recognition and Use of Consensus Standards." This notice described how FDA will 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), and April 28, 2003 (68 FR 22391), FDA modified its initial list of recognized

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 the List of Recognized Standards, Recognition List Number: 009

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: 009" to identify these current modifications.

In the following table, FDA describes modifications that involve: (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.

A. Biocompatibility

Old Item Number	Standard	Change	Replacement Item Number
36	ASTM F1408–02e1, Standard Practice for Subcutaneous Screening Test for Implant Materials	Withdrawn and replaced with newer version.	71
16	ASTM F1439–02, Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials	Withdrawn and replaced with newer version.	72
65	ASTM F2065–00e1, Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials	Withdrawn and replaced with newer version.	73
58	USP 26–NF 21 <87>, Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version.	74
59	USP 26–NF 21 <87>, Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version.	75
60	USP 26–NF 21<88>, Biological Reactivity Tests, In Vivo—Procedure—Preparation of Sample	Withdrawn and replaced with newer version.	76
61	USP 26–NF 21<88>, Biological Reactivity Test, In Vivo—Intracutaneous Test	Withdrawn and replaced with newer version.	77
62	USP 26–NF 21<88>, Biological Reactivity Tests, In Vivo—Systemic Injection Test	Withdrawn and replaced with newer version	78

B. Dental/ENT

Old Item Number	Standard	Change	Replacement Item Number
46	ANSI/ADA Specification No. 14:1998, Dental Base Metal Casting Alloys	Withdrawn and replaced with newer version; Contact person	94
49	ANSI/ADA Specification No. 17:1999, Denture Base Temporary Relining Resin	Withdrawn and replaced with newer version.	95
53	ANSI/ADA Specification No. 30:2002, Dental Zinc Oxide-Eugenol and Zinc Oxide Non-Eugenol Cements	Withdrawn and replaced with newer version.	96
56	ANSI/ADA Specification No. 57:2000, Endodontic Sealing Materials	Withdrawn and replaced with newer version.	97
60	ANSI/ADA Specification No. 96:2000, Dental Water-Based Cements	Withdrawn and replaced with newer version.	98
66	ISO 4049:2000, Dentistry—Polymer-Based Filling, Restorative and Luting Materials	Withdrawn and replaced with newer version.	99
71	ISO 6876:2001, Dental Root Canal Sealing Materials	Withdrawn and replaced with newer version.	100
77	ISO 8891:1998, Dental Casting Alloys with Noble Metal Content of At Least 25% but less than 75%	Withdrawn and replaced with newer version; Contact person	101
79	ISO 9693, Metal-Ceramic Dental Restorative Systems	Withdrawn and replaced with newer version; Contact person	102

C. General Hospital/General Plastic Surgery

Old Item Number	Standard	Change	Replacement Item Number
82	USP 26, Nonabsorbable Surgical Sutures	Withdrawn and replaced with newer version	97
88	USP 26 <11>, Sterile Sodium Chloride for Irrigation	Withdrawn and replaced with newer version	98
89	USP 26, Absorbable Surgical Sutures	Withdrawn and replaced with newer version	99
90	USP 26 <881>, Tensile Strength	Withdrawn and replaced with newer version	100
91	USP 26 <861>, Sutures—Diameter	Withdrawn and replaced with newer version	101
92	USP 26<871>, Sutures Needle Attachment	Withdrawn and replaced with newer version	102
93	USP 26, Sterile Water for Irrigation	Withdrawn and replaced with newer version	103

Old Item Number	Standard	Change	Replacement Item Number
94	USP 26, Heparin Lock Flush Solution	Withdrawn and replaced with newer version	104
95	USP 26, Sodium Chloride Injection	Withdrawn and replaced with newer version	105
33	ASTM D3772–01, Standard Specification for Rubber Finger Cots	Withdrawn and replaced with newer version	106
5	ASTM F882–84 (2002), Standard Performance and Safety Specification for Cryosurgical Medical Instrumentation	Withdrawn and replaced with newer version	107

D. In Vitro Diagnostic

Old Item Number	Standard	Change	Replacement Item Number
14	NCCLS C24–A2 Statistical Quality Control for Quantitative Measurements: Principles and Definitions: Approved Guideline—Second Edition	Withdrawn and replaced with newer version	85
17	NCCLS C29–A2 Standardization of Sodium and Potassium Ion Selective Electrode Systems to the Flame Photometric Reference Method; Approved Standard—Second Edition	Withdrawn and replaced with newer version	86
19	NCCLS C31–A2 Ionized Calcium Determinations: Precollection Variables, Specimen Choice, Collection and Handling: Approved Guideline—Second Edition	Withdrawn and replaced with newer version	87
2	NCCLS EP09–A2 Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline—Second Edition	Withdrawn and replaced with newer version	92
66	NCCLS EP10–A2 Preliminary Evaluation of Quantitative Clinical Laboratory Methods; Approved Guideline—Second Edition	Withdrawn and replaced with newer version	93

E. Materials

Old Item No.	Standard	Change	Replacement Item No.
1	ASTM F67–00, Standard Specification for Unalloyed Titanium for Surgical Implant Applications (UNS R50250, UNS R50550, UNS R50700)	Update "Process(es) Impacted" to include Design Controls.	1
2	ASTM F75–01, Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	Update "Process(es) Impacted" to include Design Controls.	2
3	ASTM F90–01, Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy for Surgical Implant Applications (UNS R30605)	Update "Process(es) Impacted" to include Design Controls.	3
5	ASTM F138–00, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants (UNS S31673)	Update "Process(es) Impacted" to include Design Controls.	5
6	ASTM F139–00, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Update "Process(es) Impacted" to include Design Controls.	6
7	ASTM F560–98, Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Update "Process(es) Impacted" to include Design Controls.	7
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)	Update "Process(es) Impacted" to include Design Controls.	9
10	ASTM 603–00, Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implant Application	Update "Process(es) Impacted" to include Design Controls.	10
11	ASTM 620–00, Standard Specification for Titanium–6 Aluminum–4 Vanadium ELI Alloy Forgings for Surgical Implants (UNS R56401)	Update "Process(es) Impacted" to include Design Controls.	11
13	ASTM F648–00, Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants	Update "Process(es) Impacted" to include Design Controls.	13

Old Item No.	Standard	Change	Replacement Item No.
14	ASTM 688–00, Standard Specification for Wrought Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants	Update "Process(es) Impacted" to include Design Controls.	14
15	ASTM F745–00, Standard Specification for 18 Chromium–12.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	Update "Process(es) Impacted" to include Design Controls.	15
16	ASTM F746–87 (1999), Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials	Update "Process(es) Impacted" to include Design Controls.	16
19	ASTM F961–96, Standard Specification for Cobalt–35 Nickel–20 Chromium–10 Molybdenum Alloy Forgings for Surgical Implants (UNS R30035)	Update "Process(es) Impacted" to include Design Controls.	19
21	ASTM F1088–87(1992)e1, Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation	Update "Process(es) Impacted" to include Design Controls.	21
25	ASTM F1295–01, Standard Specification for Wrought Titanium–6 Aluminum–7 Niobium Alloy for Surgical Implant Applications	Update "Process(es) Impacted" to include Design Controls.	25
26	ASTM F1314–01, Standard Specification for Wrought Nitrogen Strengthened–22 Chromium–12.5 Nickel–5 Manganese–2.5 Molybdenum Stainless Steel Bar and Wire for Surgical Implants	Update "Process(es) Impacted" to include Design Controls.	26
27	ASTM F1341–99, Standard Specification for Unalloyed Titanium Wire for Surgical Implant Applications	Update "Process(es) Impacted" to include Design Controls.	27
30	ASTM F1537–00, Standard Specification for Wrought Cobalt–28–Chromium–6–Molybdenum Alloy for Surgical Implants	Update "Process(es) Impacted" to include Design Controls.	30
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	Update "Process(es) Impacted" to include Design Controls.	32
33	ASTM F1609–95, Standard Specification for Calcium Phosphate Coatings for Implantable Materials	Update "Process(es) Impacted" to include Design Controls.	33
34	ASTM F1659–95, Standard Test Method for Bending and Shear Testing of Calcium Phosphate Coatings on Solid Metallic Substrates	Update "Process(es) Impacted" to include Design Controls.	34
35	ASTM F1713–96, Standard Specification for Wrought Titanium–13 Niobium–13 Zirconium Alloy for Surgical Implant Applications	Clarification of Extent of Recognition; Update "Process(es) Impacted" to include Design Controls.	35
36	ASTM F1801–97, Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials	Update "Process(es) Impacted" to include Design Controls.	36
37	ASTM F1813–01, Standard Specification for Wrought Titanium—12 Molybdenum–6 Zirconium–2 Iron Alloy for Surgical Implant (UNS R58120)	Clarification of Extent of Recognition; Update "Process(es) Impacted" to include Design Controls.	37
38	ASTM F2005–00, Standard Terminology for Nickel-Titanium Shape Memory Alloys	Update "Process(es) Impacted" to include Design Controls.	38
39	ASTM F2052–00, Standard Test Method for Measurement of Magnetically Induced Displacement Force on Passive Implants in the Magnetic Resonance Environment	Update "Process(es) Impacted" to include Design Controls.	39
40	ASTM F2063–00, Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants	Cardiovascular contact person. Clarification to Extent of Recognition with regard to biocompatibility requirements.	40
41	ASTM F2066–01, Standard Specification for Wrought Titanium–15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150)	Cardiovascular contact person; Clarification to Extent of Recognition	41
43	ASTM F2146–01, Standard Specification for Wrought Titanium–3Aluminum–2.5Vanadium Alloy Seamless Tubing for Surgical Implant Applications (UNS R56320)	Cardiovascular contact person; Clarification to Extent of Recognition	43
44	ASTM F136–02, Standard Specification for Wrought Titanium–6 Aluminum–4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)	Update "Process(es) Impacted" to include Design Controls.	44
45	ASTM F562–02, Standard Specification for Wrought 35Cobalt–35Nickel–20Chromium–10Molybdenum Alloy for Surgical Implant Applications (UNS R30035)	Update "Process(es) Impacted" to include Design Controls.	45
46	ASTM F621–02, Standard Specification for Stainless Steel Forgings for Surgical Implants	Update "Process(es) Impacted" to include Design Controls	46

Old Item No.	Standard	Change	Replacement Item No.
47	ASTM F799–02, Standard Specification for Cobalt–28 Chromium–6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	Update "Process(es) Impacted" to include Design Controls.	47
48	ASTM F899–02, Standard Specification for Stainless Steel for Surgical Instruments	Update "Process(es) Impacted" to include Design Controls.	48
49	ASTM F1058–02, Standard Specification for Wrought 40Cobalt–20Chromium–16Iron–15Nickel–7Molybdenum Alloy Wire and Strip for Surgical Implant Applications (UNS R30003 and UNS R30008)	Update "Process(es) Impacted" to include Design Controls.	49
50	ASTM F1091–02, Standard Specification for Wrought Cobalt–20 Chromium–15 Tungsten–10 Nickel Alloy Surgical Fixation Wire (UNS R30605)	Update "Process(es) Impacted" to include Design Controls.	50
51	ASTM 1108–02, Standard Specification for Titanium -6Aluminum -4Vanadium Alloy Castings for Surgical Implants (UNS R56406)	Update "Process(es) Impacted" to include Design Controls.	51
52	ASTM F1350–02, Standard Specification for Wrought 18 Chromium–14 Nickel–2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673)	Update "Process(es) Impacted" to include Design Controls.	52
53	ASTM F1472–02, Standard Specification for Wrought Titanium -6Aluminum -4Vanadium Alloy for Surgical Implant Applications (UNS R56400)	Update "Process(es) Impacted" to include Design Controls.	53
54	ASTM F1580–01, Standard Specification for Titanium and Titanium–6 Aluminum–4 Vanadium Alloy Powders for Coatings of Surgical Implants	Update "Process(es) Impacted" to include Design Controls.	54
55	ASTM F2182–02, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	Update "Process(es) Impacted" to include Design Controls.	55
Dental 30 Ortho 62	ISO 5832–1:1997, Implants for Surgery—Metallic Materials—Part 1: Wrought stainless steel	Transferred from dental/ENT and orthopaedics.	56
Dental 31 Ortho 117	ISO 5832–2:1999, Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	Transferred from dental/ENT and orthopaedics.	57
Dental 32 Ortho 64	ISO 5832–3:1996, Implants for Surgery—Metallic Materials—Part 3: Wrought titanium 6–aluminium 4–vanadium alloy	Transferred from dental/ENT and orthopaedics.	58
Dental 33 Ortho 65	ISO 5382–4:1996, Implants for Surgery—Metallic Materials—Part 4: Cobalt-chromium-molybdenum casting alloy	Transferred from dental/ENT and orthopaedics.	59
Dental 34 Ortho 66	ISO 5832–5:1993, Implants for Surgery—Metallic Materials—Part 5: Wrought cobalt-chromium-tungsten-nickel alloy	Transferred from dental/ENT and orthopaedics.	60
Dental 35 Ortho 67	ISO 5832–6:1997, Implants for Surgery—Metallic Materials—Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	Transferred from dental/ENT and orthopaedics.	61
Dental 36 Ortho 118	ISO 5832–9: 1992, Implants for Surgery—Metallic Materials—Part 9: Wrought high nitrogen stainless steel	Transferred from dental/ENT and orthopaedics.	62
Dental 38 Ortho 70	ISO 5832–11: 1994, Implants for Surgery—Metallic Materials—Part 11: Wrought titanium 6–aluminium 7–niobium alloy	Transferred from dental/ENT and orthopaedics.	63
Dental 39 Ortho 71	ISO 5832–12: 1996, Implants for Surgery—Metallic Materials—Part 12: Wrought cobalt-chromium-molybdenum alloy	Transferred from dental/ENT and orthopaedics.	64
Ortho 119	ISO 5834–2: 1998, Implants for Surgery—Ultra-High-Molecular-Weight Polyethylene—Part 2: Moulded Forms	Transferred from orthopaedics.	65
Ortho 76	ISO 6474:1994, Implants for Surgery—Ceramic materials based on high purity alumina	Transferred from orthopaedics.	66
Ortho 143	ISO 7153–1:1991/Amd 1:1999, Surgical Instruments—Metallic Materials—Part 1: Stainless steel	Transferred from orthopaedics.	67
Ortho 84	ISO 13782: 1996, Implants for Surgery—Metallic Materials—Unalloyed tantalum for surgical implant applications	Transferred from orthopaedics.	68
Dental 37	ISO 5832–10:1996, Implants for Surgery—Metallic Materials—Part 10: Wrought titanium 5–aluminium 2,5–iron	Transferred from dental/ENT.	69

F. Ophthalmic

Old Item Number	Standard	Change	Replacement Item Number
30	ANSI Z80 7–2002: Ophthalmics—Intraocular Lenses	Correction in publication date	30

G. Orthopaedics

Old Item Number	Standard	Change	Replacement Item Number
58	ASTM F1781–97, Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants	Added "Design Controls" to Process(es) Impacted	58
62	ISO 5832–1:1997, Implants for Surgery—Metallic materials—Part 1: Wrought stainless steel	Withdrawn and transferred to Materials	62
64	ISO 5832–3:1996, Implants for Surgery—Metallic materials—Part 3: Wrought titanium 6–aluminum 4–vanadium alloy	Withdrawn and transferred to Materials	64
65	ISO 5832–4:1996, Implants for Surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy	Withdrawn and transferred to Materials	65
66	ISO 5832–5:1993, Implants for Surgery—Metallic materials—Part 5: Wrought cobalt-chromium-tungsten-nickel alloy	Withdrawn and transferred to Materials	66
67	ISO 5832–6:1997, Implants for Surgery—Metallic materials—Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	Withdrawn and transferred to Materials	67
70	ISO 5832–11:1994, Implants for Surgery—Metallic materials—Part 11: Wrought titanium 6–aluminum 7–niobium alloy	Withdrawn and transferred to Materials	70
71	ISO 5832–12:1996, Implants for Surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy	Withdrawn and transferred to Materials	71
73	ISO 5838–1:1995, Implants for Surgery—Skeletal Pins and Wires—Part 1: Material and Mechanical Requirements	Added "Design Controls" to Process(es) Impacted	73
74	ISO 5838–2:1991, Implants for Surgery—Skeletal Pins and Wires—Part 2: Steinmann Skeletal Pins—Dimensions	Added "Design Controls" to Process(es) Impacted	74
75	ISO 5838–3:1993, Implants for Surgery—Skeletal Pins and Wires—Part 3: Kirschner Skeletal Wires	Added "Design Controls" to Process(es) Impacted	75
76	ISO 6474–94, Implants for surgery—Ceramic materials based on high purity alumina	Withdrawn and transferred to Materials	
78	ISO 7206–4:2002, Implants for Surgery—Partial and Total Hip Joint Prostheses—Part 4: Determination of Endurance Properties of Stemmed Femoral Components	Withdrawn and replaced with newer version; Title change; Added "Design Controls" to Process(es) Impacted	165
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	Added "Design Controls" to Process(es) Impacted	79
83	ISO 13402–95, Surgical and Dental Hand Instruments—Determination of Resistance Against Autoclaving, Corrosion and Thermal Exposure	Added "Design Controls" to Process(es) Impacted	83
84	ISO 13782:1996, Implants for Surgery—Metallic materials—Unalloyed tantalum for surgical implant applications	Withdrawn and transferred to Materials	
85	ISO 14630:1997, Non-Active Surgical Implants—General Requirements	Added "Design Controls" to Process(es) Impacted	85
101	ASTM F897–02, Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws	Withdrawn and replaced with newer version; Added "Design Controls" to Process(es) Impacted	166
104	ASTM F1089–02, Standard Test Method for Corrosion of Surgical Instruments	Withdrawn and replaced with newer version; Added "Design Controls" to Process(es) Impacted	167
107	ASTM F1147–99, Standard Test Method for Tension Testing of Calcium Phosphate and Metallic Coatings	Added "Design Controls" to Process(es) Impacted	107
111	ASTM F1814–97a, Standard Guide for Evaluating Modular Hip and Knee Joint Components	Added "Design Controls" to Process(es) Impacted	111

Old Item Number	Standard	Change	Replacement Item Number
113	ASTM F1377–98a, Standard Specification for Cobalt–28 Chromium–6 Molybdenum Powder for Coating of Orthopedic Implants (UNS R30075)	Added "Design Controls" to Process(es) Impacted	113
114	ASTM F1798–97, Standard Guide for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants	Added "Design Controls" to Process(es) Impacted	114
115	ASTM F1800–97, Standard Test Method for Cyclic Fatigue Testing of Metal Tibial Tray Components of Total Knee Joint Replacements	Added "Design Controls" to Process(es) Impacted	115
117	ISO 5832–2:1999, Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	Withdrawn and transferred to Materials	
118	ISO 5832–9:1992, Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel	Withdrawn and transferred to Materials	
119	ISO 5834–2:1998, Implants for Surgery—Ultra-High-Molecular Weight Polyethylene—Part 2: Moulded Forms	Withdrawn and transferred to Materials	
120	ASTM F382–99, Standard Specification and Test Method for Metallic Bone Plates	Added "Design Controls" to Process(es) Impacted	120
121	ISO 7207–1:1994, Implants for Surgery—Components for partial and total knee joint prostheses—Part 1: Classification, definitions and designation of dimensions	Added "Design Controls" to Process(es) Impacted	121
126	ASTM F366–82(2000), Standard Specification for Fixation Pins and Wires	Added "Design Controls" to Process(es) Impacted	126
131	ATSM F1044–99, Standard Test Method for Shear Testing of Calcium Phosphate Coatings and Metallic Coatings	Added "Design Controls" to Process(es) Impacted	131
140	ATSM F1582–98, Standard Terminology Relating to Spinal Implants	Added "Design Controls" to Process(es) Impacted	140
141	ASTM F1612–95(2000), Standard Practice for Cyclic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components With Torsion	Added "Design Controls" to Process(es) Impacted	141
142	ATSM F1672–95(2000), Standard Specification for Resurfacing Patellar Prosthesis	Added "Design Controls" to Process(es) Impacted	142
143	ISO 7153–1:1991/Amd. 1:1999, Surgical Instruments—Metallic Materials—Part 1: Stainless steel	Withdrawn and transferred to Materials	143
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	Added "Design Controls" to Process(es) Impacted	152
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	Added "Design Controls" to Process(es) Impacted	155
159	ASTM F1717–01, Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Added "Design Controls" to Process(es) Impacted	159
161	ASTM F1264–01, Standard Specification and Test Methods for Intramedullary Fixation Devices	Added "Design Controls" to Process(es) Impacted	161
162	ASTM F564–02, Standard Specification and Test Methods for Metallic Bone Staples	Added "Design Controls" to Process(es) Impacted	162
163	ASTM F543–02 Standard Specification and Test Methods for Metallic Medical Bone Screws	Added "Design Controls" to Process(es) Impacted	163
164	ASTM F1541–02, Standard Specification and Test Methods for External Skeletal Fixation Devices	Added "Design Controls" to Process(es) Impacted	164

H. Radiology

Old Item No.	Standard	Change	Replacement Item No.
38	IEC 60601–2–15, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Capacitor Discharge X-ray Generators (1988)	Withdrawn	

Old Item No.	Standard	Change	Replacement Item No.
43	IEC 60601–2–33: Medical Electrical Equipment—Part 2, Particular Requirements for the Safety of Magnetic Resonance Equipment for Medical Diagnosis (2002–2005)	Withdrawn and replaced with newer version	86
60	IEC 61217 (2002–03), Radiotherapy Equipment—Coordinates, movements, and scales	Withdrawn and replaced with newer version	87
64	IEC 60601–2–45, Ed. 2.0, (2001–05): Medical Electrical Equipment—Part 2–45: Particular Requirements for the Safety of Mammographic X-ray Equipment and Mammographic Stereotactic Devices	Correction date inserted	64
78	NEMA PS 3.1 through PS 3.16 2000, Digital Imaging and Communications in Medicine (DICOM)	Correction Parts inserted in title	78

I. Sterility

Old Item No.	Standard	Change	Replacement Item No.
1	AOAC 6.2.01:2000, Official Method 955.14, Testing Disinfectants Against *Salmonella choleraesuis*, Use-Dilution Method	Withdrawn and replaced with newer version	94
2	AOAC 6.2.02:2000, Official Method 991.47, Testing Disinfectants Against *Salmonella choleraesuis*, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	95
3	AOAC 6.2.03:2000, Official Method 991.48, Testing Disinfectants Against *Staphylococcus aureus*, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version.	96
4	AOAC 6.2.04:2000, Official Method 955.15, Testing Disinfectants Against *Staphylococcus aureus*, Use-Dilution Method	Withdrawn and replaced with newer version	97
5	AOAC 6.2.05:2000, Official Method 991.49, Testing Disinfectants Against *Pseudomonas aeruginosa*, Hard Surface Carrier Test Method	Withdrawn and replaced with newer version	98
6	AOAC 6.2.06:2000, Official Method 964.02, Testing Disinfectants Against *Pseudomonas aeruginosa*, Use-Dilution Method	Withdrawn and replaced with newer version	99
7	AOAC 6.3.02, Official Method 955.17, Fungicidal Activity of Disinfectants Using *Trichophyton mentagrophytes*	Withdrawn and replaced with newer version	100
8	AOAC 6.3.05:2000, Official Method 966.04, Sporicidal Activity of Disinfectants	Withdrawn and replaced with newer version	101
9	AOAC 6.3.06:2000, Official Method 965.12, Tuberculocidal Activity of Disinfectants	Withdrawn and replaced with newer version	102
24	ANSI/AAMI/ISO 11134:1993, Sterilization of Health Care Products—Requirements for Validation and Routine Control-Industrial Moist Heat Sterilization	Contact person	24
25	ANSI/AAMI/ISO 11135–1994, Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization	Contact person	25
27	AAMI/ANSI/ISO 11607:2000, Packaging for Terminally Sterilized Medical Devices	Withdrawn and replaced with newer version; Add to Extent of Recognition	103
51	ANSI/AAMI ST58:1996, Safe Use and Handling of Glutaraldehyde-Based Products in Health Care Facilities and ANSI/AAMI ST58:1996/Amendment 1 2002	Withdrawn and replaced with newer version	104
52	ANSI/AAMI ST59:1999, Sterilization of Health Care Products—Biological Indicators Part 1: General Requirements	Updated Relevant Guidance	52
73	ANSI/AAMI ST46:2002, Steam Sterilization and Sterility Assurance in Health Care Facilities	Withdrawn and replaced with newer version	105
75	ANSI/AAMI/ISO 11137:1994, Sterilization of Health Care Products-Requirements for Validation and Routine Control-Radiation Sterilization and ISO11137:1995 (Amendment 1:2002)	Title Correction; Additional Relevant Guidance; Contact person	75
76	AAMI/ANSI/ISO 10993–7:1995 (R) 2001, Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	Delete (e.g. hemodialyzers) from the Extent of Recognition	76
78	USP 26:2003, Biological Indicator for Dry Heat Sterilization, Paper Carrier	Withdrawn and replaced with newer version	106

Old Item No.	Standard	Change	Replacement Item No.
79	USP 26:2003, Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Withdrawn and replaced with newer version	107
80	USP 26:2003, Biological Indicator for Steam Sterilization, Paper Carrier	Withdrawn and replaced with newer version	108
81	USP 26:2003, <61> Microbial Limits Test	Withdrawn and replaced with newer version	109
82	USP 26:2003, <71>, Microbiological Tests, Sterility Tests	Withdrawn and replaced with newer version	110
83	USP 26:2003, <85> Biological Tests and Assays, Bacterial Endotoxin Test (LA)	Withdrawn and replaced with newer version	111
84	USP 26:2003, <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version	112
85	USP 26:2003 <1211> Sterilization and Sterility Assurance of Compendial Articles	Withdrawn and replaced with newer version	113
87	USP 26:2003, Transfusion and Infusion Assemblies and Similar Medical Devices <161>	Withdrawn and replaced with newer version	114
93	USP 26:2003, Biological Indicator for Steam Sterilization	Withdrawn and replaced with newer version	115

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: 009," is as follows:

A. Anesthesia

Item Number	Title of Standard	Reference Number and Date
45	Standard Specification for Ventilators Intended for use During Anesthesia	F1101–90 (1996)
46	Breathing Tubes Intended for use with Anesthetic Apparatus and Ventilators	ISO 5367:2000

B. Biocompatibility

Item No.	Title of Standard	Reference No. and Date
79	Standard Practice for Extraction of Medical Plastics	ASTM F619–02
80	Standard Practice for Characterization of Particles	ASTM F1877–98
81	Standard Practice for Selecting Tests for Determining the Propensity of Materials to Cause Immunotoxicity	ASTM F1905–98
82	Standard Practice for Evaluation of Immune Responses In Biocompatibility Testing Using ELISA Tests, Lymphocyte, Proliferation, and Cell Migration	ASTM F2147–01

C. Cardiovascular/Neurology

Item No.	Title of Standard	Reference No. and Date
50	Cardiac Defibrillator Devices	ANSI/AAMI DF2–1996 (Revision of ANSI/AAMI DF2–1989)
51	Automatic External Defibrillators and Remote-Control Defibrillators	ANSI/AAMI DF39–1993

D. Dental/ENT

Item No.	Title of Standard	Reference No. and Date
103	Denture Base Polymers	ANSI/ADA Specification No. 12:1999
104	Pit and Fissure Sealants	ANSI/ADA Specification No. 39: 1999
105	Resilient Lining Materials for Removable Dentures, Part 2: Short-Term Materials	ANSI/ADA Specification No. 75: 1997
106	Dental Reversible/Irreversible Hydrocolloid Impression Material System	ANSI/ADA Specification No. 82: 1998
107	Dental, Water-Based Cements	ISO 9917–2:1998
108	Dentistry, Resilient Lining Materials for Removable Dentures—Part 1: Short-Term Materials	ISO 10139–1:1991
109	Dentistry, Reversible-Irreversible Hydrocolloid Impression Material Systems	ISO 13716: 1999

E. In Vitro Diagnostic

Item No.	Title of Standard	Reference No. and Date
88	Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures: Approved Guideline	NCCLS C37–A:1999
89	A Designated Comparison Method for the Measurement of Ionized Calcium in Serum; Approved Standard	NCCLS C39–A:2000
90	Clinical Application of Flow Cytometry: Immunophenotyping of Leukemic Cells; Approved Guideline	NCCLS H43–A:1998
91	Interference Testing in Clinical Chemistry; Approved Guideline	NCCLS EP7–A:2002
94	User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline	NCCLS EP12–A:2002
95	User Demonstration of Performance for Precision and Accuracy; Approved Guideline	NCCLS EP15–A:2001
96	Quality Management for Unit-Use Testing; Approved Guideline	NCCLS EP18–A:2002
97	Urinalysis and Collection, Transportation, and Preservation of Urine Specimens—Second Edition; Approved Guideline	NCCLS GP16–A2:2001

F. OB–GYN/Gastroenterology

Item No.	Title of Standard	Reference No. and Date
28	Hemodialyzers	ANSI/AAMI RD 16:1996/A1:2002 Amendment 1 to ANSI/AAMI RD 16:1996
29	Hemodialyzer Blood Tubing	ANSI/AAMI RD 17:1994/A1:2002 Amendment 1 to ANSI/AAMI RD 17:1994

G. Ophthalmic

Item No.	Title of Standard	Reference No. and Date
31	Optics and Optical Instruments—Lasers and Laser-related Equipment—Test Method for the Laser-resistance of Surgical Drapes and/or Patient-protective Covers	ISO 11810:2002
32	Optics and Optical Instruments—Lasers and Laser-related Equipment—Determination of Laser Resistance of Tracheal Tube Shafts	ISO 11990:2003

H. Radiology

Item No.	Title of Standard	Reference No. and Date
88	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Remote-Controlled Automatically-Driven Gamma-Ray Afterloading Equipment (1989)	IEC 60601–2–17 (1989)
89	Optics and optical instruments—Lasers and Laser-Related Equipment—Test Method for the Laser-Resistance of Surgical Drapes and/or Patient-Protective Covers	ISO 11810:2002
90	Medical Electrical Equipment—Part 2: Particular Requirements for Medical Electron Accelerators	IEC 60601–2–1 Amendment 1—Ed. 2.0 (2002–05)
91	Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Therapeutic X-ray Equipment Operating in the Range 10 kV to 1 MV	IEC 60601–2–8 Amendment 1 (1997–98)
92	Medical Electrical Equipment—Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as used in X-ray Diagnostic Imaging	IEC 61674 (1997–10)
93	Medical Electrical Equipment—Dosimeters with Ionization Chambers and/or Semi-Conductor Detectors as used in X-ray Diagnostic Imaging	IEC 61674 Amendment 1 (2002–06)
94	Medical Electrical Equipment—Dosimeters with Ionization Chambers as used in Radiotherapy	IEC 60731 Amendment 1 (2002–06)

I. Sterility

Item No.	Title of Standard	Reference No. and Date
116	Bacterial Endotoxins—Test Methodologies, Routine Monitoring, and Alternatives to Batch Testing	ANSI/AAMI ST72:2002

J. Tissue Engineering

Item No.	Title of Standard	Reference No. and Date
3	Standard Guide for Characterization of Type 1 Collagen as a Starting Material for Surgical Implants and Substrates for Tissue Engineered Medical Products	ASTM F2212–2002

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" via your fax machine, 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 321 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing

"Modification to the List of Recognized Standards, Recognition List Number: 009" 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 hyperlink at *http://www.fda.gov/cdrh/stdsprog.html*. This **Federal Register** notice of modifications in FDA's recognition of consensus standards will be available, upon publication, 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: 009." These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: 2/13/04

ch0370

February 13, 2004.

Beverly Chernaik Rothstein

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