- When and where they viewed the video.
- Whom they recommended to view the video.
- What they learned from watching the video.
- What actions they may take because of the video.
- Whether they plan to change behaviors and knowledge about their State's activities.

The process assessment of the State videos will be conducted using telephone interviews with the State points of contact. This interview should take 10 minutes (0.167 hours). The outcome assessment of the State videos will be collected using an online form that will be completed by no more than 26 respondents and will require only 1 response per respondent. It will take an average of 10 minutes (0.167 hours) to review the instructions, complete the form, and submit it electronically.

Dissemination updates will be requested from each State point of contact every 6 months if there have been changes during that time period. These updates will be submitted electronically, and it should take approximately 5 minutes (0.083 hours) to review the instructions, complete the short form, and submit it electronically. The burden estimate is based on comments from several potential respondents who completed the online form, submitted it, and provided feedback on how long it would take them to complete it. The respondents will be employees of the State.

A short survey will also be used to collect data from viewers of the State videos. An estimated 1,000 viewers will voluntarily choose to complete this online survey, which will take 10 minutes (0.167 hours) to review, complete, and submit. The viewers are expected to represent the general public.

Form name	Number of respondents	Responses per respondent	Burden per response (hrs.)	Total burden
Process Interview	26	1	0.167	4.34
Dissemination Outcome	26	1	0.167	4.34
Dissemination Updates	26	1	0.083	2.16
Viewers Survey	1,000	1	0.167	167
Total	1,078	.....	.....	177.84

Written comments and recommendations concerning the proposed information collection should be sent by November 3, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202–395–5806.

Dated: September 28, 2010.

Elaine Parry

Director, Office of Management Technology and Operations.

[FR Doc. 2010–24849 Filed 10–1–10; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451] (formerly Docket No. 2004N–0226)

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 025

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA recognized consensus standards). This publication, entitled "Modifications to the List of Recognized Standards, Recognition List Number: 025" (Recognition List Number: 025), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written 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 of "Modifications to the List of Recognized Standards, Recognition List Number: 025" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149. Submit written comments concerning this document, or recommendations for additional standards for recognition, to the contact person (see **FOR FURTHER INFORMATION CONTACT**). Submit electronic comments by email: *standards@cdrh.fda.gov*. This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. 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: 025 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Carol L. Herman, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993–0002, 301–796–6574.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled "Recognition and Use of Consensus Standards." The notice described how FDA would implement its standard recognition

program and provided the initial list of recognized standards. Modifications to the initial list of recognized standards, as published in the **Federal Register**, are identified in table 1 of this document.

TABLE 1.—PREVIOUS PUBLICATIONS OF STANDARD RECOGNITION LISTS

February 25, 1998 (63 FR 9561)	November 8, 2005 (70 FR 67713)
October 16, 1998 (63 FR 55617)	March 31, 2006 (71 FR 16313)
July 12, 1999 (64 FR 37546)	June 23, 2006 (71 FR 36121)
November 15, 2000 (65 FR 69022)	November 3, 2006 (71 FR 64718)
May 7, 2001 (66 FR 23032)	May 21, 2007 (72 FR 28500)
January 14, 2002 (67 FR 1774)	September 12, 2007 (72 FR 52142)
October 2, 2002 (67 FR 61893)	December 19, 2007 (72 FR 71924)
April 28, 2003 (68 FR 22391)	September 9, 2008 (73 FR 52358)
March 8, 2004 (69 FR 10712)	March, 18, 2009 (74 FR 11586)
June 18, 2004 (69 FR 34176)	September 8, 2009 (74 FR 46203)
October 4, 2004 (69 FR 59240)	May 5, 2010 (75 FR 24711)
May 27, 2005 (70 FR 30756)	June 10, 2010 (75 FR 32943)

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains "hypertext markup language (HTML)" and "portable document format (PDF)" versions of the list of "FDA Recognized Consensus Standards." Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the supplementary information sheet for the standard to understand fully the extent to which FDA recognizes the standard.

II. Modifications to the List of Recognized Standards, Recognition List Number: 025

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: 025" to identify these current modifications.

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

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

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
A. Anesthesia			
1–61	1–82	IEC 60601–2–13 Edition 3.1 2009–08 Medical electrical equipment—Part 2–13: Particular requirements for the safety and essential performance of anaesthetic systems	Withdrawn and replaced with newer version
B. Biocompatibility			
2–96		ASTM F 1903–98 (Reapproved 2003) Standard Practice for Testing For Biological Responses to Particles in vitro	Type of standard and Contact person
2–98	2–156	ANSI/AAMI/ISO 10993–1:2009 Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process	Withdrawn and replaced with newer version
2–100		ASTM E1372–95 (2003) Standard Test Method for Conducting a 90-Day Oral Toxicity Study in Rats	Withdrawn
2–115		ASTM F 895—84 (Reapproved 2006) Standard Test Method for Agar Diffusion Cell Culture Screening for Cytotoxicity	Title, Type of standard , Relevant guidance and Contact person
2–117		ANSI/AAMI/ISO 10993–3:2003/(R)2009 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity	Reaffirmation, CDRH Office(s) and Division(s) associated with recognized standard and Contact person
2–118		ANSI/AAMI/ISO 10993–11:2006 Biological evaluation of medical devices—Part 11: Tests for systemic toxicity	Contact person
2–119		ASTM F 813–07 Standard Practice for Direct Contact Cell Culture Evaluation of Materials for Medical Devices	Title, Type of standard and Contact person
2–135		ANSI/AAMI/ISO 10993–12:2007 Biological evaluation of medical devices—Part 12: Sample preparation and reference materials	Title and Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
2–147	2–157	USP 33—NF 28 2010 Biological Tests <87> Biological Reactivity Test, In Vitro—Direct Contact Test	Withdrawn and replaced with newer version
2–148	2–158	USP 33–NF28 2010 Biological Tests <87> Biological Reactivity Test, In Vitro—Elution Test	Withdrawn and replaced with newer version
2–149	2–159	USP 33–NF28 2010 Biological Tests <88> Biological Reactivity Tests, In Vivo, Procedure—Preparation of Sample	Withdrawn and replaced with newer version
2–150	2–160	USP 33–NF28 2010 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Intracutaneous Test	Withdrawn and replaced with newer version
2–151	2–161	USP 33–NF28 2010 Biological Tests <88> Biological Reactivity Tests, In Vivo, Classification of Plastics—Systemic Injection Test	Withdrawn and replaced with newer version
C. Cardiology			
3–74	3–79	ASTM F 2079—09 Standard Test Method for Measuring Intrinsic Elastic Recoil of Balloon-Expandable Stents	Withdrawn and replaced with newer version
3–75		ANSI/AAMI SP10:2002/(R)2008 & ANSI/AAMI SP10:2002/A1:2003/(R)2008 & ANSI/AAMI SP10:2002/A2:2006/(R)2008 Manual, electronic or automated sphygmomanometers	Title and Extent of recognition
D. Dental/ENT			
4–86		ANSI/ADA Specification No. 38 2000 (Reaffirmed 2010) Metal-Ceramic Dental Restorative Systems	Reaffirmation
4–91		ANSI/ADA Specification No. 80 2001 (Reaffirmed 2007) Dental Materials—Determination of Color Stability Test Procedure	Reaffirmation
4–107	4–188	ISO 9917–2 Second edition 2010–04–15 Dentistry—Water-based cements—Part 2: Resin-modified cements	Withdrawn and replaced with newer version
4–117		ANSI/ADA Specification No. 12 2002 (Reaffirmed 2007) Denture Base Polymers	Reaffirmation
4–119		ANSI/ADA Specification No. 82 1998 (Reaffirmed 2009)—Dental Reversible/Irreversible Hydrocolloid Impression Material Systems	Reaffirmation
4–139		ANSI/ADA Specification No. 48-Visible Light Curing Units: 2004, Reaffirmed 2009	Reaffirmation
4–160		ANSI/ASA S3.1–1999 (Reaffirmed 2003) (Reaffirmed 2008) Maximum Permissible Ambient Noise Levels for Audiometric Test Rooms	Reaffirmation
4–164		ANSI/ASA S3.7–1997 (Reaffirmed 2003) (Reaffirmed 2008) Methods for Coupler Calibration of Earphones	Reaffirmation
4–166		ANSI/ASA S3.20–1995 (Reaffirmed 2003) (Reaffirmed 2008) Bioacoustical Terminology	Reaffirmation
4–167		ANSI/ASA S3.21–2004 (Reaffirmed 2009) Methods for Manual Pure-Tone Threshold Audiometry	Reaffirmation
4–169	4–190	ANSI/ASA S3.35–2010 (Revision of ANSI S3.35–2004) Method of Measurement of Performance Characteristics of Hearing Aids Under Simulated Real-Ear Working Conditions	Withdrawn and replaced with newer version
E. General			
5–31		ISO 15223:2000 Medical device symbols to be used with medical device labels, labeling and information to be supplied—First Edition: Amendment 1: 08/01/2002; Amendment 2: 02/15/2004	Withdrawn
5–32		CEN EN 980:1996+A1:1999+A2:2001 Graphical Symbols for Use in the Labelling of Medical Devices	Withdrawn

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
5–38	5–62	ANSI/ASQ Z1.4–2008 Sampling Procedures and Tables for Inspection by Attributes	Withdrawn and replaced with newer version
F. General Hospital/General Plastic Surgery			
6–62	6–239	ISO 8536–6 Second edition 2009–11–15 Infusion equipment for medical use—Part 6: Freeze drying closures for infusion bottles	Withdrawn and replaced with newer version
6–64	6–240	ISO 8536–3 Third edition 2009–06–01 Infusion equipment for medical use— Part 3: Aluminum caps for infusion bottles	Withdrawn and replaced with newer version
6–70		ASTM E825–98 (Reapproved 2009) Standard Specification for Phase Change-Type Disposable Fever Thermometer for Intermittent Determination of Human Temperature	Reaffirmation
6–110		ASTM F 1441–03 (Reapproved 2009) Standard Specification for Soft-Tissue Expander Devices	Reaffirmation
6–112		ANSI/AAMI PB70:2003/(R)2009 Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities	Reaffirmation
6–123		ASTM E667–98 (Reapproved 2009) Standard Specification for Mercury-in-Glass, Maximum Self-Registering Clinical Thermometers	Reaffirmation
6–124		ASTM E1104–98 (Reapproved 2009) Standard Specification for Clinical Thermometer Probe Covers and Sheaths	Reaffirmation
6–125		ASTM E1965–98 (Reapproved 2009) Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature	Reaffirmation
6–127	6–241	ISO 1135–4 Forth edition 2010–04–15 Transfusion equipment for medical use—Part 4: Transfusion sets for single use	Withdrawn and replaced with newer version
6–173	6–242	ISO 8536–2 Third edition 2010–03–15 Infusion equipment for medical use—Part 2: Closures for infusion bottles	Withdrawn and replaced with newer version
G. IVD			
7–49	7–210	CLSI H26–A2 Validation, Verification, and Quality Assurance of Automated Hematology Analyzers; Approved Standard-Second Edition	Withdrawn and replaced with newer version
7–82	7–211	CLSI C34–A3 Sweat Testing: Sample Collection and Quantitative Chloride Analysis; Approved Guideline-Third Edition	Withdrawn and replaced with newer version
7–96	7–212	CLSI EP18–A2 Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline-Second Edition	Withdrawn and replaced with newer version
7–100		ISO 15197 First edition 2003–05–01 In vitro diagnostic test systems—Requirements for blood-glucose monitoring systems for self testing in managing diabetes mellitus	Title
7–141	7–213	CLSI H18–A4 Procedures for the Handling and Processing of Blood Specimens for Common Laboratory Tests; Approved Guideline-Fourth Edition	Withdrawn and replaced with newer version
7–181	7–214	CLSI M35–A2 Abbreviated Identification of Bacteria and Yeast; Approved Guideline-Second Edition	Withdrawn, see 7–197
7–186	7–215	CLSI M44–A2 Method for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Approved Guideline-Second Edition	Withdrawn and Replaced with newer version
7–199	7–216	CLSI M100–S20 Performance Standards for Antimicrobial Susceptibility Testing; Twentieth Informational Supplement	Withdrawn and Replaced with newer version
7–208	7–217	CLSI M44–S3, Zone Diameter Interpretive Standards, Corresponding Minimal Inhibitory Concentration (MIC) Interpretive Breakpoints, and Quality Control Limits for Antifungal Disk Diffusion Susceptibility Testing of Yeasts; Third Informational Supplement	Withdrawn and replaced with newer version
H. Materials			

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
8–66	8–191	ISO 6474–1 First edition Implants for surgery—Ceramic materials—Part 1: Ceramic materials based on high purity alumina	Withdrawn and replaced with newer version
8–71	8–192	ASTM F2182—09 Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging	Withdraw and replaced with newer version
8–85	8–193	ASTM F 1854—09 Standard Test Method for Stereological Evaluation of Porous Coatings on Medical Implants	Withdraw and replaced with newer version
8–88		ASTM F2024–00 Standard Practice for X-ray Diffraction Determination of Phase Content of Plasma-Sprayed Hydroxyapatite Coatings	Type of standard and Contact person
8–130		ASTM F 620—06 Standard Specification for Alpha Plus Beta Titanium Alloy Forgings for Surgical Implants	Type of standard
8–131		ASTM F 799—06 Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)	Type of standard
8–137		ASTM F 75—07, Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)	Type of standard
8–138		ASTM F 745—07 Standard Specification for 18Chromium-12.5Nickel-2.5Molybdenum Stainless Steel for Cast and Solution-Annealed Surgical Implant Applications	Type of standard
8–156		ASTM F 139—08 Standard Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Sheet and Strip for Surgical Implants (UNS S31673)	Type of standard
8–183		ASTM F 560—08 Standard Specification for Unalloyed Tantalum for Surgical Implant Applications (UNS R05200, UNS R05400)	Type of standard
I. Neurology			
17–2		ASTM F1542–94 (2000) Standard Specification for the Requirements and Disclosure of Self-Closing Aneurysm Clips	Withdrawn
17–6	17–9	ASTM F 2129–08 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices	Withdrawn and replaced with newer version
J. OB-GYN/Gastroenterology			
9–23		ASTM F1518–00 Standard Practice for Cleaning and Disinfection of Flexible Fiberoptic and Video Endoscopes Used in the Examination of the Hollow Viscera	Withdrawn
K. Ophthalmic			
10–12	10–59	ISO 11980 Second edition 2009–10–15 Ophthalmic optics—Contact lenses and contact lens care products—Guidance for clinical investigations	Withdrawn and replaced with newer version
10–30		ANSI Z80.7 (2002) Ophthalmics—Intraocular Lenses	Withdrawn
10–34		ANSI Z80.20 (2004) Ophthalmics—Contact lenses- Standard Terminology, Tolerances, Measurements and Physicochemical Properties	Withdrawn
10–44	10–60	ISO 11981 Second edition 2009–07–01 Ophthalmic optics—Contact lenses and contact lens care products- Determination of physical compatibility of contact lens care products with contact lenses	Withdrawn and replaced with newer version
L. Orthopedics			
11–171		ASTM F 1814—97a (Reapproved 2009) Standard Guide for Evaluating Modular Hip and Knee Joint Components	Reaffirmation

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
11–179	11–220	ASTM F 2068—09 Standard Specification for Femoral Prostheses—Metallic Implants	Withdrawn and replaced with newer version
11–180		ASTM F 366—04 (Reapproved 2009) Standard Specification for Fixation Pins and Wires	Reaffirmation
11–181	11–221	ASTM F 1717—09 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model	Withdrawn and replaced with newer version
11–188	11–222	ISO 14243–1 Second edition 2009–11–15 Implants for surgery—Wear of total knee-joint prostheses—Part 1: Loading and displacement parameters for wear-testing machines with load control and corresponding environmental conditions for test	Withdrawn and replaced with newer version
11–189	11–223	ISO 14243–2 Second edition 2009–11–15 Implants for surgery—Wear of total knee-joint prostheses—Part 2: Methods of measurement	Withdrawn and replaced with newer version
11–197		ASTM F 983—86 (Reapproved 2009) Standard Practice for Permanent Marking of Orthopaedic Implant Components	Reaffirmation
11–199		ASTM F 565—04 (Reapproved 2009) ε Standard Practice for Care and Handling of Orthopedic Implants and Instruments	Reaffirmation
11–203		ASTM F 1541—02 (Reapproved 2007) ε Standard Specification and Test Methods for External Skeletal Fixation Devices	Title, Type of standard and Relevant guidance
11–210		ASTM F 543—07ε Standard Specification and Test Methods for Metallic Medical Bone Screws	Title, Type of standard and Relevant guidance
11–214		ASTM F 382—99 (Reapproved 2008) ε Standard Specification and Test Method for Metallic Bone Plates	Title and Type of standard
M. Sterility			
14–54	14–287	ANSI/AAMI/ISO 11737–2:2009 Sterilization of medical devices—Microbiological methods—Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	Withdrawn and replaced with newer version
14–55		AAMI/ANSI/ISO 14160:1998/(R)2008 Sterilization of single-use medical devices incorporating materials of animal origin—Validation and routine control of sterilization by liquid chemical	Contact person
14–63	14–288	ASTM F1886/F1886M–09 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection	Withdrawn and replaced with newer version
14–77	14–290	ANSI/AAMI ST:24:1999/(R)2009 Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities	Withdrawn and replaced with newer version
14–88	14–291	ANSI/AAMI/ISO 14937:2009 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices	Withdrawn and replaced with newer version
14–116	14–292	ANSI/AAMI ST72:2002/(R)2010 Bacterial Endotoxins—Test methodologies, routine monitoring, and alternatives to batch testing	Withdrawn and replaced with newer version
14–118	14–293	ANSI/AAMI ST50:2004/(R)2010 Dry heat (heated air) sterilizers	Withdrawn and replaced with newer version
14–152	14–294	ANSI/AAMI ST40:2004/(R)2010 Table-top dry heat (heated air) sterilization and sterility assurance in health care facilities	Withdrawn and replaced with newer version
14–164	14–295	ANSI/AAMI ST81:2004/(R)2010 Sterilization of medical devices—Information to be provided by the manufacturer for the processing of resterilizable medical devices	Withdrawn and replaced with newer version
14–181		AAMI/ANSI ST58: 2005 Chemical sterilization and high-level disinfection in health care facilities	Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
14–197		ASTM F1608–00 (Reapproved 2009) Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	Reaffirmation
14–211		AOAC 6.2.01:2006 Official Method 955.14 Testing Disinfectants against Salmonella choleraesuis, Use-Dilution Method	Contact person
14–212		AOAC 6.2.02:2006 Official Method 991.47 Testing Disinfectants against Salmonella choleraesuis, Hard Surface Carrier Test Method	Contact person
14–213		AOAC 6.2.03:2006 Official Method 991.48 Testing Disinfectant against Staphylococcus aureus, Hard Surface Carrier Test Method	Contact person
14–214		AOAC 6.2.04:2006 Official Method 955.15 Testing Disinfectants Against Staphylococcus aureus, Use-Dilution Method	Contact person
14–215		AOAC 6.2.05:2006 Official Method 991.49 Testing Disinfectants against Pseudomonas aeruginosa, Hard Surface Carrier Test Method	Contact person
14–216		AOAC 6.2.06:2006 Official Method 964.02 Testing Disinfectants against Pseudomonas aeruginosa, Use-Dilution Method	Contact person
14–217		AOAC 6.3.02:2006 Official Method 955.17 Fungicidal Activity of Disinfectants Using Trichophyton mentagrophytes	Contact person
14–218		AOAC 6.3.05:2006 Official Method 966.04 Sporicidal Activity of Disinfectants Method I	Contact person
14–219		AOAC 6.3.06:2006 Official Method 965.12 Tuberculocidal Activity of Disinfectants	Contact person
14–223	14–296	ANSI/AAMI/ISO 11138–1:2006/(R)2010 Sterilization of health care products—Biological indicators—Part 1: General requirements	Withdrawn and replaced with newer version
14–224	14–297	ANSI/AAMI/ISO 11137–1:2006/(R)2010 Sterilization of health care products—Radiation—Part 1: Requirements for development, validation, and routine control of a sterilization process for medical devices	Withdrawn and replaced with newer version
14–226	14–298	ANSI/AAMI/ISO 11137–3:2006/(R)2010 Sterilization of health care products—Radiation—Part 3: Guidance on dosimetric aspects	Withdrawn and replaced with newer version
14–234	14–299	ASTM F2097–10 Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	Withdrawn and replaced with newer version
14–265		USP 32:2009 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests	Contact person
14–266		USP 32:2009 <71> Sterility Tests	Contact person
14–267		USP 32:2009 <85> Bacterial Endotoxins Test	Contact person
14–268		USP 32:2009 <151> Pyrogen Test	Contact person
14–269		USP 32:2009 <161> Transfusion and Infusion Assemblies and Similar Medical Devices	Contact person
14–270		USP 32:2009 Biological Indicator for Steam Sterilization—Self Contained	Contact person
14–271		USP 32: 2009 Biological Indicator for Dry-Heat Sterilization, Paper Carrier	Contact person
14–272		USP 32:2009 Biological Indicator for Ethylene Oxide Sterilization, Paper Carrier	Contact person
14–273		USP 32:2009 Biological Indicator for Steam Sterilization, Paper Carrier	Contact person
14–278		USP 32:2009 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms	Contact person
14–280		AAMI/ANSI ST79:2006 and A1:2008, A2:2009 (Consolidated Text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities	Contact person

TABLE 2.—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of Standard[1]	Change
14–284	14–300	ASTM D4169–09 Standard Practice for Performance Testing of Shipping Containers and Systems	Withdrawn and replaced with newer version
14–285		AAMI/ANSI/ISO 14161:2009 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results	Contact person
N. Tissue Engineering			
15–16	15–19	ASTM F2450–10 Standard Guide for Assessing Microstructure of Polymeric Scaffolds for Use in Tissue-Engineered Medical Products	Withdrawn and replaced with newer version

[1] All standard titles in this table conform to the style requirements of the respective organizations.

III. Listing of New Entries

In table 3 of this document, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 025.

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of Standard[1]	Reference No. & Date
A. Anesthesia		
1–83	Medical electrical equipment—Particular requirements for the basic safety and essential performance of respiratory gas monitors	ISO 21647:2004 TECHNICAL CORRIGENDUM 1
B. Cardiology		
3–80	Non-invasive sphygmomanometers—Part 1: Requirements and test methods for non-automated measurement type	ANSI/AAMI/ISO 81060–1:2007
3–81	Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type	ANSI/AAMI/ISO 81060–2:2009
3–82	Implants for surgery - Cardiac pacemakers - Part 3: Low-profile connectors [IS-I] for implantable pacemakers TECHNICAL CORRIGENDUM 1	IS0 5841 -3:2000 TECHNICAL CORRIGENDUM 1
C. Dental/ENT		
4–189	Dentistry—Soft lining materials for removable dentures—Part 1: Materials for short-term use	ISO 10139–1:2005 TECHNICAL CORRIGENDUM 1 2006–03–01
D. General		
5–56	Medical devices—Symbols to be used with medical device labels, labelling, and information to be supplied—Part 2: Symbol development, selection and validation	ISO 15223–2 First edition 2010–01–15
5–57	Human factors engineering—Design of medical devices	ANSI/AAMI HE75:2009
5–58	Medical electrical equipment—Part 1–11: General requirements for basic safety and essential performance—Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment	IEC 60601–1–11 Edition 1.0 2010–04
5–59	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements	ISO 15223–1 First Edition 2007
5–60	Medical electrical equipment - Part 1–2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, Interpretation Sheet	IEC 60601–1–2 (2007) Third edition/I-SH 01
5–61	Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied—Part 1: General requirements	ANSI/AAMI/ISO 15223–1:2007
E. Materials		
8–194	Standard Test Method for Measurement of Camber, Cast, Helix and Direction of Helix of Coiled Wire	ASTM F 2754/F 2754M—09

TABLE 3.—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of Standard[1]	Reference No. & Date
8–195	Standard Specification for Wrought Seamless Nickel-Titanium Shape Memory Alloy Tube for Medical Devices and Surgical Implants	ASTM F 2633–07
F. Ophthalmic		
10–61	Ophthalmic optics—Contact lenses—Part 1: Vocabulary, classification system and recommendations for labelling specifications AMENDMENT 1	ISO 18369–1 First edition 2006–08–05 AMENDMENT 1 2009–02–15
G. Orthopedic		
11–224	Standard Test Methods for Occipital-Cervical and Occipital-Cervical-Thoracic Spinal Implant Constructs in a Vertebrectomy Model	ASTM F 2706—08
H. Radiology		
12–212	Medical electrical equipment—Characteristics of digital X-ray imaging devices—Part 1: Determination of the detective quantum efficiency	IEC 62220–1 First Edition 2003–10
12–213	Medical electrical equipment—Characteristics of digital X-ray imaging devices—Part 1–2: Determination of the detective quantum efficiency—Detectors used in mammography	IEC 62220–1–2 First Edition 2007–06
12–214	Medical electrical equipment—Characteristics of digital X-ray imaging devices—Part 1–3: Determination of the detective quantum efficiency—Detectors used in dynamic imaging	IEC 62220–1–3 Edition 1.0 2008–06
12–215	Medical electrical equipment—Exposure index of digital X-ray imaging systems—Part 1: Definitions and requirements for general radiography	IEC 62494–1 Edition 1.0 2008–08
12–216	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	IEC 62563–1 Edition 1.0 2009–12
I. Sterility		
14–289	Cleanrooms and associated controlled environments—Biocontamination control—Part 2: Evaluation and interpretation of biocontamination data	ISO 14698–2:2003 TECHNICAL CORRIGENDUM 1
J. Tissue Engineering		
15–20	Standard Guide for Characterization and Testing of Raw or Starting Biomaterials for Tissue-Engineered Medical Products	ASTM F 2027–08
15–21	Standard Guide for Characterization and Testing of Biomaterial Scaffolds Used in Tissue-Engineered Medical Products	ASTM F 2150–07
15–22	Standard Guide for Assessment of Surface Texture of Non-Porous Biomaterials in Two Dimensions	ASTM F 2791–00
15–23	Standard Guide for Quantitating Cell Viability within Biomaterial Scaffolds	ASTM F 2739–08
15–24	Standard Guide for Pre-clinical *in vivo* Evaluation in Critical Size Segmental Bone Defects	ASTM F 2721–09

[1] All standard titles in this table conform to the style requirements of the respective organizations.

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

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: 025" will be available on the CDRH home page. You may access the CDRH home page at *http://www.fda.gov/MedicalDevices*.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" through the hyperlink at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards*.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to sent two copies of mailed comments. 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: 025. These modifications to the list or recognized standards are effective upon publication of this notice in the **Federal Register**.

Dated: September 28, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–24788 Filed 10–1–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel, Relationships and Health.

Date: November 16, 2010.

Time: 1:30 p.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: Alfonso R. Latoni, PhD, Deputy Chief and Scientific Review Officer, Scientific Review Branch, National Institute on Aging, 7201 Wisconsin Avenue, Suite 2C218, Bethesda, MD 20892. 301–402–7702. *Alfonso.Latoni@nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Aging Bone and Muscle.

Date: November 18, 2010.

Time: 1 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C–212, 7201 Wisconsin Ave., Bethesda, MD 20814. 301–402–7704. *crucew@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel, Restless Leg Syndrome.

Date: November 22, 2010.

Time: 1 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892. (Telephone Conference Call.)

Contact Person: William Cruce, PhD, Scientific Review Officer, National Institute on Aging, Scientific Review Branch, Gateway Building 2C–212, 7201 Wisconsin Ave., Bethesda, MD 20814. 301–402–7704. *crucew@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: September 28, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–24784 Filed 10–1–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, October 19, 2010, 11 a.m. to October 19, 2010, 5 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on September 17, 2010, 75 FR 57042–57043.

The meeting will be two days—October 18, 2010, from 8 a.m. to October 19, 2010, 5 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: September 28, 2010.

Jennifer S. Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010–24783 Filed 10–1–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Organization, Functions and Delegations of Authority

This notice amends Part R of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services (HHS), Health Resources and Services Administration (HRSA) (60 FR 56605, as amended November 6, 1995; as last amended at 75 FR 58416–58417 dated September 24, 2010).

This notice reflects organizational changes to the Health Resources and Services Administration and updates the functional statement for the Bureau of Primary Health Care (RC). Specifically, this notice (1) Creates the Office of Administrative Management (RCM) and the Office of Training and Technical Assistance Coordination (RCS); (2) abolishes the Division of Health Information Technology State and Community Assistance (RCR); (3) renames the Office of Minority and Special Populations (RCG) to the Office