U.S. FOOD & DRUG ADMINISTRATION

January 8, 2025

Veronica Colinayo, Ph.D.
Staff Regulatory Affairs
Beckman Coulter, Inc.
250 S Kraemer Blvd,
Brea, CA 92821
Re: Revocation of EUA203021

Dear Dr. Colinayo:
This letter is in response to a notification from Beckman Coulter, Inc., in a letter dated November 22, 2024, of their intent to discontinue, as of January 1, 2025, distribution of the Access SARS-CoV-2 IgG II that was issued an EUA on March 22, 2021, revised and reissued on August 18, 2021, and amended on December 20, 2021. Beckman Coulter, Inc. confirmed in an email dated December 10, 2024, in response to clarifying questions from FDA, that they would have ceased distribution of the authorized product effective January 1, 2025, and that they intended to have FDA revoke the EUA. FDA understands that as of the date of this letter there are no viable Access SARS-CoV-2 IgG II reagents remaining in distribution in the United States.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Beckman Coulter, Inc. has requested that FDA revoke the EUA for the Access SARS-CoV-2 IgG II, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA203021 for the Access SARS-CoV-2 IgG II, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Access SARS-CoV-2 IgG II is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

//s//

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration

Dated: March 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04710 Filed 3–19–25; 8:45 am]

BILLING CODE 4164–01–C

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: 063

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: 063'' (Recognition List Number: 063), 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 20, 2025.

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: 063.'' 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: 063.

- 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: 063 is available on the internet at *https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/federal-register-documents.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 063 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: 063'' 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 Standards and Conformity Assessment Program is available at *https://www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/division-standards-and-conformity-assessment.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 063

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: 063'' 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: 063.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–153	1–180	NFPA 99:2024 Health Care Facilities Code	Withdrawn and replaced with newer version.
1–154	1–181	ASME PVHO–1–2023 Safety Standard for Pressure Vessels for Human Occupancy.	Withdrawn and replaced with newer version.
1–75	1–182	ISO 5362 Fifth edition 2024–07 Anaesthetic and respiratory equipment—Anaesthetic reservoir bags.	Withdrawn and replaced with newer version.
1–99	1–183	ASTM G175–24 Standard Test Method for Evaluating the Ignition Sensitivity and Fault Tolerance of Oxygen Pressure Regulators Used for Medical and Emergency Applications.	Withdrawn and replaced with newer version.
1–140	1–184	ISO 80601–2–55 Second edition 2018–02 [Including AMD1:2023] Medical electrical equipment—Part 2–55: Particular requirements for the basic safety and essential performance of respiratory gas monitor [Including Amendment 1 (2023)].	Withdrawn and replaced with newer version.
1–143	1–185	ISO 80601–2–79 Second edition 2024–08 Medical electrical equipment—Part 2–79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment.	Withdrawn and replaced with newer version.
1–144	1–186	ISO 80601–2–80 Second edition 2024–08 Medical electrical equipment—Part 2–80: Particular requirements for basic safety and essential.	Withdrawn and replaced with newer version.
1–146	1–187	ISO 80601–2–12 Third edition 2023–11 Medical electrical equipment—Part 2–12: Particular requirements for basic safety and essential performance of critical care ventilators.	Withdrawn and replaced with newer version.
1–160	1–188	ISO 80601–2–84 Second edition 2023–11 Medical electrical equipment—Part 2–84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–266	2–304	ASTM F2382–24 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	
3–54		ANSI AAMI ISO 7198:2016 Cardiovascular implants and extracorporeal systems—Vascular prostheses—Tubular vascular grafts and vascular patches.	Transferred. See 3–144.
3–143	3–193	ISO 12417–1 Second edition 2024–02 Cardiovascular implants and extracorporeal systems—Vascular device-drug combination products—Part 1: General requirements.	Withdrawn and replaced with newer version. Extent of recognition.
3–150	3–194	ISO 7199 Fourth edition 2024–09 Cardiovascular implants and artificial organs—Blood-gas exchangers (oxygenators).	Withdrawn and replaced with newer version.
3–157		ANSI AAMI ISO 25539–1:2017 Cardiovascular implants—Endovascular devices—Part 1: Endovascular prostheses.	Transferred. See 3–149.
3–159	3–195	ISO 5910 Second edition 2024–07 Cardiovascular implants and extracorporeal systems—Cardiac valve repair devices.	Withdrawn and replaced with newer version.
3–166	3–196	ISO 81060–2 Third edition 2018–11 [Including AMD1:2020 and AMD2:2024] Non-invasive sphygmomanometers—Part 2: Clinical investigation of intermittent automated measurement type [Including: AMENDMENT 1 (2020) and AMENDMENT 2 (2024)].	Withdrawn and replaced with newer version. Extent of recognition.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–97	4–328	ANSI/ADA Standard No. 57–2021 Endodontic Sealing Materials	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
4–149	.....	ANSI/ADA Standard No. 39–2006 (R2011) Pit and Fissure Sealants	Withdrawn. See 4–222.
4–251	4–329	ISO 6872 Fifth edition 2024–08 Dentistry—Ceramic materials	Withdrawn and replaced with newer version.
4–272	4–330	ANSI/ADA Standard No. 63–2020 Endodontic Instruments—Auxillary	Withdrawn and replaced with newer version.
4–291	4–331	ISO 28399 Third Edition 2021–03 Dentistry—External tooth bleaching products.	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)			
19–10	19–51	UL 1642 Sixth Edition September 29, 2020 Standard For Safety Lithium Batteries.	Withdrawn and replaced with newer version.
19–11	19–52	UL 2054 Third Edition November 17, 2021 Standard For Safety Household and Commercial Batteries.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–406	6–504	ASTM F1862/F1862M–24 Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity).	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–189	7–322	CLSI M47 2nd Edition; Principles and Procedures for Blood Cultures	Withdrawn and replaced with newer version.
7–266	7–323	CLSI EP19 3rd Edition A Framework for Using CLSI Documents to Evaluate Clinical Laboratory Measurement Procedures.	Withdrawn and replaced with newer version.
7–279	7–324	CLSI M07 12th Edition Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically.	Withdrawn and replaced with newer version.
7–280	7–325	CLSI M02 14th Edition Performance Standards for Antimicrobial Disk Susceptibility Tests.	Withdrawn and replaced with newer version.
7–292	7–326	CLSI M24S 2nd Edition Performance Standards for Susceptibility Testing of Mycobacteria, Nocardia spp., and Other Aerobic Actinomycetes.	Withdrawn and replaced with newer version.
7–317	7–327	CLSI M100 34th Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
I. Materials			
8–393	8–618	ASTM F1350–24 Standard Specification for Wrought 18 Chromium-14 Nickel-2.5 Molybdenum Stainless Steel Surgical Fixation Wire (UNS S31673).	Withdrawn and replaced with newer version.
8–405	8–619	ISO 5832–4 Fourth edition 2024–04 Implants for surgery—Metallic materials—Part 4: Cobalt-chromium-molybdenum casting alloy.	Withdrawn and replaced with newer version.
8–406	8–620	ISO 5832–11 Third edition 2024–03 Implants for surgery—Metallic materials—Part 11: Wrought titanium 6-aluminium 7-niobium alloy.	Withdrawn and replaced with newer version.
8–435	8–621	ISO 5832–1 Sixth edition 2024–04 Implants for surgery—Metallic materials—Part 1: Wrought stainless steel.	Withdrawn and replaced with newer version.
8–476	8–622	ASTM F2004–24 Standard Test Method for Transformation Temperature of Nickel-Titanium Alloys by Thermal Analysis.	Withdrawn and replaced with newer version.
8–481	8–623	ASTM F1314–24 Standard Specification for Wrought Nitrogen Strengthened 22Chromium-13Nickel-5Manganese-2.5Molybdenum Stainless Steel Alloy Bar and Wire for Surgical Implants (UNS S20910).	Withdrawn and replaced with newer version.
8–522	8–624	ASTM F2129–24 Standard Test Method for Conducting Cyclic Potentiodynamic Polarization Measurements to Determine the Corrosion Susceptibility of Small Implant Devices.	Withdrawn and replaced with newer version.
8–599	8–625	ASTM F1295–24 Standard Specification for Wrought Titanium-6 Aluminum-7Niobium Alloy for Surgical Implant Applications (UNS R56700).	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
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			
11–254	.....	ISO 14630 Fourth edition 2012–12–01 Non-active surgical implants—General requirements.	Withdrawn with transition. See 5–143.
11–308	11–410	ASTM F3161–24 Standard Test Method for Finite Element Analysis (FEA) of Metallic Orthopaedic Total Knee Femoral Components under Closing Conditions.	Withdrawn and replaced with newer version.
11–310	11–411	ASTM F1611–20 (Reapproved 2024) Standard Specification for Intramedullary Reamers.	Withdrawn and replaced with newer version.
11–317	11–412	ASTM F3129–24 Standard Guide for Characterization of Material Loss from Conical Taper Junctions in Total Joint Prostheses.	Withdrawn and replaced with newer version.
11–327	11–413	ASTM F543–23 Standard Specification and Test Methods for Metallic Medical Bone Screws.	Withdrawn and replaced with newer version.
11–333	11–414	ASTM F382–24 Standard Specification and Test Method for Metallic Bone Plates.	Withdrawn and replaced with newer version.
11–350	11–415	ASTM F2554–22 Standard Practice for Measurement of Positional Accuracy of Computer-Assisted Surgical Systems.	Withdrawn and replaced with newer version.
11–372	11–416	ASTM F2996–24 Standard Test Method for Finite Element Analysis (FEA) of Non-Modular Metallic Orthopaedic Hip Femoral Stems.	Withdrawn and replaced with newer version.
11–382	11–417	ASTM F3090–24 Standard Test Method for Fatigue Testing of Acetabular Devices for Total Hip Replacement and Performance Requirements.	Withdrawn and replaced with newer version.
O. Physical Medicine			
No new entries at this time.			
P. Radiology			
12–259	12–362	IEC 61674 Edition 3.0 2024–07 Medical electrical equipment—Dosimeters with ionization chambers and/or semiconductor detectors as used in X-ray diagnostic imaging.	Withdrawn and replaced with newer version.
12–352	12–363	NEMA PS 3.1–3.20 2024e Digital Imaging and Communications in Medicine (DICOM) set.	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13–116	13–140	FIRST CVSS v4.0 Common Vulnerability Scoring System version 4.0	Withdrawn and replaced with newer version.
13–18	.....	CLSI LIS03–A Standard Guide for Selection of a Clinical Laboratory Information Management System.	Withdrawn.
13–19	.....	CLSI LIS04–A Standard Guide for Documentation of Clinical Laboratory Computer Systems.	Withdrawn.
13–20	.....	CLSI LIS05–A Standard Specification for Transferring Clinical Observations Between Independent Computer Systems.	Withdrawn.
13–21	.....	CLSI LIS06–A Standard Practice for Reporting Reliability of Clinical Laboratory Information Systems.	Withdrawn.
13–22	.....	CLSI LIS07–A Standard Specification for Use of Bar Codes on Specimen Tubes in the Clinical Laboratory.	Withdrawn.
13–23	.....	CLSI LIS08–A Standard Guide for Functional Requirements of Clinical Laboratory Information Management Systems.	Withdrawn.
13–24	.....	CLSI LIS09–A Standard Guide for Coordination of Clinical Laboratory Services within the Electronic Health Record Environment and Networked Architectures.	Withdrawn.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
R. Sterility			
14–290	14–606	ANSI/AAMI ST24:2024 General-purpose ethylene oxide sterilizers with automated process control and ethylene oxide sterilant sources intended for use in health care facilities.	Withdrawn and replaced with newer version.
14–432	14–607	ANSI/AAMI ST58:2024 Chemical sterilization and high-level disinfection in health care facilities.	Withdrawn and replaced with newer version.
14–460		ISO 11140–1 Third edition 2014–11–01 Sterilization of health care products—Chemical indicators—Part 1: General requirements.	Extent of Recognition.
14–588	14–609	AAMI TIR17:2024 Compatibility of materials subjected to 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: 063. 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		
1–189	Anaesthetic and respiratory equipment—Vocabulary	ISO 4135 Fourth edition 2022–01.
1–190	Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans—Part 1: HMEs for use with minimum tidal volumes of 250 ml.	ISO 9360–1 First edition 2000–03.
1–191	Anaesthetic and respiratory equipment—Heat and moisture exchangers (HMEs) for humidifying respired gases in humans—Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml.	ISO 9360–2 First edition 2001–04.
1–192	Anaesthetic and respiratory equipment—Cuff pressure indication, control and regulation devices.	ISO 23371 First edition 2022–05.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3–197	Cardiovascular implants—Endovascular devices—Part 4: Application of ISO 17327–1 for coated endovascular devices.	ISO 25539–4 First edition 2021–11.
D. Dental/ENT		
4–332	Implantable Materials for Bone Filling and Augmentation in Oral and Maxillofacial Surgery—Contents of a Technical File.	ANSI/ADA Standard No. 206–2024.
4–333	Dentistry—Endodontic instruments—Part 4: Auxiliary instruments	ISO 3630–4 Second edition 2023–08.
4–334	Dentistry—Amalgam separators	ISO 11143 Second edition 2008–07.
4–335	Dentistry—Single-use cartridges for local anaesthetics	ISO 11499 Third edition 2014–06.
4–336	Dentistry—Powered scaler	ISO 18397 First edition 2016–01.
4–337	Dentistry—Powder jet handpieces and powders	ISO 20608 First edition 2018–04.
4–338	Dentistry—Rotational adaptability test between implant body and implant abutment in dental implant systems.	ISO 22683 First edition 2022–05.
E. General I (QS/RM)		
5–143	Non-active surgical implants—General requirements	ISO 14630 Fifth edition 2024–09.
F. General II (ES/EMC)		
19–53	Medical electrical equipment—Part 4–6: Guidance and interpretation—Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances.	IEC TS 60601–4–6 Edition 1.0 2024–04.

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

Recognition No.	Title of standard [1]	Reference No. and date
	G. GH/GPS	
6–503	Systems for evacuation of plume generated by medical device	ISO 16571 Second edition 2024–03.
	H. IVD	
	No new entries at this time.	
	I. Materials	
8–626	Standard Test Method for Conducting Rotating Bending Fatigue Tests of Solid Round Fine Wire.	ASTM E2948–24.
8–627	Standard Practice for Validating the Additive Manufacturing (AM) Production Process for Medical Devices Produced Using Laser Powder Bed Fusion.	ASTM F3604–23.
	J. Nanotechnology	
	No new entries at this time.	
	K. Neurology	
	No new entries at this time.	
	L. OB-Gyn/Gastro/Urology	
	No new entries at this time.	
	M. Ophthalmic	
	No new entries at this time.	
	N. Orthopedic	
11–418	Standard Test Method for Assessment of Intra-operative Durability of Intervertebral Body Fusion Devices.	ASTM F3631–24.
11–419	Standard Test Method for Evaluating Suture Anchor Insertion and Pull Displacement Resistance.	ASTM F3690–24.
	O. Physical Medicine	
	No new entries at this time.	
	P. Radiology	
12–364	Evaluation and routine testing in medical imaging departments—Part 3–8: Acceptance and constancy tests—Imaging performance of X-ray equipment for radiography and radioscopy.	IEC 61223–3–8 Edition 1.0 2024–03.
12–365	Diagnostic X-ray imaging equipment—Characteristics of general purpose and mammographic anti-scatter grids.	IEC 60627 Edition 3.0 2013–07.
12–366	Evaluation and routine testing in medical imaging departments—Part 3–6: Acceptance and constancy tests—Imaging performance of mammographic X-ray equipment used in a mammographic tomosynthesis mode of operation.	IEC 61223–3–6 Edition 1.0 2020–02.
	Q. Software/Informatics	
13–141	Health informatics—Device interoperability Part 10701: Point-of-care medical device communication—Metric provisioning by participants in a Service-oriented Device Connectivity (SDC) system.	ISO/IEEE 11073–10701 First Edition 2024–09.
	R. Sterility	
14–604	Sterilization of health care products—Microbiological methods—Part 3: Bacterial endotoxin testing.	ISO 11737–3 First edition 2023–06.
14–605	Sterilization of health care products—Radiation—Substantiation of selected sterilization dose: Method VDmaxSD.	ISO 13004 First edition 2022–10.
14–608	Microbiological methods—Understanding and use of product bioburden data	AAMI TIR106:2024.
	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: March 13, 2025.

P. Ritu Nalubola,

Associate Commissioner for Policy.

[FR Doc. 2025–04711 Filed 3–19–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development, Special Emphasis Panel; Small Business: Gynecological Health.

Date: April 30, 2025.

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

Agenda: To review and evaluate grant applications.

Address: Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710 B Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vera A. Cherkasova, Ph.D., Scientific Review Branch, *Eunice Kennedy Shriver* National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2137B, Bethesda, MD 20892, (240) 478–4580, email: *vera.cherkasova@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: March 17, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 1009 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: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Clinical Trials in Neurology.

Date: April 15–16, 2025.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., MSC 9529, Bethesda, MD 20892, (301) 496–9223, email: *Ana.Olariu@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS SBIR Devices.

Date: April 17–18, 2025.

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

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Ana Olariu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., MSC 9529, Bethesda, MD 20892, (301) 496–9223, email: *Ana.Olariu@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Small Business: Advancing Research on Alzheimer's Disease (AD) and AD-Related Dementias.

Date: April 22, 2025.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Mirela Milescu, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH, NSC, 6001 Executive Blvd., MSC 9529, Bethesda, MD 20892, email: *mirela.milescu@nih.gov.*

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; SBIR application review.

Date: April 29, 2025.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: W. Ernest Lyons, Ph.D., Scientific Review Officer, Scientific Review Branch, NINDS/NIH, NSC, 6001 Executive Blvd., MSC 9529, Bethesda, MD 20892, (301) 496–4056, *lyonse@ninds.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: March 17, 2025.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

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