4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2004-N-0451]

# Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 036

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) 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: 036" ("Recognition List Number: 036"), 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 for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of the document entitled "Modifications to the List of Recognized Standards, Recognition List Number: 036" to the Division of Industry and Consumer Education, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-847-8149.

Submit electronic comments on this document to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document. An electronic copy of Recognition List Number: 036 is available on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. See section VI for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 036 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3632, Silver Spring, MD 20993, 301-796-6287, standards@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C 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 we would implement our 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, can be accessed at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains HTML and PDF versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI 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: 036

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency will recognize for use in premarket submissions and other requirements for devices. We will incorporate these modifications in the list of FDA Recognized Consensus Standards in the Agency's searchable database. We will use the term "Recognition List Number: 036" to identify these current modifications.

In table 1, we describe the following modifications: (1) The withdrawal of standards and their replacement by others, if applicable, (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, we list modifications the Agency is making that involve the initial addition of standards not previously recognized by FDA.

Table 1.--Modifications to the List of Recognized Standards

| Old Recognition No. | Replacement Recognition No. | Title of Standard[1] | Change |
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| A. Anesthesia | | | |
| 1-58 | 1-99 | ASTM G175-13 Standard test method for evaluating the ignition sensitivity and fault tolerance of oxygen pressure regulators used for medical and emergency applications. | Withdrawn and replaced with newer version. |
| 1-77 | 1-100 | CGA V1:2013 Standard for compressed gas cylinder valve outlet and inlet connections. | Withdrawn and replaced with newer version. |
| 1-80 | 1-101 | CGA C-9:2013 Standard color marking of compressed gas containers for medical use. | Withdrawn and replaced with newer version. |
| B. Biocompatibility | | | |
| 2-117 | | ANSI/AAMI/ISO 10993-3:2003/(R) 2013 Biological evaluation of medical devices--Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. | Reaffirmation. |
| 2-133 | | ASTM F1408-97 (Reapproved 2013) Standard practice for subcutaneous screening test for implant materials. | Reaffirmation. |
| 2-136 | | ASTM E1262-88 (Reapproved 2013) Standard guide for performance of the Chinese hamster ovary cell/hypoxanthine guanine phosphoribosyl transferase gene mutation assay. | Reaffirmation. |
| 2-141 | | ASTM F1984-99 (Reapproved 2013) Standard practice for testing for whole complement activation in serum by solid materials. | Reaffirmation. |
| 2-145 | | ASTM F1439-03 (Reapproved 2013) Standard guide for performance of lifetime bioassay for the tumorigenic potential of implant materials. | Reaffirmation. |
| 2-146 | 2-206 | ASTM F2148-13 Standard practice for evaluation of delayed contact hypersensitivity using the murine local lymph node assay (LLNA). | Withdrawn and replaced with newer version. |
| 2-153 | | ANSI/AAMI/ISO 10993-5:2009/(R) 2014 Biological evaluation of medical devices--Part 5: Tests for in vitro cytotoxicity. | Reaffirmation. |
| 2-154 | 2-207 | ASTM F756-13 Standard practice for assessment of hemolytic properties of materials. | Withdrawn and replaced with newer version. |
| 2-156 | | ANSI/AAMI/ISO 10993-1:2009/(R) 2013 Biological evaluation of medical devices--Part 1: Evaluation and testing within a risk management process. | Reaffirmation. |
| 2-175 | | ISO 10993-3 Second edition 2003-10-15, Biological evaluation of medical devices--Part 3: Tests for genotoxicity, carcinogenicity, and reproductive toxicity. | Extent of recognition. |
| 2-199 | 2-208 | USP 37-NF32:2014 <87> Biological reactivity test, in vitro--direct contact test. | Withdrawn and replaced with newer version. |
| 2-200 | 2-209 | USP 37-NF32:2014 <87> Biological reactivity test, in vitro--elution test. | Withdrawn and replaced with newer version. |
| 2-201 | 2-210 | USP 37-NF32:2014 <88> Biological reactivity test, in vivo, procedure preparation of sample. | Withdrawn and replaced with newer version. |
| 2-202 | 2-211 | USP 37-NF32:2014 <88> Biological reactivity test, in vitro, classification of plastics--intracutaneous test. | Withdrawn and replaced with newer version. |

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| 2-203 | 2-212 | USP 37-NF32:2014 <88> Biological reactivity test, in vivo, classification of plastics--systemic injection test. | Withdrawn and replaced with newer version. |
| C. Cardiovascular | | | |
| 3-42 | | ANSI/AAMI EC13:2002/(R)2007 Cardiac monitors, heart rate meters, and alarms. | Withdrawn. See 3-101. |
| 3-65 | | ANSI/AAMI EC38:2007 Medical electrical equipment--Part 2-47: Particular requirements for the safety including essential performance of ambulatory electrocardiographic systems. | Withdrawn. See 3-127. |
| 3-72 | 3-129 | ANSI/AAMI EC53:2013 ECG trunk cables and patient lead wires. | Withdrawn and replaced with newer version. |
| 3-77 | | ANSI/AAMI PC69:2007 Active implantable medical devices--Electromagnetic compatibility--EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators. | Withdrawn. See 3-128. |
| 3-78 | 3-130 | ANSI/AAMI/ISO 80601-2-30:2009 and A1:2013 Medical electrical equipment--Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers [Amendment 1:2013]. | Withdrawn and replaced with newer version. |
| 3-79 | | F2070-09 (Reapproved 2013) Standard test method for measuring intrinsic elastic recoil of balloon-expandable stents. | Reaffirmation. |
| 3-82 | 3-125 | ISO 5841Third edition 2013-04-15 Implants for surgery--Cardiac pacemakers--Part 3: Low-profile connectors [IS-1] for implantable pacemakers. | Withdrawn and replaced with newer version. |
| 3-95 | 3-126 | IEC 60601-2-27 Edition 3.0 2011-03 Medical electrical equipment--Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment [Including: Corrigendum 1 (2012)]. | Withdrawn and replaced with newer version including technical corrigendum. |
| D. Dental/ENT | | | |
| 4-92 | | ANSI/ADA Standard No. 88 (Reaffirmed 2012) Dental brazing alloys. | Reaffirmation. |
| 4-96 | | ANSI/ADA Specification No. 30 (Reaffirmed 2010) Dental zinc oxide--eugenol and zinc oxide--non-eugenol cements. | Reaffirmation. |
| 4-97 | | ANSI/ADA Standard No. 57 (Reaffirmed 2012) Endodontic sealing materials. | Reaffirmation. |
| 4-149 | | ANSI/ADA Specification No. 39 (Reaffirmed 2011) Pit and fissure sealants. | Reaffirmation. |
| 4-160 | | ANSI S3.1 (Reaffirmed 2013) Maximum permissible ambient noise levels for audiometric test rooms. | Reaffirmation. |
| 4-162 | | ANSI S3.4-2007 (Reaffirmed 2012) Procedure for the computation of loudness of steady sounds. | Reaffirmation. |
| 4-163 | | ANSI S3.5-1987 (Reaffirmed 2012) American national standard methods for calculation of the speech intelligibility index. | Reaffirmation. |
| 4-165 | | ANSI S3.13-1987 (Reaffirmed 2012) American national standard mechanical coupler for measurement of bone vibrators. | Reaffirmation. |
| 4-171 | | ANSI S3.37-1987 (Reaffirmed 2012) American national standard preferred earhook nozzle thread for postauricular hearing aids. | Reaffirmation. |

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| 4-175 | 4-211 | ANSI S3.46-2013 American national standard method of measurement of real-ear performance characteristics of hearing aids. | Withdrawn and replaced with newer version. |
| 4-177 | | ANSI S12.65-2006 (Reaffirmed 2011) American national standard for rating noise with respect to speech interference. | Reaffirmation. |
| 4-179 | 4-212 | ISO 7405 Second edition 2008-12-15 Dentistry--Evaluation of biocompatibility of medical devices used in dentistry [Including: Amendment 1 (2013)]. | Withdrawn and replaced with newer version including amendment. |
| 4-193 | | ANSI/ADA Standard No. 15 (Reaffirmed 2013) Artificial teeth for dental prostheses. | Reaffirmation. |
| E. General I (Quality Systems/Risk Management (QS/RM)) | | | |
| 5-22 | | IS0 2768-l First edition 1999-11-15 General tolerances--Part 1: Tolerances for linear and angular dimensions without individual tolerance indications. | Withdrawn. |
| 5-23 | | IS0 2768-2 First edition 1989-11-15 General tolerances--Part 2: Geometrical tolerances for features without individual tolerance indications. | Withdrawn. |
| 5-50 | 5-87 | IEC 62366 Edition 1.1 2014-01 Medical devices--Application of usability engineering to medical devices. | Withdrawn and replaced with newer version. |
| 5-53 | 19-1 | IEC 60601-1-2 Edition 3:2007-03 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic compatibility--Requirements and tests. | Transferred to General II (ES/EMC). |
| 5-54 | 19-2 | ANSI/AAMI/IEC 60601-1-2:2007/(R)2012 Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic compatibility--Requirements and tests. | Transferred to General II (ES/EMC). |
| 5-66 | 19-3 | IEC 60601-1-10 Edition 1.0 2007-11 Medical electrical equipment--Part 1-10: General requirements for basic safety and essential performance--Collateral standard: Requirements for the development of physiologic closed-loop controllers. | Transferred to General II (ES/EMC). |
| 5-77 | 19-4 | ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). | Transferred to General II (ES/EMC). |
| 5-78 | 19-5 | ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (consolidated text) Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). | Transferred to General II (ES/EMC). |
| 5-81 | 5-88 | ISO 2859-1 First edition 1999-11-15 Sampling procedures for inspection by attributes--Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection [Including: Corrigendum 1 (2001), Amendment 1 (2011)]. | Withdrawn and replaced with newer version including amendment. |

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| 5-82 | 19-6 | IEC 60601-1-11 Edition 1.0 2010-04 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 [including: Technical corrigendum 1 (2011)]. | Transferred to General II (ES/EMC). |
| 5-83 | 19-7 | ANSI/AAMI HA60601-1-11:2011 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 60601-1-11:2010 mod). | Transferred to General II (ES/EMC). |
| 5-85 | | IEC 60601-1-6 Edition 3.0 2010-01 Medical electrical equipment--Part 1-6: General requirements for basic safety and essential performance--Collateral standard: Usability. | Transition period added. |
| 5-73 | 5-90 | ISO 15223-1 Second edition 2012-07-01 Medical devices--Symbols to be used with medical device labels, labeling, and information to be supplied--Part 1: General requirements. | Extent of recognition. |
| 5-75 | 5-91 | AAMI/ANSI/ISO 15223-1:2012 Medical devices--Symbols to be used with medical devices labels, labeling, and information to be supplied--Part 1: General requirements. | Extent of recognition. |
| 5-57 | | AAMI/ANSI HE75:2009 Human factors engineering--Design of medical devices. | Relevant guidance. |
| 5-67 | | ANSI/AAMI/IEC 62366:2007/(R)2013 Medical devices--Application of usability engineering to medical devices. | Relevant guidance. |
| F. General Hospital/General Plastic Surgery | | | |
| 6-180 | | ASTM F2407-06 (Reapproved 2013) Standard specification for surgical gowns intended for use in healthcare facilities. | Reaffirmation. |
| 6-184 | 6-323 | ASTM F1862/F1862M-13 Standard test method for resistance of medical face masks to penetration by synthetic blood (horizontal projection of fixed volume at a known velocity). | Withdrawn and replaced with newer version. |
| 6-234 | 6-324 | IEC 60601-2-50 Edition 2.0 2009-03 Medical electrical equipment--Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment [Including: Technical corrigendum 1 (2010)]. | Withdrawn and replaced with newer version including technical corrigendum. |
| 6-300 | 6-325 | IEC 60601-2-21 Edition 2.0 2009-02 Medical electrical equipment--Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers [Including: Technical corrigendum 1 (2013)]. | Withdrawn and replaced with newer version including technical corrigendum. |
| 6-309 | 6-326 | USP 37-NF 33:2014 Sodium chloride irrigation. | Withdrawn and replaced with newer version. |
| 6-310 | 6-327 | USP 37-NF 33:2014 Sodium chloride injection. | Withdrawn and replaced with newer version. |
| 6-311 | 6-328 | USP 37-NF 33:2014 Nonabsorbable surgical suture. | Withdrawn and replaced with newer version. |

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| 6-312 | 6-329 | USP 37-NF 33:2014<881> Tensile strength. | Withdrawn and replaced with newer version. |
| 6-313 | 6-330 | USP 37-NF 33:2014 <861> Sutures--Diameter. | Withdrawn and replaced with newer version. |
| 6-314 | 6-331 | USP 37-NF 33:2014 <871> Sutures--Needle attachment. | Withdrawn and replaced with newer version. |
| 6-315 | 6-332 | USP 37-NF 33:2014 Sterile water for irrigation. | Withdrawn and replaced with newer version. |
| 6-316 | 6-333 | USP 37-NF 33:2014 Heparin lock flush solution. | Withdrawn and replaced with newer version. |
| 6-317 | 6-334 | USP 37-NF 33:2014 Absorbable surgical suture. | Withdrawn and replaced with newer version. |
| G. In Vitro Diagnostics | | | |
| 7-48 | | CLSI C60-A (Formerly T/DM06-A) Blood alcohol testing in the clinical laboratory; Approved guideline. | Designation number. |
| 7-112 | | CLSI POCT14-A (Formerly H49-A) Point-of-care monitoring of anticoagulation therapy; Approved guideline. | Designation number. |
| 7-133 | 7-246 | CLSI POCT12-A3 Point-of-care blood glucose testing in acute and chronic care facilities; Approved guideline--Third edition. | Withdrawn and replaced with newer version. |
| 7-142 | | CLSI GP43-A4 (Replaces H11-A4) Procedures for the collection of arterial blood specimens; Approved standard--Fourth edition. | Designation number. |
| 7-162 | | CLSI POCT14-A (Formerly H49-A) Point-of-care monitoring of anticoagulation therapy; Approved guideline. | Designation number. |
| 7-175 | | CLSI C59-A (Formerly I/LA15-A) Apolipoprotein immunoassays: Development and recommended performance characteristics; Approved guideline. | Designation number. |
| 7-201 | | CLSI GP41-A6 (Replaces H03-A6) Procedures for the collection of diagnostic blood specimens by venipuncture; Approved standard--Sixth edition. | Designation number. |
| 7-203 | | CLSI GP42-A6 (Replaces H04-A6) Procedures and devices for the collection of diagnostic capillary blood specimens; Approved standard--Sixth edition. | Designation number. |
| 7-213 | | CLSI GP44-A4 (Replaces H18-A4) Procedures for the handling and processing of blood specimens for common laboratory tests; Approved guideline--Fourth edition. | Designation number. |
| 7-221 | | CLSI GP39-A6 (Replaces H01-A6) Tubes and additives for venous and capillary blood specimen collection; Approved standard--Sixth edition. | Designation number. |
| 7-241 | 7-247 | CLSI M100-S24 Performance standards for antimicrobial susceptibility testing; Twenty-fourth informational supplement. | Withdrawn and replaced with newer version. |
| H. Materials | | | |
| 8-173 | 8-371 | ASTM F601-13 Standard practice for fluorescent penetrant inspection of metallic surgical implants. | Withdrawn and replaced with newer version. |
| 8-183 | 8-372 | ASTM F560-13 Standard specification for unalloyed tantalum for surgical implant applications (UNS R05200, UNS R05400). | Withdrawn and replaced with newer version. |
| 8-193 | | ASTM F2754/F2754M-09 (Reapproved 2013) Standard test method for measurement of camber, cast, helix, and direction of helix of coiled wire. | Reaffirmation. |

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| 8-198 | 8-373 | ASTM F2102-13 Standard guide for evaluating the extent of oxidation in polyethylene fabricated forms intended for surgical implants. | Withdrawn and replaced with newer version. |
| 8-199 | 8-374 | ASTM F2633-13 Standard specification for wrought seamless nickel-titanium shape memory alloy tube for medical devices and surgical implants. | Withdrawn and replaced with newer version. |
| 8-221 | 8-375 | ASTM F2066-13 Standard specification for wrought titanium-15 molybdenum alloy for surgical implant applications (UNS R58150). | Withdrawn and replaced with newer version. |
| 8-224 | 8-376 | ASTM F2102-13 Standard guide for evaluating the extent of oxidation in polyethylene fabricated forms intended for surgical implants. | Withdrawn and replaced with newer version. |
| 8-341 | 8-377 | ASTM F136-13 Standard specification for wrought titanium-6aluminum-4vanadium ELI (extra low interstitial) alloy for surgical implant applications (UNS R56401). | Withdrawn and replaced with newer version. |
| 8-364 | 8-378 | ASTM D792-13 Standard test methods for density and specific gravity (relative density) of plastics by displacement. | Withdrawn and replaced with newer version. |
| 8-366 | 8-379 | ISO 11542-2 First edition 1998-11-15 Plastics--Ultra-high-molecular-weight polyethylene (PE-UHMW) moulding and extrusion materials--Part 2: Preparation of test specimens and determination of properties [Including: Technical corrigendum 1 (2007)]. | Withdrawn and replaced with newer version including technical corrigendum. |
| I. Nanotechnology | | | |
| 18-2 | | ASTM E2535-07 (Reapproved 2013) Standard guide for handling unbound engineered nanoscale particles in occupational settings. | Reaffirmation. |
| J. Neurology | | | |
| 17-10 | | ANSI/AAMI/ISO 14708-3:2008/(R)2011 Implants for surgery--Active implantable medical devices--Part 3: Implantable neurostimulators. | Reaffirmation. |
| K. OB-GYN/Gastroenterology/Urology | | | |
| 9-44 | | ASTM F623-99 (Reapproved 2013) Standard performance specification for Foley catheter. | Reaffirmation. |
| 9-87 | 9-93 | ISO 25841 Second edition 2014-01-15 Female condoms--Requirements and test methods. | Withdrawn and replaced with newer version. |
| 9-21 | 9-94 | ISO 8600-4 Second edition 2014-03-15 Optics and optical instruments--Medical endoscopes and certain accessories--Part 4: Determination of maximum width of insertion portion. | Withdrawn and replaced with newer version. |
| L. Orthopedic | | | |
| 11-211 | 11-276 | ASTM F1798-13 Standard test method for evaluating the static and fatigue properties of interconnection mechanisms and subassemblies used in spinal arthrodesis implants. | Withdrawn and replaced with newer version. |
| 11-237 | 11-277 | ISO 7206-6 Second edition 2013-11-15 Implants for surgery--Partial and total hip joint prostheses--Part 6: Endurance properties testing and performance requirements of neck region of stemmed femoral components. | Withdrawn and replaced with newer version. |
| 11-255 | 11-278 | ASTM F1717-14 Standard test methods for spinal implant constructs in a vertebrectomy model. | Withdrawn and replaced with newer version. |

| M. Radiology | | | |
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| 12-23 | | NEMA XR 10-1986 (R1992, R1998, R2003) Measurement of the maximum symmetrical radiation field from a rotating anode x-ray tube used for medical diagnosis. | Withdrawn. |
| 12-24 | | NEMA XR 11-1993 (R1999) Test standard for determination of the limiting spatial resolution of x-ray image intensifier systems. | Withdrawn. |
| 12-25 | | NEMA XR 15-1991 (R1996, R2001) Test standard for the determination of the visible entrance field size of an x-ray image intensifier system. | Withdrawn. |
| 12-26 | | 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. | Withdrawn. |
| 12-27 | | NEMA XR 17-1993 (R1999) Test standard for the measurement of the image signal uniformity of an x-ray image intensifier system. | Withdrawn. |
| 12-28 | | NEMA XR 18-1993 (R1999) Test standard for the determination of the radial image distortion of an x-ray image intensifier system. | Withdrawn. |
| 12-29 | | NEMA XR 19-1993 (R1999) Electrical, thermal, and loading characteristics of x-ray tubes used for medical diagnosis. | Withdrawn. |
| 12-66 | 12-271 | AIUM MUS Medical ultrasound safety, third edition. | Withdrawn and replaced with newer version. |
| 12-79 | | NEMA XR7-1995 (R2000) High-voltage x-ray cable assemblies and receptacles. | Withdrawn. |
| 12-80 | | NEMA XR 9-1984 (R1994, R2000) Power supply guidelines for x-ray machines. | Withdrawn. |
| 12-81 | | NEMA XR 13-1990 (R1995, R2000) Mechanical safety standard for power driven motions of electromedical equipment. | Withdrawn. |
| 12-82 | | NEMA XR 14-1990 (R1995, R2000) Recommended practices for load bearing mechanical assemblies used in diagnostic imaging. | Withdrawn. |
| 12-100 | | NEMA UD 3-2004 (R2009) Standard for real time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment. | Withdrawn. |
| 12-146 | 12-272 | IEC 60601-2-17 Edition 3.0 2013-11 Medical electrical equipment--Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment. | Withdrawn and replaced with newer version. |
| 12-168 | 12-273 | IEC 60825-1 Edition 2.0 2007-03 Safety of laser products--Part 1: Equipment classification and requirements [Including: Technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]. | Withdrawn and replaced with newer version including technical corrigendum and interpretation sheets. |
| 12-193 | | AIUM AOL 2008 Acoustic output labeling standard for diagnostic ultrasound equipment revision 1--A standard for how manufacturers should specify acoustic output data. | Withdrawn. |
| 12-194 | | ANSI/HPS N43.6-2007 (R2013) Sealed radioactive sources—Classification. | Reaffirmation. |

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| 12-201 | 12-274 | IEC 60601-2-54 Edition 1.0 2009-06 Medical electrical equipment--Part 2-54: Particular requirements for the basic safety and essential performance of x-ray equipment for radiography and radioscopy [Including: Technical corrigendum 1 (2010), technical corrigendum 2 (2011)]. | Withdrawn and replaced with newer version including technical corrigendum. |
| 12-220 | | IEC 60825-1 (Second edition-2007) Safety of laser products--Part 1: Equipment classification and requirements corrigendum 1. | Withdrawn. See 12-273. |
| 12-239 | | IEC 60825-1 (Second edition-2007) I-SH 01 Safety of laser products--Part 1: Equipment classification and requirements, interpretation sheet 1. | Withdrawn. See 12-273. |
| 12-240 | | IEC 60825-1 (2007) Second edition, I-SH 02 Safety of laser products--Part 1: Equipment classification and requirements, interpretation sheet 2. | Withdrawn. See 12-273. |
| N. Software/Informatics | | | |
| 13-4 | 13-65 | ANSI/UL 1998 Third edition 2013 Standard for software in programmable components. | Withdrawn and replaced with newer version. |
| 13-15 | | CLSI AUTO13-A2 Laboratory instruments and data management systems: Design of software user interfaces and end-user software systems validation, operation, and monitoring; Approved guideline--second edition. | New designation number. |
| 13-46 | | ASTM F2761-09 (2013) Medical devices and medical systems--Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)--Part 1: General requirements and conceptual model. | Reaffirmation. |
| 13-58 | 13-66 | ISO/IEEE 11073-10417 First edition 2014-03-01 Health informatics--Personal health device communication--Part 10417: Device specialization: Glucose meter. | Withdrawn and replaced with newer version. |
| O. Sterility | | | |
| 14-181 | 14-432 | ANSI/AAMI ST58:2013 Chemical sterilization and high-level disinfection in health care facilities. | Withdrawn and replaced with newer version. |
| 14-228 | | ANSI/AAMI/ISO 11135-1:2007 Sterilization of healthcare products--Ethylene oxide--Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. | Withdrawn. See 14-452. |
| 14-232 | 14-433 | ASTM F2227-13 Standard test method for non-destructive detection of leaks in non-sealed and empty packaging trays by $CO_2$ tracer gas method. | Withdrawn and replaced with newer version. |
| 14-233 | 14-434 | ASTM F2228-13 Standard test method for non-destructive detection of leaks in packaging which incorporates porous barrier material by $CO_2$ tracer gas method. | Withdrawn and replaced with newer version. |
| 14-256 | | ASTM F2095-07 (Reapproved 2013) Standard test methods for pressure decay leak test for flexible packages with and without restraining plates. | Reaffirmation. |
| 14-257 | | ASTM D3078-02 (Reapproved 2013) Standard test method for determination of leaks in flexible packaging by bubble emission. | Reaffirmation. |
| 14-259 | 14-435 | ASTM F2251-13 Standard test method for thickness measurement of flexible packaging material. | Withdrawn and replaced with newer version. |

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| 14-261 | | ANSI/AAMI/ISO 17665-1:2006/(R)2013 Sterilization of health care products--Moist heat--Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. | Reaffirmation. |
| 14-282 | | ASTM F2338-09 (Reapproved 2013) Standard test method for nondestructive detection of leaks in packages by vacuum decay method. | Reaffirmation. |
| 14-286 | | ANSI/AAMI ST65:2008/(R)2013 Processing of reusable surgical textiles for use in health care facilities. | Reaffirmation. |
| 14-288 | | ASTM F1886/F1886M-09 (Reapproved 2013) Standard test method for determining integrity of seals for flexible packaging by visual inspection. | Reaffirmation. |
| 14-290 | | ANSI/AAMI ST24:1999/(R)2013 Automatic, general purpose ethylene oxide sterilizers and ethylene oxide sterilant sources intended for use in health care facilities. | Reaffirmation. |
| 14-291 | | ANSI/AAMI/ISO 14937:2009/(R)2013 Sterilization of healthcare products--General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process for medical devices. | Reaffirmation. |
| 14-331 | 14-452 | ISO 11135 Second edition 2014 Sterilization of healthcare products--Ethylene oxide--Requirements for the development, validation, and routine control of a sterilization process for medical devices. | Withdrawn and replaced with newer version. |
| 14-342 | | ASTM E2628-09 (E2009) Standard practice for dosimetry in radiation. | Withdrawn. See 14-436. |
| 13-343 | | ASTM E2701-09 Standard guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing. | Withdrawn. See 14-437. |
| 14-348 | | ANSI/AAMI/ISO 13408-2:2003/(R)2013 Aseptic processing of healthcare products--Part 2: Filtration. | Reaffirmation. |
| 14-364 | 14-438 | ANSI/AAMI/ISO 11137-2:2013 Sterilization of health care products--Radiation--Part 2: Establishing the sterilization dose. | Withdrawn and replaced with newer version. |
| 14-394 | 14-439 | ANSI/AAMI ST79:2010, A1:2010, A2:2011, A3:2012, and A4:2013(consolidated text) Comprehensive guide to steam sterilization and sterility assurance in health care facilities. | Withdrawn and replaced with newer version. |
| 14-414 | 14-440 | USP 37NF32:2014 <61> Microbiological examination of nonsterile products: Microbial enumeration tests. | Withdrawn and replaced with newer version. |
| 14-415 | 14-441 | USP 37NF32:2014 <71> Sterility tests. | Withdrawn and replaced with newer version. |
| 14-416 | 14-442 | USP 37NF32:2014 <85> Bacterial endotoxins test. | Withdrawn and replaced with newer version. |
| 14-417 | 14-443 | USP 37NF32:2014 <151> Pyrogen test (USP rabbit test). | Withdrawn and replaced with newer version. |
| 14-418 | 14-444 | USP 37NF32:2014 <161> Transfusion and infusion assemblies and similar medical devices. | Withdrawn and replaced with newer version. |
| 14-419 | 14-445 | USP 37NF32:2014 Biological indicator for steam sterilization--Self-contained. | Withdrawn and replaced with newer version. |

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| 14-420 | 14-446 | USP 37NF32:2014 Biological indicator for dry-heat sterilization, paper carrier. | Withdrawn and replaced with newer version. |
| 14-421 | 14-447 | USP 37NF32:2014 Biological indicator for ethylene oxide sterilization, paper carrier. | Withdrawn and replaced with newer version. |
| 14-422 | 14-448 | USP 37NF32:2014 Biological indicator for steam sterilization, paper carrier. | Withdrawn and replaced with newer version. |
| 14-423 | 14-449 | USP 37NF32:2014 <62> Microbiological examination of nonsterile products: Tests for specified microorganisms. | Withdrawn and replaced with newer version. |
| 14-425 | | ANSI/AAMI/ISO 13408-6:2005/(R)2013 and A1:2013 Aseptic processing of healthcare products--Part 6: Isolator systems. | Reaffirmation. |
| P. Tissue Engineering | | | |
| 15-21 | 15-39 | ASTM F2150-13 Standard guide for characterization and testing of biomaterial scaffolds used in tissue-engineered medical products(TEMPs). | Withdrawn and replaced with newer version. |
| 15-26 | 15-40 | ASTM F2211-13 Standard classification for tissue-engineered medical products (TEMPs). | Withdrawn and replaced with newer version. |
| 15-33 | 15-41 | ASTM F2602-13 Standard test method for determining the molar mass of chitosan and chitosan salts by size exclusion chromatography with multi-angle light scattering detection (SEC-MALS). | 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 2, we provide the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 036.

Table 2.--New Entries to the List of Recognized Standards

| Recognition No. | Title of Standard[1] | Reference No. and Date |
|---|---|---|
| A. Cardiovascular | | |
| 3-127 | Medical electrical equipment--Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems. | ANSI/AAMI/IEC 60601-2-47:2012. |
| 3-128 | Active implantable medical devices--Electromagnetic compatibility--EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators, and cardiac resynchronization devices. | ANSI/AAMI/ISO 14117:2012. |
| B. General I (Quality System/Risk Management (QS/RM)) | | |
| 5-89 | Medical electrical equipment--Part 1-6: General requirements for basic safety and essential performance--Collateral standard: Usability. | IEC 60601-1-6 Edition 3.1 2013-10. |
| 5-92 | Medical Electrical Equipment--Part 1-8: General requirements for basic safety and essential performance--Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. | ANSI/AAMI/IEC 60601-1-8:2006 & A1:2012. |
| C. General II (Electrical Safety/Electromagnetic Compatibility (ES/EMC)) | | |
| 19-1 | Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: electromagnetic compatibility--requirements and tests. | IEC 60601-1-2 Edition 3:2007-03. |

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| 19-2 | Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: electromagnetic compatibility--requirements and tests. | ANSI/AAMI/IEC 60601-1-2:2007/(R)2012. |
| 19-3 | Medical electrical equipment--Part 1-10: General requirements for basic safety and essential performance--Collateral standard: requirements for the development of physiologic closed-loop controllers. | IEC 60601-1-10 Edition 1.0:2007-11. |
| 19-4 | Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). | ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,C1:2009/(R)2012 and A2:2010/(R)2012. |
| 19-5 | Medical electrical equipment--Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, mod). | ANSI/AAMI ES60601-1:2005/(R)2012 and C1:2009/(R)2012 and, A2:2010/(R)2012 (Consolidated text). |
| 19-6 | 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 [Including: Technical corrigendum 1 (2011)]. | IEC 60601-1-11 Edition 1.0:2010-04. |
| 19-7 | 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 60601-1-11:2010 mod). | ANSI/AAMI HA60601-1-11:2011. |
| 19-8 | Medical electrical equipment--Part 1-2: General requirements for basic safety and essential performance--Collateral standard: Electromagnetic disturbances--Requirements and tests. | IEC 60601-1-2 Edition 4.0:2014-02. |
| 19-9 | Medical electrical equipment--Part 1-10: General requirements for basic safety and essential performance--Collateral standard: Requirements for the development of physiologic closed-loop controllers. | IEC 60601-1-10 Edition 1.1:2013-11. |
| 19-10 | Lithium batteries. | UL 1642 5th Edition 2013. |
| 19-11 | Household and commercial batteries. | UL 2054 2nd Edition 2011. |
| | D. Orthopedics | |
| 11-279 | Standard practice for finite element analysis (FEA) of non-modular metallic orthopaedic hip femoral stems. | ASTM F2996-13. |
| 11-280 | Standard test method for static, dynamic, and wear assessment of extra-discal single level spinal constructs. | ASTM F2624-12. |
| | E. Radiology | |
| 12-275 | Ultrasonics--Power measurement--Radiation force balances and performance requirements. | IEC 61161 Edition 3.0:2013-01. |
| 12-276 | Ultrasonics--Output test--Guide for the maintenance of ultrasound physiotherapy systems. | IEC TS 62462 First edition 2007-05. |
| 12-277 | Ultrasonics--Hydrophones--Part 1: Measurement and characterization of medical ultrasonic fields up to 40 megahertz (MHz). | IEC 62127-1 Edition 1.1:2013-02. |
| 12-278 | Ultrasonics--Hydrophones--Part 2: Calibration for ultrasonic fields up to 40 MHz (including corrigendum 1:2008 and amendment 1:2013). | IEC 62127-2 Edition 1.0:2007-08. |
| 12-279 | Ultrasonics--Hydrophones--Part 3: Properties of hydrophones for ultrasonic fields up to 40 MHz. | IEC 62127-3 Edition 1.1:2013-05. |
| 12-280 | Ultrasonics--Power measurement--High intensity therapeutic ultrasound (HITU) transducers and systems. | IEC 62555 Edition 1.0:2013-11. |

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| 12-281 | Medical electrical equipment--Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment. | IEC 60601-2-62 Edition 1.0:2013-07. |
| 12-282 | Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications--Part 1: Specification for products. | ISO 12609-1 First edition 2013-07-15. |
| 12-283 | Eyewear for protection against intense light sources used on humans and animals for cosmetic and medical applications--Part 2: Guidance for use. | ISO 12609-2 First edition 2013-07-15. |
| F. Software/Informatics | | |
| 13-67 | Health informatics--Personal health device communication--Part 10418: Device specialization--International normalized ratio (INR) monitor. | ISO/IEEE 11073-10418 First edition 2014-03-01. |
| 13-68 | Health informatics--Point-of-care medical device communication--Part 90101: Analytical instruments--Point-of-care test. | ISO 11073-90101 First edition 2008-01-15. |
| 13-69 | Health Informatics--Personal health device communication--Part 10472: Device specialization--Medication monitor. | ISO/IEEE 11073-10472 First edition 2012-11-01. |
| G. Sterility | | |
| 14-436 | Practice for dosimetry in radiation processing. | ISO/ASTM 52628 First edition 2013-11-15. |
| 14-437 | Guide for performance characterization of dosimeters and dosimetry systems for use in radiation processing. | ISO/ASTM 52701 First edition 2013-11-15. |
| 14-450 | Biological indicators--Resistance performance tests. | USP 37-NF32:2014 <55>. |
| 14-451 | Biological indicators for sterilization. | USP 37-NF32:2014 <1035>. |

[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 our Internet site at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. We will incorporate the modifications and revisions described in this notice into the database and, upon publication in the Federal Register, this recognition of consensus standards will be effective. We will announce additional modifications and revisions to the list of recognized consensus standards, as needed, in the Federal Register once a year, or more often if necessary. Beginning with Recognition List 033, we will no longer announce minor revisions to the list of recognized consensus standards such as technical contact person, devices affected, processes affected, Code of Federal Regulations citations, and product codes.

## V. Recommendation of Standards for Recognition by FDA

Any person may recommend consensus standards as candidates for recognition under section 514 of the FD&C Act by submitting such recommendations, with reasons for the recommendation, to www.standards@cdrh.fda.gov. 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. The Center for Devices and Radiological Health (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: 036" will be available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm. 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" at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.

## VII. Submission of Comments and Effective Date

Interested persons may submit either electronic comments regarding this document to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at http://www.regulations.gov. 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: 036. These modifications to the list of recognized standards are effective upon publication of this notice in the Federal Register.

Dated: July 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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