TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR or FD&C Act Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Periodic reports (814.84(b))	764	1	764	10	7,640
Breakthrough Devices Program (515(B) of the FD&C Act)	11	1	11	10	110
Agreement meeting (520(g)(7) of the FD&C Act)	1	1	1	50	50
Determination Meeting (513(a)(3)(D) of the FD&C Act)	1	1	1	50	50
Panel meeting (515(c)(3) of the FD&C Act)	1	1	1	30	30
Day 100 meeting (515(d)(3) of the FD&C Act)	14	1	14	10	140
Total					384,936

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total Hours
Maintenance of records (814.82(a)(5) and (6))	446	1	446	17	7,582

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We made the following changes to the information collection:

- Added the burden estimate for ''Information on clinical investigations conducted outside the United States (814.20(b)(6)(ii)(C)),'' which is associated with the ''Human Subject Protection; Acceptance of Data from Clinical Investigations for Medical Devices'' final rule as described previously in this document.
- Revised the burden description and table to reflect that the Expedited Access Pathway and Priority Review have been superseded by the Breakthrough Devices Program.
- Updated our burden estimate with FYs 2016 to 2018 data.

These adjustments resulted in an overall increase of 34,782 hours to the estimated burden.

Dated: October 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23204 Filed 10–23–19; 8:45 am]

BILLING CODE 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: 052

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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: 052'' (Recognition List Number: 052), 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 on the notice at any time. These modifications to the list of recognized standards are applicable October 24, 2019.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 052.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. 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: 052.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of Recognition List Number: 052 is available on the internet at *https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm.* See section IV for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 052 modifications and other standards related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 052'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5514, Silver Spring, MD 20993, 301–796–6287, *CDRHStandardsStaff@fda.hhs.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 (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 the **Federal Register** of September 14, 2018 (83 FR 46738), FDA announced the availability of a guidance entitled ''Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.'' The guidance describes how FDA has implemented its standards recognition program and is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.* Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents.*

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. Additional information on the Agency's Standards and Conformity Assessment Program is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 052

FDA is announcing the addition, withdrawal, correction, and revision of certain consensus standards the Agency is recognizing for use in premarket submissions and other requirements for devices. FDA is incorporating these modifications to the list of FDA Recognized Consensus Standards in the Agency's searchable database. FDA is using the term ''Recognition List Number: 052'' to identify the current modifications.

In Table 1, FDA describes 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, FDA lists modifications the Agency is making that involve new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 052.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old Recognition No.	Replacement Recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–116		ISO 5360 Fourth edition 2016–02–15 Anaesthetic vaporizers—Agent specific filling systems.	Extent of Recognition.
1–122		ISO 5364 Fifth edition 2016–09–01 Anaesthetic and respiratory equipment—Oropharyngeal airways.	Extent of Recognition.
1–125		ISO 8836 Fourth edition 2014–10–15 Suction catheters for use in the respiratory tract.	Extent of Recognition.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of standard [1]	Change
1–126		ISO 11712 First edition 2009–05–15 Anaesthetic and respiratory equipment—Supralaryngeal airways and connectors.	Extent of Recognition.
1–131	1–142	ISO 10079–1 Third Edition 2015–11–01 Medical suction equipment—Part 1: Electrically powered suction equipment [Including AMENDMENT 1 (2018)].	Withdrawn and replaced with newer version including amendment.
		B. Biocompatibility	
2–162	2–263	ASTM F1903–18 Standard Practice for Testing for Cellular Responses to Particles in vitro.	Withdrawn and replaced with newer version.
2–206	2–264	ASTM F2148–18 Standard Practice for Evaluation of Delayed Contact Hypersensitivity Using the Murine Local Lymph Node Assay (LLNA).	Withdrawn and replaced with newer version.
2–223	2–265	ASTM F2901–19 Standard Guide for Selecting Tests to Evaluate Potential Neurotoxicity of Medical Devices.	Withdrawn and replaced with newer version.
2–257	2–266	ASTM F2382–18 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT).	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–122	3–160	ISO 81060–2 Third edition 2018–11 Non-invasive sphygmomanometers—Part 2: Clinical investigation of intermittent automated measurement type.	Withdrawn and replaced with newer version.
3–123		IEC 80601–2–30 Edition 2.0 2018–03 Medical electrical equipment—Part 2–30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.	Extent of Recognition.
3–137		ASTM F3036–13 Standard Guide for Testing Absorbable Stents	Extent of Recognition.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–182	4–258	ISO 10139–2 Third edition 2016–06–15 Dentistry—Soft lining materials for removable dentures—Part 2: Materials for long-term use.	Withdrawn and replaced with newer version.
4–196		ISO 6872 Third edition 2008–09–01 Dentistry—Ceramic materials	Withdrawn. See #4–223.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
5–109	5–123	ISO 80369–3 First edition 2016–07–01 Small-bore connectors for liquids and gases in healthcare applications —Part 3: Connectors for enteral applications [Including AMENDMENT 1 (2019)].	Withdrawn and replaced with newer version including amendment.
5–115		ISO 80369–7 First edition 2016–10–15 Small-bore connectors for liquids and gases in healthcare applications—Part 7: Connectors for intravascular or hypodermic applications.	Transition removed.
		F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
		No new entries at this time.	
		G. General Hospital/General Plastic Surgery (GH/GPS)	
6–11		ISO 594–1 First edition 1986–06–15 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 1: General requirements.	Transition removed. Recognition restored.
6–129		ISO 594–2 Second edition 1998–09–01 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment—Part 2: Lock fittings.	Transition removed. Recognition restored.
6–403	6–421	ISO 80601–2–56 Second edition 2017–03 Medical electrical equipment—Part 2–56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement [Including AMENDMENT 1 (2018)].	Withdrawn and replaced with newer version including amendment.
		H. In Vitro Diagnostics (IVD)	
7–215	7–287	CLSI M44–S3 (2018) 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.
7–222	7–288	CLSI M24 3rd Edition Susceptibility Testing of Mycobacteria, *Nocardia* spp., and Other Aerobic Actinomycetes.	Withdrawn and replaced with newer version.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of standard [1]	Change
7–274	7–289	CLSI MM17 2nd Edition Validation and Verification of Multiplex Nucleic Acid Assays.	Withdrawn and replaced with newer version.
		I. Materials	
8–132	8–491	ASTM F1088–18 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Withdrawn and replaced with newer version.
8–150	8–492	ISO 5832–9 Third edition 2019–02 Implants for surgery—Metallic materials—Part 9: Wrought high nitrogen stainless steel.	Withdrawn and replaced with newer version.
8–188	8–493	ISO 13779–2 Third edition 2018–12 Implants for surgery—Hydroxyapatite—Part 2: Thermally sprayed coatings of hydroxyapatite.	Withdrawn and replaced with newer version.
8–194	8–494	ISO 6474–1 Second edition 2019–03 Implants for surgery—Ceramic materials—Part 1: Ceramic materials based on high purity alumina.	Withdrawn and replaced with newer version.
8–213	8–495	ISO 5834–3 Second edition 2019–02 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 3: Accelerated ageing methods.	Withdrawn and replaced with newer version.
8–214	8–496	ISO 5834–4 Second edition 2019–02 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 4: Oxidation index measurement method.	Withdrawn and replaced with newer version.
8–215	8–497	ISO 5834–5 Second edition 2019–02 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 5: Morphology assessment method.	Withdrawn and replaced with newer version.
8–229	8–498	ASTM F75–18 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Withdrawn and replaced with newer version.
8–331	8–499	ASTM F1580–18 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Withdrawn and replaced with newer version.
8–351	8–500	ISO 5832–12 Third edition 2019–02 Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy.	Withdrawn and replaced with newer version.
8–352	8–501	ISO 5834–1 Fourth edition 2019–02 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form.	Withdrawn and replaced with newer version.
8–359	8–502	ASTM F2038—18 Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials.	Withdrawn and replaced with newer version.
8–360	8–503	ASTM F2042–18 Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part II—Crosslinking and Fabrication.	Withdrawn and replaced with newer version.
8–370	8–504	ASTM F561–19 Standard Practice for Retrieval and Analysis of Medical Devices, and Associated Tissues and Fluids.	Withdrawn and replaced with newer version.
8–388	8–505	ISO 6474–2 Second edition 2019–03 Implants for surgery—Ceramic materials—Part 2: Composite materials based on a high-purity alumina matrix with zirconia reinforcement.	Withdrawn and replaced with newer version.
8–397	8–506	ASTM F2516–18 Standard Test Method for Tension Testing of Nickel-Titanium Superelastic Materials.	Withdrawn and replaced with newer version.
8–402	8–507	ASTM F688–19 Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Withdrawn and replaced with newer version.
8–411	8–508	ASTM F2579–18 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants.	Withdrawn and replaced with newer version.
		J. Nanotechnology	
		No new entries at this time.	
		K. Neurology	
		No new entries at this time.	
		L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
		No new entries at this time.	
		M. Ophthalmic	
10–89	.....	ANSI Z80.7–2013 (R2018) American National Standard for Ophthalmic Optics—Intraocular Lenses.	Extent of recognition.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS—Continued

Old Recognition No.	Replacement Recognition No.	Title of standard [1]	Change
		N. Orthopedic	
11–250	11–349	ISO 14242–3 First edition 2009–03–15 Implants for surgery—Wear of total hip-joint prostheses—Part 3: Loading and displacement parameters for orbital bearing type wear testing machines and corresponding environmental conditions for test [Including AMENDMENT 1 (2019)].	Withdrawn and replaced with newer version.
11–251	11–350	ASTM F2554–18 Standard Practice for Measurement of Positional Accuracy of Computer Assisted Surgical Systems.	Withdrawn and replaced with newer version.
11–273	11–351	ISO 18192–1 Second edition 2011–03–01 Implants for surgery—Wear of total intervertebral spinal disc prostheses—Part 1: Loading and displacement parameters for wear testing and corresponding environmental conditions for test [Including AMENDMENT 1 (2018)].	Withdrawn and replaced with newer version.
11–291	11–352	ISO 14242–1 Third edition 2014–10–15 Implants for surgery—Wear of total hip-joint prostheses —Part 1: Loading and displacement parameters for wear-testing machines and corresponding environmental conditions for test [Including AMENDMENT 1 (2018)].	Withdrawn and replaced with newer version including amendment.
		O. Physical Medicine	
		No new entries at this time.	
		P. Radiology	
12–225	12–325	NEMA XR 25–2019 Computed Tomography Dose Check	Withdrawn and replaced with newer version.
12–265	12–326	NEMA NU 2–2018 Performance Measurements of Positron Emission Tomographs (PETS).	Withdrawn and replaced with newer version.
		Q. Software/Informatics	
		No new entries at this time.	
		R. Sterility	
14–377	14–527	ASTM F2638–18 Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier.	Withdrawn and replaced with newer version.
14–428	14–528	ISO 11137–1 First edition 2006–04–15 Sterilization of health care products—Radiation—Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices [Including AMENDMENT 1 (2013) and AMENDMENT 2 (2018)].	Withdrawn and replaced with newer version including amendment.
14–452	14–529	ISO 11135 Second edition 2014–07–15 Sterilization of health-care products—Ethylene oxide—Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: AMENDMENT 1 (2018)].	Withdrawn and replaced with newer version including amendment.
14–454	14–530	ISO 11607–1 Second edition 2019–02 Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems.	Withdrawn and replaced with newer version.
14–455	14–531	ISO 11607–2 Second edition 2019–02 Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes.	Withdrawn and replaced with newer version.
		S. Tissue Engineering	
15–27	15–57	F2315–18 Standard Guide for Immobilization or Encapsulation of Living Cells or Tissue in Alginate Gels.	Withdrawn and replaced with newer version.
15–28	15–58	F2103–18 Standard Guide for Characterization and Testing of Chitosan Salts as Starting Materials Intended for Use in Biomedical and Tissue-Engineered Medical Product Applications.	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, FDA provides the listing of new entries and consensus standards added as modifications to the list of recognized standards under Recognition List Number: 052. These entries are of standards not previously recognized by FDA.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS

Recognition No.	Title of standard [1]	Reference No. and date
	A. Anesthesiology	
1–143	Medical electrical equipment—Part 2–79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment.	ISO 80601–2–79 First edition 2018–07.
1–144	Medical electrical equipment—Part 2–80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency.	ISO 80601–2–80 First edition 2018–07.
	B. Biocompatibility	
2–267	Standard Practice for Platelet Leukocyte Count—An In-Vitro Measure for Hemocompatibility Assessment of Cardiovascular Materials.	ASTM F2888—19.
2–268	Biological evaluation of medical devices—Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of medical device constituents.	ISO/TS 21726 First edition 2019–02.
	C. Cardiovascular	
	No new entries at this time.	
	D. Dental/Ear, Nose, and Throat (ENT)	
4–259	Dentistry—Implants—Dynamic loading test for endosseous dental implants	ISO 14801 Third edition 2016–11–01.
	E. General I (Quality Systems/Risk Management) (QS/RM)	
	No new entries at this time.	
	F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–35	Standard for Standby Batteries	UL 1989 Edition 5, 2013–10–02, ANSI November 2018.
	G. General Hospital/General Plastic Surgery (GH/GPS)	
6–422	Medical device safety assurance case guidance	AAMI TIR38:2019.
6–423	CONSOLIDATED VERSION Medical electrical equipment—Part 2–6: Particular requirements for the basic safety and essential performance of microwave therapy equipment.	IEC 60601–2–6 Edition 2.1 2016–04.
	H. In Vitro Diagnostics (IVD)	
7–290	Establishing and Verifying an Extended Measuring Interval Through Specimen Dilution and Spiking.	CLSI EP34 1st Edition.
7–291	How to Construct and Interpret an Error Grid for Quantitative Diagnostic Assays; Approved Guideline.	CLSI EP27–A Vol. 32 No. 12, Replaces EP27–P Vol. 29 No. 16.
7–292	Performance Standards for Susceptibility Testing of Mycobacteria, *Nocardia* spp., and other Aerobic Actinomycetes.	CLSI M62 1st Edition.
	I. Materials	
8–509	Standard Specification for Polysulfone Resin for Medical Applications	ASTM F702—18.
8–510	Standard Specification for Polycarbonate Resin for Medical Applications	ASTM F997—18.
8–511	Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.	ASTM F1925—17.
8–512	Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	ASTM F2026—17.
8–513	Implants for surgery—Metallic materials—Classification of microstructures for alpha+beta titanium alloy bars.	ISO 20160 First edition 2006–05–01.
8–514	Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 2: Moulded forms.	ISO 5834–2 Fifth edition 2019–02.
8–515	Implants for surgery—Hydroxyapatite—Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity.	ISO 13779–3 Second edition 2018–12.
8–516	Implants for surgery—Hydroxyapatite—Part 4: Determination of coating adhesion strength.	ISO 13779–4 Second edition 2018–12.
8–517	Non-active surgical implants—Implant coating—Part 1: General requirements	ISO 17327–1 First edition 2018–02.
8–518	Standard Test Method for Ion Release Evaluation of Medical Implants	ASTM F3306—19.

TABLE 2—NEW ENTRIES TO THE LIST OF RECOGNIZED STANDARDS—Continued

Recognition No.	Title of standard [1]	Reference No. and date
	J. Nanotechnology	
18–13	Nanotechnologies—Electron spin resonance (ESR) as a method for measuring reactive oxygen species (ROS) generated by metal oxide nanomaterials.	ISO/TS 18827 First edition 2017–06.
18–14	Nanotechnologies—Methodology for the classification and categorization of nanomaterials.	ISO/TR 11360 First edition 2010–07–15.
	K. Neurology	
	No new entries at this time.	
	L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)	
	No new entries at this time.	
	M. Ophthalmic	
10–116	American National Standard for Ophthalmics—Extended Depth of Focus Intraocular Lenses.	ANSI Z80.35–2018.
10–117	American National Standard for Ophthalmics—Slit-Lamp Microscopes	ANSI Z80.37–2017.
10–118	American National Standard for Ophthalmics—Light Hazard from Operation Microscopes Used in Ocular Surgery.	ANSI Z80.38–2017.
	N. Orthopedic	
11–353	Implants for surgery—Wear of total intervertebral spinal disc prostheses —Part 3: Impingement-wear testing and corresponding environmental conditions for test of lumbar prostheses under adverse kinematic conditions.	ISO 18192–3 First edition 2017–06.
11–354	Standard Guide for Impingement Testing of Total Disc Prostheses	ASTM F3295—18.
11–355	Implants for surgery—Metal intramedullary nailing systems—Part 1: Intramedullary nails.	ISO 15142–1 First edition 2003–08–01.
11–356	Implants for surgery—Metal intramedullary nailing systems—Part 2: Locking components.	ISO 15142–2 First edition 2003–08–01.
11–357	Implants for surgery—Metal intramedullary nailing systems—Part 3: Connection devices and reamer diameter instruments.	ISO 15142–3 First edition 2003–08–01.
11–358	Implants for surgery—Wear of total hip-joint prostheses—Part 4: Testing hip prostheses under variations in component positioning which results in direct edge loading.	ISO 14242–4 First edition 2018–05.
11–359	Implants for surgery—Partial and total hip-joint prostheses—Part 10: Determination of resistance to static load of modular femoral heads.	ISO 7206–10 Second edition 2018–08.
	O. Physical Medicine	
16–206	Wheelchairs—Part 30: Wheelchairs for changing occupant posture—Test methods and requirements.	ISO 7176–30 First edition 2018–12.
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
13–108	Health informatics—Point-of-care medical device communication—Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding.	IEEE Std 11073–20701–2018.
13–109	(American National Standard) Standard for Safety for Medical Device Interoperability.	ANSI/AAMI/UL 2800–1: 2019.
	R. Sterility	
14–532	Standard Test Method for Nondestructive Detection of Leaks in Packages by Mass Extraction Method.	ASTM F3287—17e1.
14–533	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10^{-6}.	ISO/TS 19930 First edition 2017–12.
	S. Tissue Engineering	
	No new entries at this time.	

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

IV. List of Recognized Standards

FDA maintains the current list of FDA Recognized Consensus Standards in a searchable database that may be accessed at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm.* Such standards are those that FDA has recognized by notice published in the **Federal Register** or that FDA has decided to recognize but for which recognition is pending (because a periodic notice has not yet appeared in the **Federal Register**). FDA 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.

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 *CDRHStandardsStaff@fda.hhs.gov.* To be considered, such recommendations should contain, at a minimum, the following information available at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/recognition-standard.*

Dated: October 18, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–23198 Filed 10–23–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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: Center for Scientific Review Special Emphasis Panel; Microbial (non-HIV) Diagnostics and Detection of Infectious Agents, Food and Waterborne Pathogens, and Methods in Microbial Sterilization, Disinfection and Bioremediation.

Date: November 14–15, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Gagan Pandya, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, RM 3200, MSC 7808, Bethesda, MD 20892, 301–435–1167, *pandyaga@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cardiovascular Sciences.

Date: November 14–15, 2019.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites DC Convention Center, 900 10th Street NW, Washington, DC 20001.

Contact Person: Margaret Chandler, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4126, MSC 7814, Bethesda, MD 20892, (301) 435–1743, *margaret.chandler@nih.gov*.

Name of Committee: AIDS and Related Research Integrated Review Group; Population and Public Health Approaches to HIV/AIDS Study Section.

Date: November 14–15, 2019.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Holiday Inn Old Town, 625 First Street, Alexandria, VA 22315.

Contact Person: Jose H. Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Hematology.

Date: November 14–15, 2019.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bukhtiar H. Shah, DVM, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4120, MSC 7802, Bethesda, MD 20892, 301–806–7314, *shahb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Radiation Therapy and Biology.

Date: November 14–15, 2019.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, *hongb@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR Panel: Accelerating the Pace of Drug Abuse Research Using Existing Data.

Date: November 14, 2019.

Time: 11:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–2309, *fothergillke@mail.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Topics in Nephrology.

Date: November 14, 2019.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jianxin Hu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2156, Bethesda, MD 20892, 301–827–4417, *jianxinh@csr.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 18, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–23150 Filed 10–23–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, 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