Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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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: 064

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the 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: 064'' (Recognition List Number: 064), 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 26, 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: 064.'' 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: 064.

- 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: 064 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: 064 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: 064'' 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: 064

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: 064'' 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: 064.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
		A. Anesthesiology	
1–120	1–193	ISO 18190 Second edition 2025–02 Anaesthetic and respiratory equipment—General requirements for airway devices and related equipment.	Withdrawn and replaced with newer version.
		B. Biocompatibility	
2–136	2–305	ASTM E1262–24 Standard Guide for Performance of Chinese Hamster Ovary Cell/Hypoxanthine Guanine Phosphoribosyl Transferase Gene Mutation Assay.	Withdrawn and replaced with newer version.
2–145	2–306	ASTM F1439–24 Standard Guide for Performance of Lifetime Bioassay for the Tumorigenic Potential of Implant Materials.	Withdrawn and replaced with newer version.
2–246	2–307	ASTM F1877–24 Standard Practice for Characterization of Particles	Withdrawn and replaced with newer version.
		C. Cardiovascular	
3–103	3–198	ISO 25539–3 Second edition 2024–10 Cardiovascular implants—Endovascular devices—Part 3: Vena cava filters.	Withdrawn and replaced with newer version.
3–165	3–199	ASTM F1841–25 Standard Practice for Assessment of Hemolysis in Blood Pumps.	Withdrawn and replaced with newer version.
3–184	3–200	ASTM F2477–24 Standard Test Methods for in vitro Pulsatile Durability Testing of Vascular Stents and Endovascular Prostheses.	Withdrawn and replaced with newer version.
		D. Dental/Ear, Nose, and Throat (ENT)	
4–293	4–339	ANSI/ADA Standard No. 119–2023 Dentistry—Manual Toothbrushes	Withdrawn and replaced with newer version.
		E. General I (Quality Systems/Risk Management) (QS/RM)	
5–97	5–144	ISO 80369–20 Second edition 2024–11 Small-bore connectors for liquids and gases in healthcare applications—Part 20: Common test methods.	Withdrawn and replaced with newer version.
5–102	5–145	IEC 60417:2025 DB Graphical symbols for use on equipment	Withdrawn and replaced with newer version.
		F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–24	19–54	IEC 60086–5 Edition 5.0 2021–09 Primary batteries—Part 5: Safety of batteries with aqueous electrolyte [Including Corrigendum 1 (2022)].	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
19–33	19–55	IEC 62133–2 Edition 1.1 2021–07 CONSOLIDATED VERSION 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.	Withdrawn and replaced with newer version.
19–40	19–56	IEC 60086–4 Edition 6.0 2025–01 Primary batteries—Part 4: Safety of lithium batteries.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–179	6–505	ISO 21649 Second edition 2023–01 Needle-free injection systems for medical use—Requirements and test methods.	Withdrawn and replaced with newer version.
6–242	6–506	ISO 8536–2 Fourth edition 2023–01 Infusion equipment for medical use—Part 2: Closures for infusion bottles.	Withdrawn and replaced with newer version.
6–273	6–507	ISO 23908 Second edition 2024–12 Sharps injury protection—Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration—Requirements and test methods.	Withdrawn and replaced with newer version.
6–405	6–508	IEC 80601–2–59 Edition 2.1 2023–01 CONSOLIDATED VERSION Medical electrical equipment—Part 2–59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening.	Withdrawn and replaced with newer version.
6–407	6–509	ASTM F3186–24 Standard Specification for Adult Portable Bed Rails and Related Products.	Withdrawn and replaced with newer version.
6–438	6–510	IEC 80601–2–77 Edition 1.1 2023–11 CONSOLIDATED VERSION Medical electrical equipment—Part 2–77: Particular requirements for the basic safety and essential performance of robotically assisted surgical equipment.	Withdrawn and replaced with newer version.
6–464	6–511	ISO 11040–4 Fourth edition 2024–06 Prefilled syringes—Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling.	Withdrawn and replaced with newer version.
6–483	6–512	IEC 60601–2–35 Edition 2.1 2023–12 CONSOLIDATED VERSION Medical electrical equipment—Part 2–35: Particular requirements for the basic safety and essential performance of heating devices using blankets pads and mattresses and intended for heating in medical use.	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
7–327	7–328	CLSI M100 35th Edition Performance Standards for Antimicrobial Susceptibility Testing.	Withdrawn and replaced with newer version.
I. Materials			
No new entries at this time.			
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
17–4	17–21	ASTM F647–22 Standard Practice for Evaluating and Specifying Implantable Shunt Assemblies for Neurosurgical Application.	Withdrawn and replaced with newer version.
17–16	17–22	IEC 60601–2–10 Edition 2.2 2023–01 CONSOLIDATED VERSION Medical electrical equipment—Part 2–10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.	Withdrawn and replaced with newer version.
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
10–98	10–137	ISO 11979–2 Third edition 2024–10 Ophthalmic implants—Intraocular lenses—Part 2: Optical properties and test methods.	Withdrawn and replaced with newer version.
N. Orthopedic			
11–344	11–420	ASTM F2580–24 Standard Test Method for Evaluation of Modular Connection of Proximally Fixed Femoral Hip Prostheses.	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
11–347	11–421	ASTM F2077–24 Standard Test Methods for Intervertebral Body Fusion Devices.	Withdrawn and replaced with newer version.
11–402	11–422	ASTM F1798–24 Standard Test Method for Evaluating the Static and Fatigue Properties of Interconnection Mechanisms and Subassemblies Used in Spinal Arthrodesis Implants.	Withdrawn and replaced with newer version.
O. Physical Medicine			
No new entries at this time.			
P. Radiology			
12–115	12–367	ISO 13695 Second edition 2024–11 Optics and photonics—Lasers and laser-related equipment—Test methods for the spectral characteristics of lasers.	Withdrawn and replaced with newer version.
12–116	12–368	ISO 13696 Second edition 2022–06 Optics and photonics—Test methods for radiation scattered by optical components.	Withdrawn and replaced with newer version.
12–134	12–369	ISO 11146–1 Second edition 2021–07 Lasers and laser-related equipment—Test methods for laser beamwidths, divergence angles and beam propagation ratios—Part 1: Stigmatic and simple astigmatic beams.	Withdrawn and replaced with newer version.
12–142	12–370	ISO 11146–2 Second edition 2021–07 Lasers and laser-related equipment—Test methods for laser beamwidths, divergence angles and beam propagation ratios—Part 2: General astigmatic beams.	Withdrawn and replaced with newer version.
12–171	12–371	ISO 14880–2 Second edition 2024–11 Optics and photonics—Microlens arrays—Part 2: Test methods for wavefront aberrations.	Withdrawn and replaced with newer version.
12–172	12–372	ISO 14880–3 Second edition 2024–11 Optics and photonics—Microlens arrays—Part 3: Test methods for optical properties other than wavefront aberrations.	Withdrawn and replaced with newer version.
12–173	12–373	ISO 14880–4 Second edition 2024–11 Optics and photonics—Microlens arrays—Part 4: Test methods for geometrical properties.	Withdrawn and replaced with newer version.
12–175	12–374	ISO 24013 Second edition 2023–06 Optics and photonics—Lasers and laser-related equipment—Measurement of phase retardation of optical components for polarized laser radiation.	Withdrawn and replaced with newer version.
12–177	12–375	ANSI/UL 122–2019 Standard for Safety Photographic Equipment—Ed. 5.0 [Including revisions through October 15, 2019].	Withdrawn and replaced with newer version.
12–266	12–376	IEC 61689 Edition 4.0 2022–03 Ultrasonics—Physiotherapy systems—Field specifications and methods of measurement in the frequency range 0.5 MHz to 5 MHz.	Withdrawn and replaced with newer version.
12–279	12–377	IEC 62127–03 Edition 2.0 2022–12 Ultrasonics—Hydrophones—Part 3: Properties of hydrophones for ultrasonic fields.	Withdrawn and replaced with newer version.
12–282	12–378	ISO 12609–1 Second edition 2021–10 Eye and face protection against intense light sources used on humans and animals for cosmetic and medical applications—Part 1: Specification for products.	Withdrawn and replaced with newer version.
12–291	12–379	IEC 62127–2 Edition 2.0 2025–01 Ultrasonics—Hydrophones—Part 2: Calibration for ultrasonic fields.	Withdrawn and replaced with newer version.
12–293	12–380	IEC 60601–2–37 Edition 3.0 2024–07 Medical electrical equipment—Part 2–37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.	Withdrawn and replaced with newer version.
12–319	12–381	IEC 60601–2–68 Second edition 2025–02 Medical electrical equipment—Part 2–68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment.	Withdrawn and replaced with newer version.
12–326	12–382	NEMA NU 2–2024 Performance Measurements of Positron Emission Tomographs.	Withdrawn and replaced with newer version.
12–337	12–383	NEMA NU 1–2023 Performance Measurements of Gamma Cameras	Withdrawn and replaced with newer version.
Q. Software/Informatics			
13–9	.....	CLSI AUTO02–A2 Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition.	Transferred. See 7–331.
13–10	.....	CLSI AUTO01–A Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard.	Transferred. See 7–332.
13–12	.....	CLSI AUTO04–A Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard.	Transferred. See 7–333.
13–13	.....	CLSI AUTO05–A Laboratory Automation: Electromechanical Interfaces; Approved Standard.	Transferred. See 7–334.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
13–14		CLSI POCT01–A2 Point-of-Care Connectivity; Approved Standard—Second Edition.	Transferred. See 7–335.
13–15		CLSI AUTO13–A2 (Formerly GP19–A2) Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition.	Transferred. See 7–345.
13–17		CLSI LIS02–A2 Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard—Second Edition.	Transferred. See 7–336.
13–25		CLSI AUTO08–A Managing and Validating Laboratory Information Systems; Approved Guideline.	Transferred. See 7–337.
13–26		CLSI AUTO10–A Autoverification of Clinical Laboratory Test Results; Approved Guideline.	Transferred. See 7–338.
13–28		CLSI AUTO09–A Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard.	Transferred. See 7–339.
13–29		CLSI LIS01–A2 Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition.	Transferred. See 7–340.
13–30		CLSI AUTO03–A2 Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition.	Transferred. See 7–341.
13–31		CLSI AUTO12–A Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.	Transferred. See 7–342.
13–36	13–143	AAMI TIR45:2023 Guidance on the use of AGILE practices in the development of medical device software.	Withdrawn and replaced by newer version.
13–37		CLSI AUTO07–A Laboratory Automation: Data Content for Specimen Identification; Approved Standard.	Transferred. See 7–343.
13–56	13–147	IEEE Std 11073–10406–2023 Health Informatics—Device Interoperability Part 10406: Personal Health Device Communication—Device Specialization—Basic Electrocardiograph (ECG) (1- to 3-lead ECG).	Withdrawn and replaced by newer version.
13–72	13–144	IEEE Std 11073–10425–2023 Health Informatics—Device Interoperability Part 10425: Personal Health Device Communication—Device Specialization—Continuous Glucose Monitor (CGM).	Withdrawn and replaced by newer version.
13–81	13–145	IEEE Std 11073–10419–2023 Health Informatics—Device Interoperability Part 10419: Personal Health Device Communication—Device Specialization—Insulin Pump.	Withdrawn and replaced by newer version.
13–84	13–146	IEEE Std 11073–10103–2023 Health Informatics—Device Interoperability Part 10103: Point-of-Care Medical Device Communication—Nomenclature—Implantable Device, Cardiac.	Withdrawn and replaced by newer version.
13–85		CLSI AUTO11–A2 Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard—Second Edition.	Transferred. See 7–344.
13–88		ISO IEEE 11073–10417 Third edition 2017–04 Health informatics—Personal health device communication—Part 10417: Device specialization—Glucose meter.	Transferred. See 13–90.
13–89		ISO IEEE 11073–10406 First edition 2012–12–01 Health informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).	Transferred. See 13–56.
13–90	13–148	IEEE Std 11073–10417–2023 Health Informatics—Device Interoperability Part 10417: Personal Health Device Communication—Device Specialization—Glucose Meter.	Withdrawn and replaced by newer version.
13–91		ISO IEEE 11073–10419 First edition 2016–06–15 Health informatics—Personal health device communication—Part 10419: Device specialization—Insulin pump.	Transferred. See 13–81.
13–95		ISO IEEE 11073–10425 First edition 2016–06–15 Health informatics—Personal health device communication—Part 10425: Device specialization—Continuous glucose monitor (CGM).	Transferred. See 13–72.
13–116	13–142	FIRST CVSS v3.1 Common Vulnerability Scoring System	Withdrawn and replaced by newer version.
13–142	13–140	FIRST CVSS v4.0 Common Vulnerability Scoring System.	Withdrawn and replaced by newer version.
		R. Sterility	
14–336		ISO 14161 Second edition 2009–09–15 Sterilization of health care products—Biological indicators—Guidance for the selection, use and interpretation of results.	Withdrawn with transition. See 14–610. Extent of recognition.

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

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
14–528	14–611	ISO 11137–1 Second edition 2025–04 Sterilization of health care products—Radiation—Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices.	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: 064. 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		
1–194	Anaesthetic and respiratory equipment—Nebulizing systems and components	ISO 27427 Fourth edition 2023–07.
1–195	Small-bore connectors for liquids and gases in healthcare applications—Part 2: Connectors for respiratory applications.	ISO 80369–2 First edition 2024–09.
1–196	Medical electrical equipment—Part 2–90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy equipment.	ISO 80601–2–90 First edition 2021–08.
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
No new entries at this time.		
D. Dental/ENT		
4–340	Dental Patient Chair	ANSI/ADA Standard No. 46–2016.
4–341	Stationary Dental Units and Patient Chairs—Part 1: General Requirements	ANSI/ADA Standard No. 47–1–2021.
4–342	Stationary Dental Units and Patient Chairs—Part 2: Air, Water, Suction and Wastewater Systems.	ANSI/ADA Standard No. 47–2–2021.
4–343	Elastomeric Auxiliaries for Use in Orthodontics	ANSI/ADA Standard No. 105–2024.
4–344	Dentistry—Polymer-based Machinable Blanks	ANSI/ADA Standard No. 186–2024.
4–345	Dentistry—Dental CAD/CAM Machinable Ceramic Blanks	ANSI/ADA Standard No. 187–2024.
4–346	Dentistry—Operating lights	ISO 9680 Fourth edition 2021–11.
4–347	Dentistry—Manual toothbrushes—Resistance of tufted portion to deflection	ISO 22254 First edition 2005–08.
E. General I (QS/RM)		
No new entries at this time.		
F. General II (ES/EMC)		
No new entries at this time.		
G. GH/GPS		
6–513	Non-active surgical implants—Mammary implants—Specific requirements	ISO 14607 Fourth Edition 2024–12.
H. IVD		
7–329	Developer Validation of Linearity	CLSI EP06–EG 2nd Edition.
7–330	Performance Standards for Antifungal Susceptibility Testing of Filamentous Fungi.	CLSI M38M51S 3rd Edition
7–331	Laboratory Automation: Bar Codes for Specimen Container Identification; Approved Standard—Second Edition.	CLSI AUTO02–A2.
7–332	Laboratory Automation: Specimen Container/Specimen Carrier; Approved Standard.	CLSI AUTO01–A.
7–333	Laboratory Automation: Systems Operational Requirements, Characteristics, and Information Elements; Approved Standard.	CLSI AUTO04–A.
7–334	Laboratory Automation: Electromechanical Interfaces; Approved Standard	CLSI AUTO05–A.
7–335	Point-of-Care Connectivity; Approved Standard—Second Edition	CLSI POCT01–A2.

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

Recognition No.	Title of standard [1]	Reference No. and date
7–336	Specification for Transferring Information Between Clinical Instruments and Computer Systems; Approved Standard—Second Edition.	CLSI LIS02–A2.
7–337	Managing and Validating Laboratory Information Systems; Approved Guideline	CLSI AUTO08–A.
7–338	Autoverification of Clinical Laboratory Test Results; Approved Guideline	CLSI AUTO10–A.
7–339	Remote Access to Clinical Laboratory Diagnostic Devices via the Internet; Approved Standard.	CLSI AUTO09–A.
7–340	Specification for Low-Level Protocol to Transfer Messages Between Clinical Laboratory Instruments and Computer Systems; Approved Standard—Second Edition.	CLSI LIS01–A2.
7–341	Laboratory Automation: Communications with Automated Clinical Laboratory Systems, Instruments, Devices, and Information Systems; Approved Standard—Second Edition.	CLSI AUTO03–A2.
7–342	Specimen Labels: Content and Location, Fonts, and Label Orientation; Approved Standard.	CLSI AUTO12–A.
7–343	Laboratory Automation: Data Content for Specimen Identification; Approved Standard.	CLSI AUTO07–A.
7–344	Information Technology Security of In Vitro Diagnostic Instruments and Software Systems; Approved Standard—Second Edition.	CLSI AUTO11–A2.
7–345	Laboratory Instruments and Data Management Systems: Design of Software User Interfaces and End-User Software Systems Validation, Operation, and Monitoring; Approved Guideline—Second Edition.	CLSI AUTO13–A2 (Formerly GP19–A2).
I. Materials		
No new entries at this time.		
J. Nanotechnology		
No new entries at this time.		
K. Neurology		
17–20	Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment.	IEC 60601–2–40 Third edition 2024–12.
L. OB-Gyn/G/Urology		
9–151	Standard Specification for Ureteral Stents	ASTM F1828–22.
M. Ophthalmic		
10–138	Ophthalmic instruments—Optical coherence tomographs—Part 1: Optical coherence tomographs for the posterior segment of the human eye.	ISO 16971–1 First edition 2024–11.
N. Orthopedic		
No new entries at this time.		
O. Physical Medicine		
No new entries at this time.		
P. Radiology		
No new entries at this time.		
Q. Software/Informatics		
No new entries at this time.		
R. Sterility		
14–610	Sterilization of health care products—Biological indicators—Part 7: Guidance for the selection, use and interpretation of results.	ISO 11138–7 First edition 2019–03.
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 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–D–0810]

Conducting Remote Regulatory Assessments—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Conducting Remote Regulatory Assessments—Question and Answers.'' The final guidance describes FDA's current thinking regarding its use of remote regulatory assessments (RRAs) and provides answers to frequently asked questions. FDA has used RRAs to conduct oversight, mitigate risk, meet critical public health needs, and help evaluate compliance of FDA-regulated products with applicable regulatory requirements.

DATES: The announcement of the guidance is published in the **Federal Register** on June 26, 2025.

ADDRESSES: You may submit comments on any guidance 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–2022–D–0810 for ''Conducting Remote Regulatory Assessments; Questions and Answers; Guidance for Industry.'' 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.

- 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Inspectorate Policy, Office of Inspections and Investigations (OII), Food and Drug Administration, Element Building, 12420 Parklawn Dr., Rockville, MD 20852. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by emailing OII at *oiipolicystaffs@fda.hhs.gov.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.