

of the workshop. Registration is free and in-person attendance is based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Onsite registration on the day of the workshop will be based on space availability.

If you need special accommodations due to a disability, please contact Danielle Villata (see **FOR FURTHER INFORMATION CONTACT**) no later than July 8, 2024, 11:59 p.m. Eastern Time.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during a public comment session. You must register online to present comments during the public workshop. All requests to make oral presentations must be received by the close of registration on July 8, 2024, 11:59 p.m. Eastern Time. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by July 15, 2024. If selected for presentation, any presentation materials must be emailed to Danielle Villata (see **FOR FURTHER INFORMATION CONTACT**) no later than July 18, 2024, 11:59 p.m. Eastern Time. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming of the Public Workshop: This public workshop will also be available via Zoom webinar to registered attendees. To view the Zoom webinar of this public workshop, please register at https://fda.zoomgov.com/webinar/register/WN_2im_5zChQ8WvhX_kfS3CdQ. For more information about Zoom, please visit <https://support.zoom.us/hc/en-us/articles/206175806-Frequently-asked-questions>.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13776 Filed 6–21–24; 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: 062

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: 062” (Recognition List Number: 062), 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 June 24, 2024.

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:** <https://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: 062.” 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, 240–402–7500. 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: 062.

- **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, 240-402-7500.

An electronic copy of Recognition List Number: 062 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: 062 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: 062” to Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301-796-2503. 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: Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301-796-2503, 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 on its website HTML

and PDF versions of the list of FDA Recognized Consensus Standards, available at <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/federal-register-documents>. Additional information on the Agency’s Division of Standards and Conformity Assessment 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: 062

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: 062” 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: 062.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
A. Anesthesiology			
1-81	1-167	CGA V-5:2019 Standard for Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications).	Withdrawn and replaced with newer version.
1-97	1-168	CGA V-7.1:2021 Standard Method of Determining Cylinder Valve Outlet Connections for Medical Gases.	Withdrawn and replaced with newer version.
1-100	1-169	CGA V-1:2021 Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections.	Withdrawn and replaced with newer version.
1-101	1-170	CGA C-9:2019 Standard Color Marking of Compressed Gas Containers for Medical Use.	Withdrawn and replaced with newer version.
1-103	1-171	ISO 5367 Sixth edition 2023-07 Anaesthetic and respiratory equipment—Breathing sets and connectors.	Extent of recognition. Withdrawn and replaced with newer version.
1-126	1-172	ISO 11712 Second edition 2023-11 Anaesthetic and respiratory equipment—Supralaryngeal airways and connectors.	Withdrawn and replaced with newer version.
1-134	1-173	ISO 18562-1 Second edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 1: Evaluation and testing within a risk management process.	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
1-135	1-174	ISO 18562-2 Second edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 2: Tests for emissions of particulate matter.	Withdrawn and replaced with newer version.
1-136	1-175	ISO 18562-3 Second edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 3: Tests for emissions of volatile organic substances.	Withdrawn and replaced with newer version.
1-137	1-176	ISO 18562-4 Second edition 2024-03 Biocompatibility evaluation of breathing gas pathways in healthcare applications—Part 4: Tests for leachables in condensate.	Withdrawn and replaced with newer version.
1-138	1-177	ISO 80601-2-74 Second edition 2021-07 Medical electrical equipment—Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.	Withdrawn and replaced with newer version.
B. Biocompatibility			
No new entries at this time.			
C. Cardiovascular			
3-163	3-191	ISO 18242 First edition 2016-09-01 [Including AMD1:2023] Cardiovascular implants and extracorporeal systems—Centrifugal blood pumps [Including AMENDMENT 1 (2023)].	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4-215	4-325	ANSI/ADA Standard No. 96-2020 Dental Water-based Cements	Withdrawn and replaced with newer version.
E. General I (Quality Systems/Risk Management) (QS/RM)			
No new entries at this time.			
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19-19	19-50	IEC TS 60601-4-2 Edition 1.0 2024-03 Medical electrical equipment—Part 4-2: Guidance and interpretation—Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6-295	ANSI AAMI BF7:2012 Blood transfusion microfilters	Withdrawn.
6-322	6-498	ISO 10555-4 Third edition 2023-11 Intravascular catheters—Sterile and single-use catheters—Part 4: Balloon dilatation catheters.	Withdrawn and replaced with newer version.
6-408	6-499	ISO 10555-1 Third edition 2023-11 Intravascular catheters—Sterile and single-use catheters—Part 1: General requirements.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
No new entries at this time.			
I. Materials			
8-159	8-611	ISO 9584 Second edition 2023-10 Implants for surgery—Nondestructive testing—Radiographic examination of cast metallic surgical implants.	Withdrawn and replaced with newer version.
8-527	8-612	ASTM F899-23 Standard Specification for Wrought Stainless Steels for Surgical Instruments.	Withdrawn and replaced with newer version.
8-580	IEC 63145-20-10 Edition 1.0 2019-08 Eyewear display—Part 20-10: Fundamental measurement methods—Optical properties.	Transferred. See 12-357.
8-581	IEC 63145-20-20 Edition 1.0 2019-09 Eyewear display—Part 20-20: Fundamental measurement methods—Image quality.	Transferred. See 12-358.
8-582	IEC 63145-22-10 Edition 1.0 2020-01 Eyewear display—Part 22-10: Specific measurement methods for AR type—Optical properties.	Transferred. See 12-359.

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

Old recognition No.	Replacement recognition No.	Title of standard ¹	Change
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
17-13	17-18	IEEE Std 2010–2023 Recommended Practice for Electroencephalography (EEG) Neurofeedback Systems.	Withdrawn and replaced with newer version.
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
10-56	ANSI Z80.12-2007 (R2022) American National Standard for Ophthalmics—Multifocal Intraocular Lenses.	Withdrawn with transition. See 10-135.
10-70	10-134	ISO 10943 Fourth edition 2023-01—ophthalmic instruments—Indirect ophthalmoscopes.	Withdrawn and replaced with newer version.
10-125	10-135	ISO 11979-7 Fifth edition 2024-01 Ophthalmic implants—Intraocular lenses—Part 7: Clinical investigations of intraocular lenses that are implanted in the eye in order to correct aphakia.	Withdrawn and replaced with newer version.
10-126	10-136	IEC 80601-2-58 Edition 3.0 2024-03 Medical electrical equipment—Part 2-58: Particular requirements for basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery.	Withdrawn and replaced with newer version.
N. Orthopedic			
No new entries at this time.			
O. Physical Medicine			
No new entries at this time.			
P. Radiology			
12-232	12-354	NEMA MS 4-2023 Acoustic Noise Measurement Procedure for Magnetic Resonance Equipment.	Withdrawn and replaced with newer version.
12-242	12-355	IEC 60601-2-57 Edition 2.0 2023-07 Medical Electrical Equipment—Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring, cosmetic and aesthetic use.	Withdrawn and replaced with newer version.
12-268	12-356	IEC 60601-2-22 Edition 4.0 2019-11 Medical electrical equipment—Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13-52	13-132	ISO/IEEE 11073-10408 Second edition 2022-12 Health informatics—Point-of-care medical device communication—Part 10408: Device specialization—Thermometer.	Withdrawn and replaced with newer version.
13-53	13-133	ISO/IEEE 11073-10415 Second edition 2022-12 Health informatics—Point-of-care medical device communication—Part 10415: Device specialization- Weighing scale.	Withdrawn and replaced with newer version.
13-54	13-134	ISO/IEEE 11073-10404 Second edition 2022-12 Health informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.	Withdrawn and replaced with newer version.
13-57	13-135	ISO/IEEE 11073-10407 Second edition 2022-12 Health informatics—Personal health device communication—Part 10407: Device Specialization—Blood pressure monitor.	Withdrawn and replaced with newer version.
13-113	13-136	ISO/IEEE 11073-20601 Third Edition 2022-12 Health informatics—Personal health device communication—Part 20601: Application profile—Optimized exchange protocol.	Withdrawn and replaced with newer version.
13-114	13-137	IEEE Std 11073-10101b-2023 Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.	Withdrawn and replaced with newer version.
R. Sterility			
14-242	14-598	ISO 14644-3 Second edition 2020-06 Cleanrooms and associated controlled environments—Part 3: Test methods.	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
14-243	ISO 14644-6 First edition 2007-07 Cleanrooms and associated controlled environments—Part 6: Vocabulary.	Withdrawn.
14-277	ISO TS 17665-2 First edition 2009-01 Sterilization of health care products—Moist heat—Part 2: Guidance on the application of ISO 17665-1.	Withdrawn with transition. See 14-601.
14-333	ISO 17665-1 First edition 2006-08 Sterilization of health care products—Moist heat—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.	Withdrawn with transition. See 14-601.
14-389	14-599	ISO 14644-9 Second edition Cleanrooms and associated controlled environments—Part 9: Assessment of surface cleanliness for particle concentration.	Withdrawn and replaced with newer version.
14-484	14-600	ASTM F1929-23 Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.	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: 062. 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		
1-178	Anaesthetic and respiratory equipment—Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans.	ISO 23747 Second edition 2015-08.
1-179	Anaesthetic and respiratory equipment—Spirometers intended for the measurement of time forced expired volumes in humans [Including: Technical Corrigendum 1 (2009)].	ISO 26782 First edition 2009-07.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3-192	Cardiovascular implants—Transcatheter cardiac occluders	ISO 22679 First edition 2021-11.
D. Dental/ENT		
4-326	Dentistry—Graphical symbols for dental equipment [Including AMENDMENT 1 (2018)].	ISO 9687 Second edition 2015-02.
4-327	Dentistry—Graphical symbols for dental instruments	ISO 21531 First edition 2009-02.
E. General I (QS/RM)		
5-142	Packaging—Distribution packaging—Graphical symbols for handling and storage of packages.	ISO 780 Fifth edition 2015-12-01.
F. General II (ES/EMC)		
No new entries at this time.		
G. GH/GPS		
6-500	Ultrasonics—Non-focusing short pressure pulse sources including ballistic pressure pulse sources—Characteristics of fields.	IEC 63045 Edition 1.0 2020-05.
6-501	Plastic containers for intravenous injections	ISO 15747 Third edition 2018-09.
6-502	Injection systems for self-administration by paediatric patients—Requirements and guidelines for design.	ISO 23217 First edition 2024-02.

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

Recognition No.	Title of standard ¹	Reference No. and date
H. IVD		
7-321	Molecular Methods for Genotyping and Strain Typing of Infectious Organisms	CLSI MM24 1st Edition.
I. Materials		
8-613	Standard Specification for Wrought Seamless and Welded and Drawn Cobalt Alloy Small Diameter Tubing for Surgical Implants.	ASTM F2527-24.
8-614	Standard Guide for Powder Reuse Schema in Powder Bed Fusion Processes for Medical Applications for Additive Manufacturing Feedstock Materials.	ASTM F3456-22.
8-615	Additive manufacturing of metals—Qualification principles—Part 1: General qualification of operators.	ISO/ASTM 52926-1 First edition 2023-11.
8-616	Additive manufacturing of metals—Qualification principles—Part 2: Qualification of operators for PBF-LB.	ISO/ASTM 52926-2 First edition 2023-11.
8-617	Additive manufacturing of metals—Qualification principles—Part 3: Qualification of operators for PBF-EB.	ISO/ASTM 52926-3 First edition 2023-11.
J. Nanotechnology		
No new entries at this time.		
K. Neurology		
17-19	Medical electrical equipment—Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment.	ISO 80601-2-85 Edition 1.0 2021-03.
L. OB-Gyn/G/Urology		
No new entries at this time.		
M. Ophthalmic		
No new entries at this time.		
N. Orthopedic		
No new entries at this time.		
O. Physical Medicine		
No new entries at this time.		
P. Radiology		
12-357	Eyewear display—Part 20-10: Fundamental measurement methods—Optical properties.	IEC 63145-20-10 Edition 1.0 2019-08.
12-358	Eyewear display—Part 20-20: Fundamental measurement methods—Image quality.	IEC 63145-20-20 Edition 1.0 2019-09.
12-359	Eyewear display—Part 22-10: Specific measurement methods for AR type—Optical properties.	IEC 63145-22-10 Edition 1.0 2020-01.
12-360	Eyewear display—Part 10: Specifications	IEC 63145-10 Edition 1.0 2023-09.
12-361	Information Display Measurements Standard	ICDM IDMS Version 1.2 May 2023.
Q. Software/Informatics		
13-138	Health Informatics—Device Interoperability Part 10700: Point-of-Care Medical Device Communication—Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System.	IEEE Std 11073-10700-2022.
13-139	Health informatics—Device interoperability—Part 10206: Personal health device communication—Abstract Content Information Model.	IEEE Std 11073-10206-2022.
R. Sterility		
14-601	Sterilization of health care products—Moist heat—Requirements for the development, validation and routine control of a sterilization process for medical devices.	ISO 17665 First edition 2024-03.
14-602	Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers.	AAMI TIR12:2020/(R)2023.
14-603	Product adoption and process equivalence for ethylene oxide sterilization	AAMI TIR28:2016/(R)2020.

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

Recognition No.	Title of standard ¹	Reference No. and date
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 available at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#process>.

Dated: June 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13777 Filed 6–21–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Applications for and Monitoring of New, One-Time Funding Programs Administered by the Health Resources and Services Administration

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 24, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review—Open for Public Comments" or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Joella Roland, the HRSA Information Collection Clearance Officer, at paperwork@hrsa.gov or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Applications for and Monitoring of New, One-Time Funding Programs Administered by the Health Resources

and Services Administration (HRSA)—OMB Control No. 0906–xxxx–New

Abstract: HRSA is seeking approval for a generic umbrella clearance to collect applications for awards for HRSA-funded programs that provide one-time funding, including pilot programs. Should any of these pilot programs become permanent, HRSA will seek OMB clearance for these programs using a mechanism outside of this generic umbrella clearance. OMB guidance allows for the use of generic packages in cases where there may be a need for a data collection, but the agency "cannot determine the details of the specific individual collections until a later time."¹ HRSA will only use this collection for HRSA-funded programs that provide one-time funding, including pilot programs. HRSA would only request OMB approval for collections under this generic umbrella collection if the collection is low-burden, uncontroversial, and is a one-time application.

Furthermore, if Congress appropriates additional funding for such a program or HRSA plans to use the information from the applications for policy decisions not related to funding awards, HRSA will prepare a standard information collection request for that program, which will include the required 60- and 30-day **Federal Register** notices.

A 60-day notice published in the **Federal Register** on March 22, 2024, vol. 89, No. 57; pp. 20484–85. There were no public comments.

Need and Proposed Use of the Information: HRSA seeks to use an umbrella generic clearance for HRSA-funded programs that provide one-time funding, including pilot programs, so that funding can be awarded expeditiously. Expedient awarding of funding is helpful not only for administrative ease, but also for cases in which a pilot program or a program receiving one-time funding has a statutory deadline for completion. Approval of this proposed generic

¹ Memorandum for the Heads of Executive Departments and Agencies and Independent Regulatory Agencies (July 2016), "Flexibilities under the Paperwork Reduction Act for Compliance with Information Collection Requirements." Pages 4–5.