The tracking network collects: (1) reports of pet food-related illness and product defects associated with dog food, cat food, and food for other pets, which are submitted via the Pet Event Tracking Network (PETNet); (2) reports of animal food-related illness and product defects associated with animal food for livestock animals, aquaculture species, and horses (LivestockNet); and (3) reports about animal food laboratory samples considered adulterated by State or FDA regulators (SampleNet).

PETNet and LivestockNet reports share the following common data elements, the majority of which are drop down menu choices: product details (product name, lot code, product form, and the manufacturer or distributor/packer (if known)), the species affected, number of animals exposed to the product, number of animals affected, body systems affected, product problem/defect, date of onset or the date product problem was detected, the State where the incident occurred, the origin of the information, whether there are supporting laboratory results, and contact information for the reporting member (*i.e.,* name, telephone number will be captured automatically when member logs in to the system). For the LivestockNet report, additional data elements specific to livestock animals are captured: product details (indication of whether the product is a medicated product, product packaging, and intended purpose of the product), class of the animal species affected, and production loss. For PETNet reports, the only additional data field is the animal life stage. The SampleNet reports have the following data elements, many of which are drop down menu choices: product information (product name, lot code, guarantor information, date and location of sample collection, and product description); laboratory information (sample identification number, the reason for testing, whether the food was reported to the Reportable Food Registry, who performed the analysis); and results information (analyte, test method, analytical results, whether the results contradict a label claim or guarantee, and whether action was taken as a result of the sample analysis).

Description of Respondents: Voluntary respondents to this collection of information are Federal, State, and Territorial regulatory and public health Agency employees with membership access to the Animal Feed Network.

In the **Federal Register** of November 22, 2019 (84 FR 64533), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received offering general support for the information collection, but did not suggest a change to our burden estimate. At the same time, upon our own reevaluation we have reduced the number of respondents to the collection, which results in an overall reduction of 225 responses and 57 hours annually. We made this adjustment to better reflect current use of the tracking networks. We, therefore, estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PETNet	5	5	25	0.25 (15 minutes)	6.25
LivestockNet	5	5	25	0.25 (15 minutes)	6.25
SampleNet	5	5	25	0.25 (15 minutes)	6.25
Total			75		18.75

Dated: March 20, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06537 Filed 3–27–20; 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: 053

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: 053'' (Recognition List Number: 053), 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 March 30, 2020.

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: 053.'' 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: 053.

• 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.govinfo.gov/content/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: 053 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: 053 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: 053'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, 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. 5606, 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 of the FD&C Act 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 a portable document format (PDF) version 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: 053

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: 053'' 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: 053.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. Anesthesiology			
1–47	.....	AS 4259–1995 Ancillary devices for expired air resuscitation	Withdrawn.
1–102	.....	ISO 80601–2–69 First edition 2014–07–15 Medical electrical equipment—Part 2–69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.	Extent of Recognition.
B. Biocompatibility			
2–259	2–269	USP 42–NF37:2019 <87> Biological Reactivity Test, In Vitro—Direct Contact Test.	Withdrawn and replaced with newer version.
2–260	2–270	USP 42–NF37:2019 <87> Biological Reactivity Test, In Vitro-Elution Test.	Withdrawn and replaced with newer version.
2–261	2–271	USP 42–NF37:2019 <88> Biological Reactivity Tests, In Vivo	Withdrawn and replaced with newer version.
2–262	2–272	USP 42–NF37:2019 <151> Pyrogen Test (USP Rabbit Test)	Withdrawn and replaced with newer version.
C. Cardiovascular			
3–139	3–161	ISO 14117 Second edition 2019–09 Active implantable medical devices—Electromagnetic compatibility—EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices.	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4–186	4–260	ANSI/ASA S12.2–2019 American National Standard Criteria for Evaluating Room Noise.	Withdrawn and replaced with newer version.
4–212	4–261	ISO 7405 Third edition 2018–10 Corrected version 2018–12 Dentistry—Evaluation of biocompatibility of medical devices used in dentistry.	Withdrawn and replaced with newer version.
4–229	4–262	IEC 80601–2–60 Edition 2.0 2019–06 Medical electrical equipment—Part 2–60: Particular requirements for the basic safety and essential performance of dental equipment.	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–103	5–124	ISO 7000 Sixth edition 2019–07 Graphical symbols for use on equipment—Registered symbols.	Withdrawn and replaced with newer version.
5–40	5–125	ISO 14971 Third edition 2019–12 Medical devices—Application of risk management to medical devices.	Withdrawn and replaced with newer version.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–13	.....	IEC 62133 Edition 2.0 2012–12 Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications [Including CORRIGENDUM 1 (2013)].	Transition removed. Recognition restored.
19–32	.....	IEC 62133–1 Edition 1.0 2017–02 Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications—Part 1: Nickel systems.	Transition removed.
19–33	.....	IEC 62133–2 Edition 2017–02 Secondary cells and batteries containing alkaline or other non-acid electrolytes—Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications—Part 2: Lithium systems.	Transition removed.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–175	6–424	ASTM D5151–19 Standard Test Method for Detection of Holes in Medical Gloves.	Withdrawn and replaced with newer version.
6–254	6–425	ASTM F2100–19 Standard Specification for Performance of Materials Used in Medical Face Masks.	Withdrawn and replaced with newer version.
6–293	6–426	ISO 23907–1 First edition 2019–01 Sharps injury protection—Requirements and test methods—Part 1: Single-use sharps containers.	Withdrawn and replaced with newer version.
6–335	6–427	ASTM F2101–19 Standard Test Method for Evaluating the Bacterial Filtration Efficiency (BFE) of Medical Face Mask Materials, Using a Biological Aerosol of Staphylococcus aureus.	Withdrawn and replaced with newer version.
6–412	6–428	USP 42–NF37:2019 Sodium Chloride Irrigation	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
6–413	6–429	USP 42–NF37:2019 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–414	6–430	USP 42–NF37:2019 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–415	6–431	USP 42–NF37:2019 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–416	6–432	USP 42–NF37:2019 <861> Sutures—Diameter	Withdrawn and replaced with newer version.
6–417	6–433	USP 42–NF37:2019 <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–418	6–434	USP 42–NF37:2019 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–419	6–435	USP 42–NF37:2019 Heparin Lock Flush Solution	Withdrawn and replaced with newer version.
6–420	6–436	USP 42–NF37:2019 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
		H. In Vitro Diagnostics (IVD)	
7–226	7–293	CLSI QMS01, 5th ed. June 2019 (Replaces QMS01–A4) A Quality Management System Model for Laboratory Services.	Withdrawn and replaced with newer version.
7–281	7–294	CLSI M100, 29th ed. January 2019 (Replaces M100 28th ed.) Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
		I. Materials	
8–68	8–519	ISO 13782 Second edition 2019–04 Implants for surgery—Metallic materials—Unalloyed tantalum for surgical implant applications.	Withdrawn and replaced with newer version.
8–218	8–520	F799–19 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539).	Withdrawn and replaced with newer version.
8–391	8–521	F2313–18 Standard Specification for Poly(glycolide) and Poly(glycolide-co-lactide) Resins for Surgical Implants with Mole Fractions Greater Than or Equal to 70% Glycolide.	Withdrawn and replaced with newer version.
8–477	8–522	F2129–19a Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Withdrawn and replaced with newer version.
8–480		ASTM F2063–18 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants.	Transition period extended.
8–481		ASTM F1314–18 Standard Specification for Wrought Nitrogen Strengthened 22 Chromium-13 Nickel-5 Manganese-2.5 Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910).	Transition period extended.
8–484		ASTM F2066–18 Standard Specification for Wrought Titanium-15 Molybdenum Alloy for Surgical Implant Applications (UNS R58150).	Transition period extended.
8–491		ASTM F1088–18 Standard Specification for Beta-Tricalcium Phosphate for Surgical Implantation.	Transition period extended.
8–492		ISO 5832–9 Third edition 2019–02 Implants for surgery—Metallic materials—Part 9: Wrought high nitrogen stainless steel.	Transition period extended.
8–494		ISO 6474–1 Second edition 2019–03 Implants for surgery—Ceramic materials—Part 1: Ceramic materials based on high purity alumina.	Transition period extended.
8–498		ASTM F75–18 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075).	Transition period extended.
8–499		ASTM F1580–18 Standard Specification for Titanium and Titanium-6 Aluminum-4 Vanadium Alloy Powders for Coatings of Surgical Implants.	Transition period extended.
8–500		ISO 5832–12 Third edition 2019–02 Implants for surgery—Metallic materials—Part 12: Wrought cobalt-chromium-molybdenum alloy.	Transition period extended.
8–501		ISO 5834–1 Fourth edition 2019–02 Implants for surgery—Ultra-high-molecular-weight polyethylene—Part 1: Powder form.	Transition period extended.
8–502		ASTM F2038–18 Standard Guide for Silicone Elastomers, Gels, and Foams Used in Medical Applications Part I—Formulations and Uncured Materials.	Transition period extended.
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.	Transition period extended.
8–507		ASTM F688–19 Standard Specification for Wrought Cobalt-35Nickel-20Chromium-10Molybdenum Alloy Plate, Sheet, and Foil for Surgical Implants (UNS R30035).	Transition period extended.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
8–508		ASTM F2579–18 Standard Specification for Amorphous Poly(lactide) and Poly(lactide-co-glycolide) Resins for Surgical Implants.	Transition period extended.
8–511		ASTM F1925–17 Standard Specification for Semi-Crystalline Poly(lactide) Polymer and Copolymer Resins for Surgical Implants.	Withdrawn. Duplicate recognition. See 8–471.
8–512		ASTM F2026–17 Standard Specification for Polyetheretherketone (PEEK) Polymers for Surgical Implant Applications.	Withdrawn. Duplicate recognition. See 8–475.
		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)	
9–84	9–123	ISO 8600–3 Second edition 2019–08 Endoscopes—Medical endoscopes and endotherapy devices—Part 3: Determination of field of view and direction of view of endoscopes with optics.	Withdrawn and replaced with newer version.
		M. Ophthalmic	
		No new entries at this time.	
		N. Orthopedic	
11–328	11–360	ASTM F1378–18 ε1 Standard Specification for Shoulder Prostheses	Withdrawn and replaced with newer version.
		O. Physical Medicine	
16–168	16–207	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 1: Determination of static stability.	Withdrawn and replaced with a newer version.
16–169	16–208	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 2: Determination of dynamic stability of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16–170	16–209	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 3: determination of effectiveness of brakes.	Withdrawn and replaced with a newer version.
16–171	16–210	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 4 Energy consumption of electrically powered wheelchairs and scooters for determination of theoretical distance range.	Withdrawn and replaced with a newer version.
16–172	16–211	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 5: Determination of dimensions, mass and maneuvering space.	Withdrawn and replaced with a newer version.
16–173	16–212	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 6: Determination of maximum speed of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16–174	16–213	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 7: Method of measurement of seating and wheel dimensions.	Withdrawn and replaced with a newer version.
16–175	16–214	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 8: Requirements and test methods for static, impact and fatigue strengths.	Withdrawn and replaced with a newer version.
16–176	16–215	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 9: Climatic tests for electrically powered wheelchairs.	Withdrawn and replaced with a newer version.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
16–177	16–216	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 10: Determination of obstacle-climbing ability of electrically powered wheelchairs.	Withdrawn and replaced with a newer version.
16–178	16–217	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 11: Test mannequins.	Withdrawn and replaced with a newer version.
16–179	16–218	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 13: Determination of coefficient of friction of test surfaces.	Withdrawn and replaced with a newer version.
16–180	16–219	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 14: Power and control systems for electrically powered wheelchairs, scooters and add-on devices—Requirements and test methods.	Withdrawn and replaced with a newer version.
16–181	16–220	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 15: Requirements for information disclosure, documentation and labeling.	Withdrawn and replaced with a newer version.
16–182	16–221	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 16: Resistance to ignition of postural support devices.	Withdrawn and replaced with a newer version.
16–183	16–222	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 20: Determination of the performance of stand-up type wheelchairs.	Withdrawn and replaced with a newer version.
16–184	16–223	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 22: Set-up procedures.	Withdrawn and replaced with a newer version.
16–185	16–224	ANSI/RESNA WC–2:2019 American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems Section 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers.	Withdrawn and replaced with a newer version.
16–187	16–225	ANSI/RESNA WC–1:2019 American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters) Section 26: Vocabulary.	Withdrawn and replaced with a newer version.
16–205	.....	ANSI/RESNA W–4:2017 American National Standard for Wheelchairs—Volume 4: Wheelchairs and Transportation.	Withdrawn. See 16–226, 16–227, 16–228, and 16–229.
		P. Radiology	
12–110	12–327	ISO 11551 Third edition 2019–10 Optics and optical instruments—Lasers and laser-related equipment—Test method for absorptance of optical laser components.	Withdrawn and replaced with newer version.
12–270	12–328	IEC 61223–3–5 Edition 2.0 2019–09 Evaluation and routine testing in medical imaging departments—Part 3–5: Acceptance tests—Imaging performance of computed tomography X-ray equipment.	Withdrawn and replaced with newer version.
12–308	12–329	IEC 60601–2–43 Edition 2.2 2019–10 CONSOLIDATED VERSION Medical electrical equipment—Part 2–43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures.	Withdrawn and replaced with newer version.
12–309	.....	IEC 60601–2–28 Edition 3.0 2017–06 Medical electrical equipment—Part 2–28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.	Transition period extended.
12–317	.....	IEC 60601–2–54 Edition 1.1 2015–04 CONSOLIDATED VERSION Medical electrical equipment—Part 2–54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy [Including AMENDMENT 2 (2018)].	Transition period extended.
		Q. Software/Informatics	
13–47	13–110	ISO/IEEE 11073–10101 First edition 2004–12–15 Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature [Including AMENDMENT 1 (2017)].	Withdrawn and replaced with newer version including amendment.
13–48	13–111	IEEE Std 11073–10201–2018 Health informatics—Point-of-care medical device communication Part 10201: Domain Information Model.	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
R. Sterility			
14–325	14–528	ISO 11139 First edition 2018–08 Sterilization of health care products—Vocabulary of terms used in sterilization and related equipment and process standards.	Withdrawn and replaced with newer version.
14–354	14–529	ISO 18472 Second edition 2018–08 Sterilization of health care products—Biological and chemical indicators—Test equipment.	Withdrawn and replaced with newer version.
14–382	14–530	ISO/ASTM 51276 Fourth edition 2019–08 Practice for use of a polymethylmethacrylate dosimetry system.	Withdrawn and replaced with newer version.
14–520	14–531	USP 42–NF37:2019 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–521	14–532	USP 42–NF37:2019 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–522	14–533	USP 42–NF37:2019 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
14–523	14–534	USP 42–NF37:2019 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14–524	14–535	USP 42–NF37:2019 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–525	14–536	USP 42–NF37:2019 <55> Biological Indicators—Resistance Performance Tests.	Withdrawn and replaced with newer version.
14–526	14–537	USP 42–NF37:2019 <1229.5> Biological Indicators for Sterilization	Withdrawn and replaced with newer version.
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.

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: 053. 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		
1–145	Lung ventilators and related equipment—Vocabulary and semantics	ISO 19223 First edition 2019–07.
B. Biocompatibility		
	No new entries at this time.	
C. Cardiovascular		
3–162	Standard Guide for Active Fixation Durability of Endovascular Prostheses	ASTM F3374–19.
3–163	Cardiovascular implants and extracorporeal systems—Centrifugal blood pumps	ISO 18242 First edition 2016–09–01.
D. Dental/Ear, Nose, and Throat (ENT)		
	No new entries at this time.	
E. General I (Quality Systems/Risk Management) (QS/RM)		
	No new entries at this time.	
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)		
	No new entries at this time.	
G. General Hospital/General Plastic Surgery (GH/GPS)		
6–437	Sharps injury protection—Requirements and test methods—Part 2: Reusable sharps containers.	ISO 23907–2 First edition 2019–11.

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

Recognition No.	Title of standard [1]	Reference No. and date
6–438	Medical electrical equipment—Part 2–77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT.	IEC 80601–2–77 Edition 1.0 2019–07.
H. In Vitro Diagnostics (IVD)		
7–295	Verification of Commercial Microbial Identification and Antimicrobial Susceptibility Testing Systems.	CLSI M52, 1st ed. August 2015.
I. Materials		
8–523	Standard Guide for Using a Force Tester to Evaluate Performance of a Brush Part Designed to Clean the Internal Channel of a Medical Device.	ASTM F3275–19.
8–524	Standard Guide for Using a Force Tester to Evaluate the Performance of a Brush Part Designed to Clean the External Surface of a Medical Device.	ASTM F3276–19.
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		
	No new entries at this time.	
N. Orthopedic		
11–361	Implants for surgery—Wear of total knee prostheses—Part 5: Durability performance of the patellofemoral joint.	ISO 14243–5 First edition 2019–05.
11–362	Implants for surgery—Wear of total ankle-joint prostheses—Loading and displacement parameters for wear-testing machines with load or displacement control and corresponding environmental conditions for test.	ISO 22622 First edition 2019–07.
O. Physical Medicine		
16–226	American National Standard for Wheelchairs—Volume 4: Wheelchairs and Transportation Section 10 Wheelchair containment and occupant retention systems for use in large accessible transit vehicles: systems for rearward-facing passengers.	ANSI/RESNA WC–4:2017 Section 10.
16–227	American National Standard for Wheelchairs—Volume 4: Wheelchairs and Transportation Section 18: Wheelchair tiedown and occupant restraint systems for use in motor vehicles.	ANSI/RESNA WC–4:2017 Section 18.
16–228	ANSI/RESNA W–4:2017 American National Standard for Wheelchairs—Volume 4: Wheelchairs and Transportation Section 19: Wheelchairs used as seats in motor vehicles.	ANSI/RESNA WC–4:2017 Section 19.
16–229	American National Standard for Wheelchairs—Volume 4: Wheelchairs and Transportation Section 20: Wheelchair seating systems for use in motor vehicles.	ANSI/RESNA WC–4:2017 Section 20.
P. Radiology		
	No new entries at this time.	
Q. Software/Informatics		
13–112	Principles for medical device security—Postmarket risk management for device manufacturers.	AAMI TIR97:2019.
R. Sterility		
14–538	Standard Guide for Designing Reusable Medical Devices for Cleanability	ASTM F3357–19.
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 information listed on FDA's website, which is specifically available at *https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/recognition-standard.*

Dated: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Notice of Designation of Scarce Materials or Threatened Materials Subject to COVID–19 Hoarding Prevention Measures

AGENCY: Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) announces the issuance of a Notice under Executive Order 13910 (Executive order) and section 102 of the Defense Production Act of 1950 (the Act), as amended, designating health and medical resources necessary to respond to the spread of Coronavirus Disease 2019 (COVID–19) that are scarce or the supply of which would be threatened by excessive accumulation. These designated materials are subject to the hoarding prevention measures authorized under the Executive order and the Act. The Notice was issued on March 25, 2020.

DATES: This action took effect March 25, 2020.

FOR FURTHER INFORMATION CONTACT: Bryan Shuy: 202–703–8610; *Bryan.Shuy@hhs.gov.*

SUPPLEMENTARY INFORMATION: On March 23, 2020, and in response to the spread of COVID–19, President Trump signed Executive Order 13910 (Executive order) to prevent hoarding of health and medical resources necessary to respond to the spread of COVID–19 within the United States. As provided in the Executive order, it is the policy of the United States that health and medical resources needed to respond to the spread of COVID–19, such as personal protective equipment and sanitizing and disinfecting products, are appropriately distributed. This policy furthers the goal of protecting the Nation's healthcare systems from undue strain.

Through the Executive order, the President delegated, to the Secretary of Health and Human Services (the Secretary), his authority under section 102 of the Defense Production Act of 1950, 50 U.S.C. 4512, as amended (the Act), to prevent hoarding of health and medical resources necessary to respond to the spread of COVID–19 within the United States, and his authority to implement the Act in subsection III of chapter 55 of title 50, United States Code (50 U.S.C. 4554, 4555, 4556, and 4660). Under this delegation and the Act, the Secretary may designate such resources as scarce materials or materials the supply of which would be threatened by such accumulation (threatened materials). The Secretary may also prescribe conditions with respect to accumulation of such materials in excess of the reasonable demands of business, personal, or home consumption. The Act prohibits any person from accumulating designated materials (1) in excess of the reasonable demands of business, personal, or home consumption, or (2) for the purpose of resale at prices in excess of prevailing market prices.

HHS is issuing this Notice designating scarce materials or threatened materials that are subject to the hoarding prevention measures authorized under the Executive order and the Act. Under 50 U.S.C. 4552(13), the term ''materials'' includes any raw materials (including minerals, metals, and advanced processed materials), commodities, articles, components (including critical components), products, and items of supply; and any technical information or services ancillary to the use of any such materials, commodities, articles, components, products, or items. For purposes of this Notice, the term ''scarce materials or threatened materials'' means health or medical resources, or any of their essential components, determined by the Secretary to be needed to respond to the spread of COVID–19 and which are, or are likely to be, in short supply or the supply of which would be threatened by hoarding. Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

This designation is not a ''regulation'' under the Act. *See* 50 U.S.C. 4559. To the extent that it were, the Secretary finds that, in light of the current global pandemic, urgent and compelling circumstances make compliance with public comment requirements impracticable.

See id. This designation shall terminate after 120 days from the date of publication, unless superseded by a subsequent notice.

A copy of the Notice is provided below and also can be found on HHS's website.

NOTICE OF DESIGNATION OF SCARCE MATERIALS OR THREATENED MATERIALS

Health or medical resources, or any of their essential components, determined by the Secretary of HHS to be needed to respond to the spread of COVID–19 and which are, or are likely to be, in short supply (scarce materials) or the supply of which would be threatened by hoarding (threatened materials). Designated scarce materials or threatened materials are subject to periodic review by the Secretary.

The following materials are designated pursuant to section 102 of the Defense Production Act (50 U.S.C. 4512) and Executive Order 13190 of March 23, 2020 (Preventing Hoarding of Health and Medical Resources to Respond to the Spread of COVID–19) as scarce materials or threatened materials:

1. N–95 Filtering Facepiece Respirators, including devices that are disposable half-face-piece non-powered air-purifying particulate respirators intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates
2. Other Filtering Facepiece Respirators (*e.g.,* those designated as N99, N100, R95, R99, R100, or P95, P99, P100), including single-use, disposable half-mask respiratory protective devices that cover the user's airway (nose and mouth) and