FDA Modernization Act of 1997: Guidance for the Recognition and Use of Consensus Standards; Availability

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. 98D-0085]

FDA Modernization Act of 1997: Guidance for the Recognition and Use of Consensus Standards; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is: (1) Announcing the availability of a guidance entitled ``Guidance on the Recognition and Use of Consensus Standards,'' the purpose of which is to provide guidance to industry and reviewers within the Center for Devices and Radiological Health (CDRH) on the use of recognized consensus standards, including declarations of conformity to the standards, during the evaluation of premarket submissions for medical devices; (2) publishing the initial list of standards that will be recognized for use in the premarket review process; and (3) announcing the agency's policy on updating the list of recognized standards. This guidance will assist manufacturers who elect to declare conformity with consensus standards to meet all or part of medical device review requirements.

DATES: This guidance is effective on February 19, 1998; however, written comments concerning this guidance may be submitted at any time.

ADDRESSES: Written comments concerning this guidance must be submitted to the first contact person listed below. Comments should be identified with the docket number found in brackets in the heading of this document. Submit written requests for single copies of ``Recognition and Use of Consensus Standards'' to the Division of Small Manufacturers Assistance (DSMA), 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 request, or fax your request to 301-443-8818. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance. This guidance document may also be accessed via the Internet at FDA's web site ``http://www.fda.gov/cdrh''.

FOR FURTHER INFORMATION CONTACT:
To comment on this guidance: Melvyn R. Altman, Associate Director for Standards Policy, enter for Devices and Radiological Health (HFZ-101),

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Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4766, ext. 103.
To recommend additional standards for recognition:
James J. McCue, Director, Standards Program Coordination Staff, enter for Devices and Radiological Health (HFZ-101), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-4766, ext. 137.

SUPPLEMENTARY INFORMATION:

I. Background

Many domestic and international consensus standards address relevant aspects of safety and/or effectiveness of medical devices. Many of these consensus standards have been developed with the participation of FDA staff. Section 204 of the Food and Drug Administration Modernization Act of 1997, Pub. L. 105-115, 111 Stat. 2296 (1997) (FDAMA) amends section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d), allowing the agency to recognize consensus standards established by international and national standards development organizations that may be used to satisfy identified portions of device review requirements. This notice announces the availability of a guidance document entitled ``Guidance on the Recognition and Use of Consensus Standards,'' which describes how FDA will implement that part of the FDAMA.
The agency has adopted Good Guidance Practices (GGP's), which set

forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). Although ``Guidance on the Recognition and Use of Consensus Standards'' is Level 1 guidance under the GGP's, this guidance will become effective upon issuance. Under the GGP's the agency may elect not to solicit public comment prior to implementation when there is a new statutory requirement * * * that requires immediate implementation and guidance is needed to help effect such implementation'' (62 FR 8961 at 8968). However, comments may be submitted at any time by interested parties, and these comments will be considered in any future revisions to the guidance.

This guidance document may contain collections of information that require OMB clearance under the Paperwork Reduction Act of 1995. FDA will seek such approval and provide an opportunity for comment, as appropriate.

II. Use of Recognized Standards

A person required to submit a premarket application (i.e., Premarket Notification (510(k)), Investigational Device Exemptions application (IDE), Premarket Approval application (PMA), Humanitarian Device Exemption application (HDE), or Product Development Protocol (PDP)) must provide information as required by the statute and regulations to allow FDA to make an appropriate decision regarding the clearance or approval of the submission. This guidance document describes how FDA will recognize consensus standards and use conformance with recognized standards to satisfy review requirements. It does not affect FDA's ability to obtain any information authorized by the statute or regulations. Use of consensus standards in this manner is authorized by section 514 of the act, as amended by FDAMA.

FDA believes that conformance with applicable recognized consensus standards can provide a reasonable assurance of safety and/or effectiveness for many devices. Therefore, information submitted on conformance with such standards will have a direct bearing on determinations of safety and effectiveness made during the review of IDE's, HDE's, PMA's, and PDP's. In case of 510(k)s, information on conformance with recognized consensus standards may help establish the substantial equivalence of a new device to a legally marketed predicate device. This information can serve as a surrogate for comparative information to show that the new device is as safe and effective as the predicate in the areas covered by the standards. Moreover, if a premarket submission contains a declaration of conformity to recognized consensus standards, this will, in most cases, eliminate the need to review actual test data for those aspects of the device addressed by the standards. The content of a declaration of conformity is described in the guidance document and is consistent with the ISO/IEC Guide 22.

Conformance with recognized consensus standards in and of itself,

however, may not always be a sufficient basis for regulatory decisions. For example, a specific device may raise a safety or effectiveness issue not addressed by any standard, or a specific FDA regulation may require additional information beyond that which conformity to the recognized consensus standards provides. Under such circumstances, conformity with recognized standards will not satisfy all requirements for marketing, or investigating, the product in the United States.

The guidance document, ``Guidance on the Recognition and Use of Consensus Standards'', represents the agency's current thinking on the use of recognized consensus standards for medical 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 approach satisfies the requirements of the applicable statute, regulations, or both.

III. List of Recognized Standards

The initial list of consensus standards to be recognized for use in premarket review is presented at the end of this document. This list is also maintained on the FDA web site ``http://www.fda.gov/cdrh''. Also posted on the web site are supplemental data sheets for each recognized standard. These data sheets list the address(es) where the standard can be obtained, information on any limitations to the application of the standard in medical device review, and a list of devices for which declarations of conformity with the recognized standard will be routinely accepted by agency reviewers. In addition to these documents, the web site contains answers to frequently asked questions regarding the use of recognized standards.

IV. Recommendation of Standards for Recognition by FDA

Modifications to the list of recognized consensus standards related to medical devices will be announced in the Federal Register at least once a year, or more often if necessary. FDA intends that the next revision to the list of recognized standards will include standards to be recognized by the Center for Biologics Evaluation and Research as well as by CDRH.

Any person may recommend consensus standards as candidates for recognition under new paragraph of section 514 of the act, by submitting such recommendations, with justification, to the address identified at the beginning of this document. 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 nationally or internationally recognized standards development organization, (4) a proposed list of devices for which a declaration of conformity should routinely apply, and (5) a brief identification of the testing or

performance or other characteristics of

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the device(s) that would be addressed by a declaration of conformity.

Opportunity to Recommend Standards for CDRH Recognition

V. Electronic Access

In order to receive the guidance document ``Recognition and Use of Consensus Standards,'' via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at the second voice prompt press 2, and then enter the document number 321, followed by the pound sign (#). Then follow the remaining voice prompts to complete your request. Persons interested in obtaining a copy of the guidance may also do so by using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH Home Page includes the guidance Document ``Guidance on the Recognition and Use of Consensus Standards'', as well as the list of recognized standards and details on their application and information on obtaining copies. The CDRH home page may be accessed at ``http://www.fda.gov/cdrh''.

A text-only version of the CDRH Web site is also available from a computer or VT-100 compatible terminal by dialing 800-222-0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA Bulletin Board Service. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select Center for Devices and Radiological Health for general information, or arrow down for specific topics.

VI. Comments

Interested persons may, at any time, submit to the contact person listed above written comments regarding the guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments will be considered in determining whether to amend the current guidance.

	Title of standard	Reference number and date	Name of standards development organization
	Generally Applicable Standards		
1.....	Biological Evaluation of Medical Devices--Part 1: Guidance on Selection of Tests--First Edition.	ANSI/AAMI/ISO 10993-1	Association for the Advancement of Medical Instrumentation.
2.....	Medical Electrical Equipment--Part 1: General Requirements for Safety.\1\.	IEC 60601-1	International Electrotechnical Commission (IEC).
3.....	Biological Evaluation of Medical Devices--Part 1: Guidance on Selection of Tests--First Edition (Corrigendum 1-1992)(CEN EN 30993-1:1994).	ISO 10993-1	International Organization for Standardization (ISO).
	In Vitro Devices		
1.....	How to Define, Determine and Utilize Reference Intervals in the Clinical Laboratory; Approved Guideline.	C28-A (1995)	National Committee for Clinical Laboratory Standards (NCCLS).
2.....	Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline.	EP9-A (1995)	NCCLS.
3.....	Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; Approved Guideline.	GP-10-A (1995)	NCCLS.
4.....	Labeling of Home-Use In Vitro Testing Products; Approved Guideline.	GP14-A (1996)	NCCLS.
5.....	Procedures for the Handling and Processing of Blood Specimens;	H18-A (1990)	NCCLS.

	Approved Guidelines.		
6.....	Specifications for Immunological Testing for Infectious Diseases; Approved Guideline.	ILA18-A (1994)	NCCLS.
7.....	Assessing the Quality of Radioimmunassay Systems--Second Edition; Approved.	LAI-A2 (1994)	NCCLS.
8.....	Performance Standards for Antimicrobial Disk Susceptibility Tests--Sixth Edition; Approved Standard.	M2-A6 (1997)	NCCLS.
9.....	Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria--Third Edition; Approved Standard.	M11-A3 (1993)	NCCLS.
10.....	Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters.	M23A	NCCLS.
11.....	Molecular Diagnostic Methods for Infectious Diseases; Approved Guideline.	MM3-(1995)	NCCLS.

OB-GYN/Gastroenterology

1.....	Hemodialysis Systems.....	ANSI/AAMI RD5-1992	Association for the Advancement of Medical Instrumentation (AAMI).
2.....	Standard Performance Specifications for Rubber Contraceptives (Male Condom).	ASTM-D3492-96	American Society for Testing and Materials (ASTM).
3.....	Standard Performance Specifications for Foley Catheters.	ASTM F623-89	ASTM.

Ophthalmic

1.....	Optics and Optical Instruments--Contact Lenses--Determination of the Diameters.	ISO 9338:1996	International Organization for Standardization (ISO).
2.....	Optics and Optical Intruments--Contact Lenses--Determination of the Thickness--Part 1: Rigid Contact Lenses.	ISO 9339-1:1996	ISO.
3.....	Optics and Optical Intruments--Contact Lenses--Determination of Strains for Rigid Contact Lenses.	ISO 9340:1996	ISO.
4.....	Optics and Optical Intruments--Contact Lenses--Determination of Inclusions and Surface Imperfections for Rigid Contact Lens.	ISO 9341:1996	ISO.
5.....	Optics and Optical Intruments--Contact Lenses--Determination of Cytotoxicity of Contact Lens Material--Part 1: Agar Overlay Test and Growth Inhibition Test.	ISO 9363-1:1994	ISO.
6.....	Optics and Optical Intruments--Contact Lenses--Determination of Biological Compatibility of Contact Lens Material--Testing of the Contact Lens System by Ocular Study with Rabbit Eyes.	ISO 9394:1994	ISO.
7.....	Optics and Optical Intruments--Contact Lenses--Determination of Oxygen Permeability and Transmissibility with the FATT Method.	ISO 9913-1:1996	ISO.
8.....	Optics and Optical Intruments--Contact Lenses--Determination of Curvature.	ISO 10338:1996	ISO.

9.....	Optics and Optical Intruments--Contact Lenses--Determination of Water Content of Hydrogel Lenses.	ISO 10339:1997	ISO.
10.....	Optics and Optical Intruments--Contact Lenses--Method for Determining the Extractable Substances.	ISO 10340:1995	ISO.
11.....	Optics and Optical Intruments--Contact Lenses--Saline Solution for Contact Lens Testing.	ISO 10344:1996	ISO.
12.....	Optics and Optical Intruments--Contact Lenses and Contact Lens Care Products-- Guidance for Clinical Investigations.	ISO 11980:1997	ISO.

Orthopaedics

1.....	Standard Specifications for Unalloyed Titanium for Surgical Implant Applications.	ASTM F67-95	American Society for Testing and Materials (ASTM)
2.....	Standard Specifications for Cast Cobalt-Chromium-Molybdenum Alloy for Surgical Implant Applications.	ASTM F75-92	ASTM.
3.....	Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	ASTM F86-91	ASTM.
4.....	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-10 Nickel Alloy for Surgical Implant Aplications (UNS R30605).	ASTM F90-96	ASTM.
5.....	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial)	ASTM F136-96	ASTM.

	Alloy (R56401) for Surgical Implant Applications.		
6.....	Standard Specification for Stainless Steel Bar and Wire for Surgical Implants (Special Quality).	ASTM F138-92	ASTM.
7.....	Standard Specification for Wrought-18 Chromium-14 Nickel-2.5 Molybdenum Stainless Sheet and Strip for Surgical Implants (UNS S31673).	ASTM F-139-96	ASTM.
8.....	Standard Specification for Fixation Pins and Wires.	ASTM F366-82(r1993)	ASTM.
9.....	Standard Specification for Unalloyed Tantalum for Surgical Implant Applications.	ASTM F560-92	ASTM.
10.....	Standard Practice for Analysis of Retrieved Metallic Orthopaedic Implants.	ASTM F561-87	ASTM.
11.....	Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy for Surgical Implant Applications.	ASTM F562-95	ASTM.
12.....	Standard Practice for Care and Handling of Orthopaedic Implants and Instruments.	ASTM F565	ASTM.
13.....	Standard Practice for Fluorescent Penetrant Inspection of Metallic Surgical Implants.	ASTM F601-86(1992)	ASTM.

14.....	Standard Specification for High-Purity Dense Aluminum Oxide for Surgical Implants.	ASTM F603	ASTM.
15.....	Standard Specification	ASTM F604	ASTM.

	Classifications for Silicone Elastomers Used in Medical Applications.		
16.....	Standard Specification for Titanium 6A1-4V E11 Alloy Forgings for Surgical.	ASTM F620	ASTM.
17.....	Standard Specification for Stainless Steel Forgings for Surgical Implants.	ASTM F621	ASTM.
18.....	Standard Practice for Radiography of Cast Metallic Surgical Implants.	ASTM F629-86	ASTM.
19.....	Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.	ASTM F648-84	ASTM.
20.....	Standard Specification for Wrought Cobalt-35 Nickel-20 Chromium-10 Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants.	ASTM F688-95	ASTM.
21.....	Standard Specification for 18 Chromium--12.5 Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications.	ASTM F745-95	ASTM.
22.....	Standard Test Method for Pitting or Crevice Corrosion of Metallic Surgical Implant Materials.	ASTM F746-87	ASTM.
23.....	Standard Specification for Metallic Bone Plates.	ASTM F786-82	ASTM.
24.....	Standard Specification for Metallic Nail-Plate Appliances.	ASTM F787-82	ASTM.
25.....	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy	ASTM F799-96	ASTM.

	Forgings for Surgical Implants (UNS R31537).		
26.....	Standard Test Method for Measuring Fretting Corrosion of Osteosynthesis Plates and Screws.	ASTM F897-84 (r1993)	ASTM.
27.....	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments.	ASTM F899-95	ASTM.
28.....	Standard Specification for Cobalt-Nickel-Chromium-Molybdenum Alloy Forgings for Surgical Implant Applications.	ASTM F961-96	ASTM.
29.....	Standard Practice for Permanent Marking of Orthopaedic Implant Components.	ASTM F983-86	ASTM.
30.....	Standard Test Method for Shear Testing of Porous Metal Coatings.	ASTM F1044-95	ASTM.
31.....	Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	ASTM F1088-87(R1992)	ASTM.
32.....	Standard Test Method for Corrosion of Surgical Instruments.	ASTM F1089-87	ASTM.
33.....	Standard Specification for Wrought Cobalt-20 Chromium-15 Tungsten-20 Nickel Alloy Surgical Fixation Wire UNS R30605.	ASTM F1091-91 (R1996)	ASTM.
34.....	Standard Specification for Titanium-6 Aluminum-4 Vanadium Alloy Castings for Surgical Implants (UNS R56406).	ASTM F1108-97	ASTM.
35.....	Standard Test Method for Tension Testing of Porous Metal Coatings.	ASTM F1147-95	ASTM.
36.....	Standard Test Method for Constant Stree Amplitude Fatigue Testing of	ASTM F1160-91	ASTM.

	Porous Metal-Coated Metallic Materials.		
37.....	Standard Specification...	ASTM F1185-88(1993)	ASTM.
38.....	Standard Guide for Mechanical Performance Considerations for Intramedullary Fixation Devices.	ASTM F1264-96a	ASTM.
39.....	Standard Specification for Wrought Titanium-6 Aluminum-7 Niobium Alloy for Surgical Implant Applications.	ASTM F1295-97	ASTM.
40.....	Standard Specification for Wrought Nitrogen Strengthened-22 Chromium-12.5 Nickel-5 Manganese-2.5 Molybdemum Stainless Steel Bar and Wire for Surgical Implants.	ASTM F1314-95	ASTM.
41.....	Standard Specification for Unalloyed Titanium Wire for Surgical Implant Applications.	ASTM F1341-92	ASTM.
42.....	Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).	ASTM F1350-96	ASTM.
43.....	Standard Specification for Cobalt-Chromium-Molybdenum Powder for Coating of Orthopaedic Implants.	ASTM F1377-92	ASTM.
44.....	Standard Specification for Wrought T1-6A1-4V Alloy for Surgical Implant Applications.	ASTM F1472-93	ASTM.

45.....	Standard Test Methods for Tension Testing of Calcium Phosphate Coatings.	ASTM F1501-95	ASTM.

46.....	Standard Specification For Wrought Cobalt-28-Chromium-6-Molybdenum Alloy for Surgical Implants.	ASTM F1537-94	ASTM.
47.....	Standard Classification of External Skeletal Fixators.	ASTM F1541-94	ASTM.
48.....	Standard Specification for Titanium and Titanium-6% Aluminum-4% Vanadium Alloy Powders for Coatings of Surgical Implants.	ASTM F1580-95	ASTM.
49.....	Standard Terminology Relating to Spinal Implants.	ASTM F1582-95	ASTM.
50.....	Standard Specification for Wrought Nitrogen Strengthened-21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants.	ASTM F1586-95	ASTM.
51.....	Standard Specification for Calcium Phosphate Coatings for Implantable Materials.	ASTM F1609-95	ASTM.
52.....	Standard Practice for Cydic Fatigue Testing of Metallic Stemmed Hip Arthroplasty Femoral Components With Torsion.	ASTM F1612-95	ASTM.
53.....	Standard Test Method for Shear Testing of Calcium Phosphate Coatings.	ASTM F1658-95	ASTM.
54.....	Standard Test Method for Bending and Shear Fatigue Testing of Calcium Phosphate Coatings on Solid Metallic Substrates.	ASTM F1659-95	ASTM.
55.....	Standard Specification for Resurfacing Patellar Prosthesis.	ASTM F1672-95	ASTM.
56.....	Standard Specification for Wrought Titanium-13	ASTM F1713-96	ASTM.

	Niobium-13 Zirconium Alloy for Surgical Implant Applications.		
57.....	Standard Test Methods for Static and Fatigue for Spinal Implant Constructs in a Corpectomy Model.	ASTM F1717-96	ASTM.
58.....	Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants.	ASTM F1781-97	ASTM.
59.....	Standard Test Methods for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis.	ASTM F1798	ASTM.
60.....	Cyclic Fatigue Testing of Metal Tibial Tray Components of TKR.	ASTM F1800	ASTM.
61.....	Standard Recommended Practice for Corrosion Fatigue Testing of Metallic Implant Materials.	ASTM F1801	ASTM.
62.....	Implants for Surgery--Metallic Materials--Part 1: Wrought Stainless Steel.	ISO 5832-1 (1997)	ISO.
63.....	Implants for Surgery--Metallic Materials--Part 2: Unalloyed Titanium.	ISO5832-2-93	ISO.
64.....	Implants for Surgery--Metallic--Part 3: Wrought Titanium 6-Aluminum 4-Vanadium Alloy Third Edition (CAN/CSA-Z310.8-M91).	ISO 5832-3 (1996)	ISO.
65.....	Implants for Surgery--Metallic Materials--Part 4: Cobalt-Chromium-Molybdenum Casting Alloy.	ISO 5832-4-96	ISO.
66.....	Implants for Surgery--Metal Materials--Part 5: Wrought Cobalt-Chromium-	ISO 5832-5-93	ISO.

	Tungsten-Nickel Alloy.		
67.....	Implants for Surgery--Metallic Materials--Part 6: Wrought Cobalt-Nickel-Chromium-Molybdenum Alloy.	ISO 5832-6	ISO.
68.....	Implants for Surgery--Metallic Materials--Part 9: Wrought High Nitrogen Stainless Steel First Edition.	ISO 5832-9 (1992)	ISO.
69.....	Implants for Surgery--Metallic Materials--Part 10: Wrought Titanium 5-Aluminum 2.5-Iron.	ISO 5832-10:1996	ISO.
70.....	Implants for Surgery--Metallic Materials--Part 11: Wrought Titanium 6-Aluminum 7-Niobium Alloy First Edition; CABN/CSA-Z310.7:M91.	ISO 5832-11 (1994)	ISO.
71.....	Implants for Surgery--Metalic Materials--Part 12: Wrought Cobalt-Chromium-Molybdenum Alloy.	ISO 5832-12-96	ISO.
72.....	Implants for Surgery--Ultra-High Molecular Weight Polyethylene--Part 2: Moulded Forms.	ISO 5834-2:1985	ISO.
73.....	Implants for Surgery--Skeletal Pins and Wires--Part 1: Material and Mechanical Requirements.	ISO 5838-1:1995	ISO.

74.....	Implants for Surgery--Skeletal Pins and Wires--Part 2: Steinmann Skeletal Pins--Dimensions.	ISO 5838-2:1991	ISO.
75.....	Implants for Surgery--Skeletal Pins and Wires--Part 3: Kirschner Skeletal Wires.	ISO 5838-3:1993	ISO.

76.....	Implants for Surgery--Ceramic Materials Based on High Purity Alumina.	ISO 6474-94	ISO.
77.....	Surgical Instruments--Metallic Materials--Part 1: Stainless Steel.	ISO 7153-1:1991	ISO.
78.....	Implants for Surgery--Partial and Total Hip Joint Prosthesis--Part 4: Determination of Endurance Properties of Stemmed Femoral Components with Application of Torsion.	ISO 7206-4:1989	ISO.
79.....	Implants for Surgery--Partial and Total Hip Joint Prosthesis--Part 8: Endurance Performance of Stemmed Femoral Components with Application of Torsion.	ISO 7206-8:1995	ISO.
80.....	Implants for Surgery--Guidance on Care and Handling of Orthopaedic Implants.	ISO 8828	ISO.
81.....	Implants for Surgery--Non Destructive Testing--Liguid Penetrant Inspection of Metallic Surgical Implants.	ISO 9583:1993	ISO.
82.....	Implants for Surgery--Non Destructive Testing--Radiological Examination of Cast Metallic Surgical Implants.	ISO 9584:1993	ISO.
83.....	Surgical and Dental Hand Instruments--Determination of Resistance Against Autoclaving, Corrosion and Thermal Exposure.	ISO 13402	ISO.
84.....	Implants for Surgery--Metallic Materials--Unalloyed Tantalum for Surgical Implant Applications.	ISO 13782: 1996	ISO.
85.....	Non-Active Surgical Implants--General	ISO 14630:1997	ISO

	Requirements.		
	Physical Medicine		
1.....	Determination of Static Stability.	ANSI/RESNA WC/01-1990	Rehabilitation Engineering and Assistive Technology Society of North American (RESNA).
2.....	Determination of Dynamic Stability of Electric Wheelchairs.	ANSI/RESNA WC/02-1991	RESNA.
3.....	Determination of the Effectiveness of Brakes.	ANSI/RESNA WC/03-1990	RESNA.
4.....	Determination of Energy Consumption of Electric Wheelchairs.	ANSI/RESNA WC/04-1990	RESNA.
5.....	Determination of Overall Dimensions, Mass and Turning Space--Wheelchair.	ANSI/RESNA WC/05-1990	RESNA.
6.....	Determination of Maximum Speed, Acceleration, and Retardation of Electric Wheelchairs.	ANSI/RESNA WC/06-1991	RESNA.
7.....	Wheelchairs--Determination of Seating and Wheel Dimensions.	ANSI/RESNA WC/07-1991	RESNA.
8.....	Wheelchairs--Static, Impact and Fatigue Strength Tests.	ANSI/RESNA WC/08-1991	RESNA.
9.....	Climatic Tests for Electric Wheelchairs.	ANSI/RESNA WC/09-1991	RESNA.
10.....	Determination of the Obstacle-Climbing Ability of Electric Wheelchairs.	ANSI/RESNA WC/10-1990	RESNA.
11.....	Wheelchairs--Test Dummies	ANSI/RESNA WC/11-1991	RESNA.
12.....	Coefficient of Friction of Test Surfaces.	ANSI/RESNA WC/13-1991	RESNA.
13.....	Wheelchairs--Testing of Power and Control Systems for Electric Wheelchairs.	ANSI/RESNA WC/14-1991	RESNA.
14.....	Wheelchairs--Requirements for Information	ANSI/RESNA WC/15-1991	RESNA.

	Disclosure, Documentation and Labelling.		
15.....	Wheelchairs--Determination of Flammability.	ANSI/RESNA WC/16-1991	RESNA.
16.....	Wheelchairs--Part 1: Determination of Static Stability.	ISO 7176-1:1986	ISO.
17.....	Wheelchairs--Part 2: Determination of Dynamic Stability of Electric Wheelchairs.	ISO 7176-2:1990	ISO.
18.....	Wheelchairs--Part 3: Determination of Efficiency of Brakes.	ISO 7176-3:1988	ISO.
19.....	Wheelchairs--Part 4: Energy Consumption of Electric Wheelchairs and Scooters for Determination of Theoretical Distance Range.	ISO 7176-4:1997	ISO.
20.....	Wheelchairs--Part 5: Determination of Overall Dimensions, Mass and Turning Space.	ISO 7176-5:1986	ISO.

21.....	Wheelchairs--Part 6: Determination of Maximum Speed, Acceleration and Retardation of Electric Wheelchairs.	ISO 7176-6:1988	ISO.
22.....	Wheelchairs--Part 9: Climatic Tests for Electric Wheelchairs.	ISO 7176-9:1988	ISO.
23.....	Wheelchairs--Part 10: Determination of Obstacle-Climbing Ability of Electric Wheelchairs.	ISO 7176-10:1988	ISO.
24.....	Wheelchairs--Part 11: Test Dummies.	ISO 7176-11:1992	ISO.
25.....	Wheelchairs--Part 13: Determination of	ISO 7176-13:1989	ISO.

	Coefficient of Friction of Test Surfaces.		
26.....	Wheelchairs--Part 14: Power and Control Systems for Electric Wheelchairs--Requirements and Test Methods.	ISO 7176-14:1997	ISO.
27.....	Wheelchairs--Part 15: Requirements for Information Disclosure, Documentation and Labeling.	ISO 7176-15:1996	ISO.
28.....	Wheelchairs--Part 16: Resistance to Ignition of Upholstered Parts--Requirements and Test Methods.	ISO 7176-16:1997	ISO.

Radiology

1.....	Medical X-Ray Screen-Film-Processing Systems, Method for the Sensitometry.	ANSI PH2.43-1982	American National Standards Institute (ANSI).
2.....	Photography (films)--Medical Hard Copy Imaging Films--Dimensions and Specifications.	ANSI/NAPM IT1.49-1995	National Association of Photographic Manufacturers, (NAPM).
3.....	Photography (Films)--Medical Radiographic Cassettes/Screens/Films--Dimensions.	ANSI/NAPM IT1.49-1995	NAPM.
4.....	Medical Ultrasound Safety	AIUM-1994	American Institute of Ultrasound in Medicine (AIUM).
5.....	Photography-Direct--Exposing Medical and Dental Radiographic Film/Process Systems--Determination of ISO Speed and ISO Average Gradient.	ANSI/NAPM IT2.48-1993	NAPM.
6.....	Determination of the Maximum Symmetrical Radiation Field from a	IEC 806(R1984)	IEC.

	Rotating Anode X-Ray Tube for Medical Diagnosis.		
7.....	Information Technology-Digital Compression and Coding of Continuous-Tone Still Images: Requirements and Guidelines.	ISO/IEC 10918-1:1994	ISO or IEC.
8.....	X-Ray Tube Assemblies for Medical Diagnosis Characteristics of Focal Spots.	IEC60336(R1993)	IEC.
9.....	Performance Measurements of Scintillation Cameras.	NEMA NU1-1994	NEMA.
10.....	Determination of Signal to Noise Ratio (SNR) in Magnetic Resonance Images.	NEMA MS1-1988(R1994)	NEMA.
11.....	Determination of Two-Dimensional Geometric Distortion in Diagnostic Magnetic Resonance Images.	NEMA MS2-1989	NEMA.
12.....	Determination of Image Uniformity in Diagnostic Magnetic Resonance Images.	NEMA MS3-1989	NEMA.
13.....	Acoustic Noise Measurement Procedure for Diagnostic Magnetic Resonance Imaging Devices.	NEMA MS4-1989	NEMA.
14.....	Determination of Slice Thickness in Diagnostic Magnetic Resonance Imaging.	NEMA MS5-1991	NEMA.
15.....	Characterization of Special Purpose Coils for Diagnostic Magnetic Resonance Images.	NEMA MS6-1991	NEMA.
16.....	Measurement Procedure for Time-Varying Gradiant Fields (dB/dt) for Magnetic Resonance Imaging Systems.	NEMA MS7-1993	NEMA.
17.....	Characterization of the	NEMA MS8-1993	NEMA.

	Specific Absoption Rate for Magnetic Resonance Imaging Systems.		
18.....	Performance Measurements of Positron Emission Tomographs.	NEMA NU2-1994	NEMA.
19.....	DICOM set--Digital Imaging and Communications in Medicine--Set Includes PS3.1 through PS3.13.	NEMA PS3 (Set)	NEMA.
20.....	Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment.	NEMA UD2-1992	NEMA.
21.....	Standard for Real-Time Display of Thermal and Mechanical Acoustic Output.	NEMA UD3-1992	NEMA.
22.....	Measurement of Dimensions and Properties of Focal Spots of Diagnostic X-Ray Tubes.	NEMA XR5-1992	NEMA.

23.....	Measurement of the Maximum Symmetrical Radiation Field from a Rotating Anode X-Ray Tube Used for Medical Diagnosis.	NEMA XR10-1986 (R1992)	NEMA.
24.....	Test Standard for Determination of the Limiting Spatial Resolution of X-Ray Image Intensifier Systems.	NEM XR11-1993	NEMA.
25.....	Test Standard for the Determination of the Visible Entrance Field Size of an X-Ray Image Intensifier System.	NEMA XR15-1991	NEMA.
26.....	Test Standard for the Determination of the System Contrast Ratio	NEMA XR16-1991	NEMA.

	and the System Veiling Glare Index of an X-Ray Image Intensifier System.		
27.....	Test Standard for the Measurement for the Image Signal Uniformity of an X-Ray Image Intensifier System.	NEMA XR17-1993	NEMA.
28.....	Test Standard for the Determination of the Radial Image Distortion of an X-Ray Image Intensifier System.	NEMA XR18-1993	NEMA.
29.....	Electrical Thermal and Loading Characteristics of X-Ray Tubes Used for Medical Diagnosis.	NEMA XR19-1993	NEMA.
30.....	Standard for Safety: Photographic Equipment.	UL-122	Underwriters Laboratory (UL).
31.....	Standard for Safety: X-Ray Equipment.	UL-187	UL.
32.....	Standard for Safety: Medical and Dental Equipment--Third Edition.	UL-544	UL.

\1\ The recognition of this standard for all devices was proposed for comment January 13, 1998 (63 FR 1974), and
is not yet final. This listing applies only to radiological imaging devices.

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