

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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PDM

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 010

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: 010" (Recognition List Number: 010), 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: 010" 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: 010 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 document 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),

April 28, 2003 (68 FR 22391), and March 8, 2004 (69 FR 10712), 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: 010

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: 010" 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. Anesthesia

Old Item No.	Standard	Change	Replacement Item No.
19	ISO 8382:1988, Resuscitators Intended for Use with Humans	Processes impacted, extent of recognition, relevant guidance	19
42	ISO 5360:1993, Anaesthetic vaporizers—Agent-specific filling systems	Devices affected, processes impacted, extent of recognition	42

B. General

Old Item No.	Standard	Change	Replacement Item No.
2	IEC 60601-1, Medical Electrical Equipment—Part 1: General Requirements for Safety	Contact person	2
28	IEC 60601-1-2 (Second Edition, 2001) Medical Electrical Equipment—Part 1: General Requirements for Safety; Electromagnetic Compatibility—Requirements and Tests	Contact person	28
30	ANSI/AAMI/IEC 60601-1-2:2001, Medical Electrical Equipment—Parts 1 to 2: General Requirements for Safety—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests	Correct title of standard	30

C. General Hospital/General Plastic Surgery

Old Item No.	Standard	Change	Replacement Item No.
3	ASTM F754-88, Standard Specification for Implantable Polytetrafluoroethylene (PTFE) Polymer Fabricated in Sheet, Tube and Rod Shapes	Withdrawn and replaced with new version	108
4	ASTM F881-94, Standard Specification for Elastomer Facial Implants	Withdrawn and replaced with newer version	109
6	ASTM F1441-92, Standard Specification for Soft Tissue Expanders	Withdrawn and replaced with newer version	110
10	IEC 60601-2-38, Medical Electrical Equipment—Part 2: Particular Requirements for the Safety of Electrically Operated Hospital Beds	Withdrawn and replaced with newer version	111

D. In Vitro Diagnostic

Old Item No.	Standard	Change	Replacement Item No.
47	NCCLS MM2-A2 Immunoglobulin and T-Cell Receptor Gene Rearrangement Assays; Approved Guideline—Second Edition	Withdrawn and replaced with newer version	98
84	CEN 13640, Stability Testing of In Vitro Diagnostic Reagents	Correction to date of standard	84

E. Materials

Old Item No.	Title of Standard	Change	Replacement Item No.
26	ASTM F1314-01, Standard Specification for Wrought Nitrogen Strengthened 22 Chromium - 13 Nickel - 5 Manganese - 2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910)	Title change	26
39	ASTM F2052-02, Standard Test Method for Measurement of Magnetically Induced Displacement Force on medical Devices in the Magnetic Resonance Environment	Recognizing a newer version with a revised title	70
55	ASTM F2182-02a, Standard Test Method for Measurement of Radio Frequency Induced Heating Near Passive Implants During Magnetic Resonance Imaging	Recognizing a newer version	71
62	ISO 5832-1:1997, Implants for Surgery—Metallic materials—Part 1: Wrought stainless steel	Transferred from Orthopedics 62 to Materials 56	56

Old Item No.	Title of Standard	Change	Replacement Item No.
64	ISO 5832-3:1996, Implants for Surgery—Metallic materials—Part 3: Wrought titanium 6-aluminum 4-vanadium alloy	Transferred from Orthopedics 64 to Materials 58	58
65	ISO 5832-4:1996, Implants for Surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy	Transferred from Orthopedics 65 to Materials 59	59
62	ISO 5832-1:1997, Implants for Surgery—Metallic materials—Part 1: Wrought stainless steel	Transferred from Orthopedics 62 to Materials 56	56
64	ISO 5832-3:1996, Implants for Surgery—Metallic materials—Part 3: Wrought titanium 6-aluminum 4-vanadium alloy	Transferred from Orthopedics 64 to Materials 58	58
65	ISO 5832-4:1996, Implants for Surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy	Transferred from Orthopedics 65 to Materials 59	59
66	ISO 5832-5:1993, Implants for Surgery—Metallic materials—Part 5: Wrought cobalt-chromium-tungsten-nickel alloy	Transferred from Orthopedics 66 to Materials 60	60
67	ISO 5832-6:1997, Implants for Surgery—Metallic materials—Part 6: Wrought cobalt-nickel-chromium-molybdenum alloy	Transferred from Orthopedics 67 to Materials 61	61
70	ISO 5832-11:1994, Implants for Surgery—Metallic materials—Part 11: Wrought titanium 6-aluminum 7-niobium alloy	Transferred from Orthopedics 70 to Materials 63	63
71	ISO 5832-12:1996, Implants for Surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy	Transferred from Orthopedics 71 to Materials 64	64
76	ISO 6474-94, Implants for surgery—Ceramic materials based on high purity alumina	Transferred from Orthopedics 76 to Materials 66	66
84	ISO 13782:1996, Implants for surgery—Metallic materials—Unalloyed tantalum for surgical implant applications	Transferred from Orthopedics 84 to Materials 68	68
117	ISO 5832-2:1999, Implants for Surgery—Metallic Materials—Part 2: Unalloyed Titanium	Transferred from Orthopedics 117 to Materials 57	57
118	ISO 5832-9:1992, Implants for Surgery—Metallic Materials—Part 9: Wrought High Nitrogen Stainless Steel	Transferred from Orthopedics 118 to Materials 62	62
119	ISO 5834-2:1998, Implants for Surgery—Ultra-High-Molecular Weight Polyethylene—Part 2: Moulded Forms	Transferred from Orthopedics 119 to Materials 65	65
143	ISO 7153-1:1991/Amd. 1:1999, Surgical instruments—Metallic materials—Part 1: Stainless steel	Transferred from Orthopedics 143 to Materials 67	67

F. Radiology

Old Item No.	Standard	Change	Replacement Item No.
5	ANSI Ph 2.50-1983, Photography—Direct-Exposing Medical and Dental Radiographic Film/Process Systems—Determination of ISO Speed and Average Gradient	Title correction	5
7	ISO/IEC 10918-1:1994, Information Technology—Digital Compression and Coding of Continuous—Tone Still Images: Requirements and Guidelines	Title correction	7
8	IEC 60336 (R1993), X-ray Tube Assemblies for Medical Diagnosis Characteristics of Focal Spots	Title correction	8
17	NEMA MS 8-1993 (2000), Characterization of the Specific Absorption Rate for Magnetic Resonance Imaging Systems	Reaffirmation	17
22	NEMA XR 5-1992 (R1999), Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-ray Tubes	Reaffirmation	22
23	NEMA XR 10-1986 (R1992, R1998), Measurement of the Maximum Symmetrical Radiation Field from a Rotating Node X-ray Tube used for Medical Diagnosis	Reaffirmation	23
24	NEMA XR 11-1993 (R1999), Test Standard for Determination of the Limiting Spatial Resolution of X-ray Image Intensifier Systems	Title correction	24
25	NEMA XR 15-1991 (R1996, R2001), Test Standard for the Determination of the Visible Entrance Field Size of an X-ray Image Intensifier System	Reaffirmation	25

Old Item No.	Standard	Change	Replacement Item No.
26	NEMA XR 16-1991 (R1996, R2001), Test Standard for the Determination of the System Contrast Ratio and the System Veiling Glare Index of an X-ray Image Intensifier System	Reaffirmation	26
27	NEMA XR 17-1993 (R1999), Test Standard for the Measurement of the Image Signal Uniformity of an X-ray Image Intensifier System	Reaffirmation	27
28	NEMA XR 18-1993 (R1999), Test Standard for the Determination of the Radial Image Distortion of an X-ray Image Intensifier System	Reaffirmation	28
29	NEMA XR 19-1993 (R1999), Thermal and Loading Characteristics of X-ray Tubes used for Medical Diagnosis	Reaffirmation	29
44	AIUM AOMS—Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment	Title correction and reaffirmation	44
46	AIUM RTD1—Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment Revision 1	Title correction and reaffirmation	46
48	AIUM AOL—Acoustic Output Labeling Standard for Diagnostic Ultrasound Equipment: A Standard for How Manufacturers Should Specify Acoustic Output Data	Title correction	48
61	UL 122-1999, Standard for Safety of Photographic Equipment—4th Edition	Title correction	61
66	AIUM MUS—Medical Ultrasound Safety	Title correction and reaffirmation	66
72	NEMA UD 3-1998, Revision 1, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment	Title correction	72
11	NEMA MS 2-2003, Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images	Withdrawn and replaced with newer version	95
12	NEMA MS 3-2003, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images	Withdrawn and replaced with newer version	96
77	NEMA MS-1-2001, Determination of Signal to Noise Ratio (SNR) in Diagnostic Magnetic Resonance Images	Withdrawn and replaced with newer version	97
69	NEMA MS 6-1991 (R2000), Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images	Reaffirmation	69
3	ANSI IT1.49-1995, Photography (Films)—Medical Radiographic Cassettes/Screens/Films-Dimensions	Withdrawn and replaced with Item 98	
14	NEMA MS 5-2003, Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging	Withdrawn and replaced with newer version	99

G. Sterility

Old Item No.	Standard	Change	Replacement Item No.
76	AAMI/ANSI/ISO 10993-7:1995 (R) 2001, Biological Evaluation of Medical Devices—Part 7: Ethylene Oxide Sterilization Residuals	Deleted "Hemodialyzers" from Extent of Recognition	76

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: 010, is as follows:

A. Anesthesia

Item No.	Title of Standard	Reference No. and Date
47	Ancillary devices for expired air resuscitation	AS 4259-1995

Item No.	Title of Standard	Reference No. and Date
48	Standard Specification for Electrically Powered Home Care Ventilators, Part 1—Positive-Pressure Ventilators and Ventilator Circuits	ASTM F1246-91(1999)
49	Standard Specification for Suction Catheters for Use in the Respiratory Tract	ASTM F1981-99

B. General

Item No.	Title of Standard	Reference No. and Date
33	Medical Electrical Equipment—Parts 1 to 8: General requirements for safety—Collateral Standard: Alarm systems—Requirements, tests, and guidelines—General requirements and guidelines for alarm systems in medical equipment	IEC 60601-1-8:2003

C. In Vitro Diagnostic

Item No.	Title of Standard	Reference No. and Date
99	Nucleic Acid Amplification Assays for Molecular Hematopathology; Approved Guideline	NCCLS MM5-A:2000
100	In Vitro Diagnostic Test Systems—Requirements for In Vitro Whole Blood Glucose Monitoring Systems Intended for Use by Patients for Self Testing in Management of Diabetes Mellitus, First Edition	ISO 15197:2003
101	Assays of vonWillebrand Factor Antigen and Ristocetin Cofactor Activity; Approved Guideline	NCCLS H51-A:2002

D. Materials

Item No.	Title of Standard	Reference No. and Date
72	Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment	ASTM F2213-04

E. Radiology

Item No.	Title of Standard	Reference No. and Date
98	Medical Electrical Equipment—Dosimeters with Ionization Chambers as Used in Radiotherapy	IEC 60731—Amendment 1 2002-06

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.

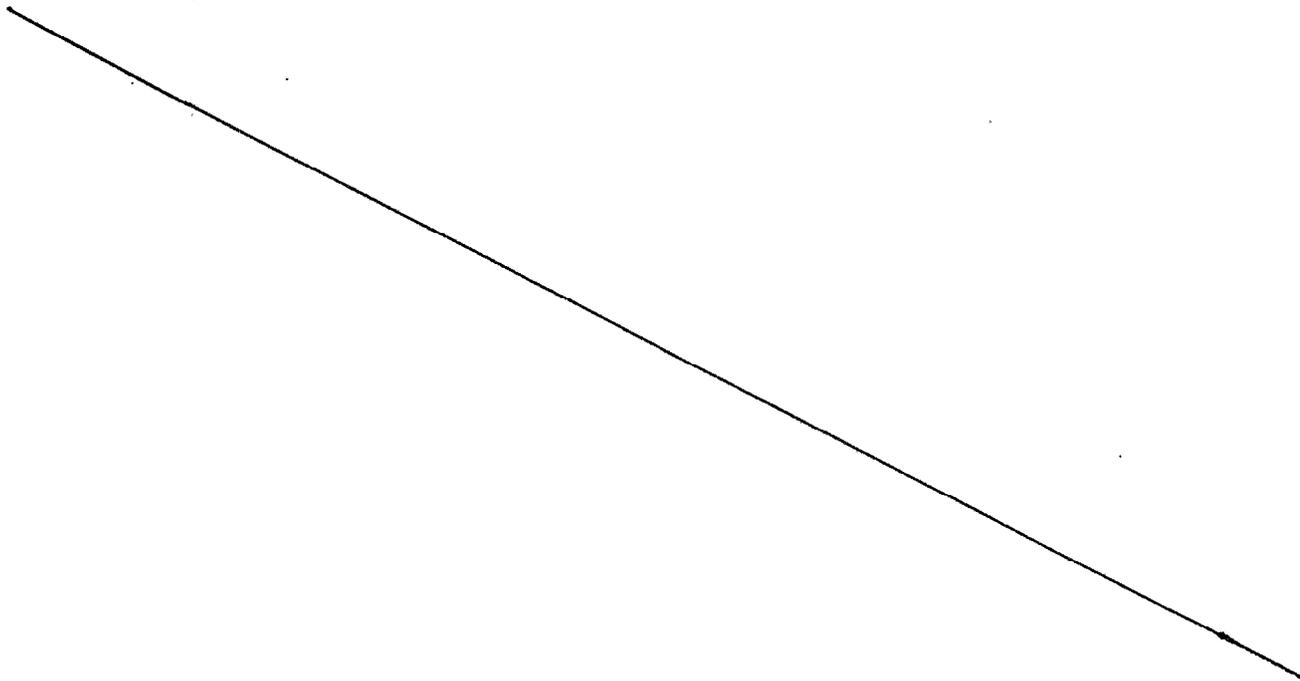
You may obtain a copy of “Guidance on the Recognition and Use of Consensus Standards” by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a 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: 010” 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: 010." These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: 6/02/04

June 2, 2004.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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