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: 057

AGENCY: Food and Drug Administration, Health and Human Services (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: 057'' (Recognition List Number: 057), 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 April 22, 2022.

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: 057.'' 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: 057.

- 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: 057 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: 057 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: 057'' to Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301–796–6287. Send one self-addressed adhesive label to assist that office in processing your request, or Fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5606, Silver Spring, MD 20993, 301–796–6287, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 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 hypertext markup language (HTML) and portable document format (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/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program.*

II. Modifications to the List of Recognized Standards, Recognition List Number: 057

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: 057'' 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: 057.

TABLE 1—MODIFICATIONS TO THE LIST OF RECOGNIZED STANDARDS

Old recognition No.	Replacement recognition No.	Title of standard [1]	Change
A. Anesthesiology			
No new entries at this time.			
B. Biocompatibility			
2–275	.....	ISO 10993–7 Second edition 2008–10–15 Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals [Including: Technical Corrigendum 1 (2009), AMENDMENT 1: Applicability of allowable limits for neonates and infants (2019)].	Title change.
2–284	2–292	USP–NF M98833_01_01 <87> Biological Reactivity Test, In Vitro—Direct Contact Test.	Withdrawn and replaced with newer version.
2–285	2–293	USP–NF M98833_01_01 <87> Biological Reactivity Test, In Vitro—Elution Test.	Withdrawn and replaced with newer version.
2–286	2–294	USP–NF M98834_01_01 <88> Biological Reactivity Tests, In Vivo	Withdrawn and replaced with newer version.
2–287	2–295	USP–NF M98900_01_01 <151> Pyrogen Test (USP Rabbit Test).	Withdrawn and replaced with newer version.
C. Cardiovascular			
3–88	3–171	ASTM F2514–21 Standard Guide for Finite Element Analysis (FEA) of Metallic Vascular Stents Subjected to Uniform Radial Loading.	Withdrawn and replaced with newer version.
3–99	3–172	AAMI TIR42:2021 Evaluation of particulate associated with vascular medical devices.	Withdrawn and replaced with newer version.
3–133	3–173	ISO 5840–3 Second edition 2021–01 Cardiovascular implants—Cardiac valve prostheses—Part 3: Heart valve substitutes implanted by transcatheter techniques.	Withdrawn and replaced with newer version.
3–145	3–174	ISO 5840–1 Second edition 2021–01 Cardiovascular implants—Cardiac valve prostheses—Part 1: General requirements.	Withdrawn and replaced with newer version.
3–147	3–175	ISO 5840–2 Second edition 2021–01 Cardiovascular implants—Cardiac valve prostheses—Part 2: Surgically implanted heart valve substitutes.	Withdrawn and replaced with newer version.
D. Dental/Ear, Nose, and Throat (ENT)			
4–89	.....	ANSI/ADA Standard No. 53—2008 (R2013) Polymer-Based Crown and Bridge Materials.	Withdrawn.
4–282	4–284	ISO 10873 Second edition 2021–07 Dentistry—Denture adhesives	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
E. General I (Quality Systems/Risk Management) (QS/RM)			
5–117	5–134	ISO 15223–1 Fourth edition 2021–07 Medical devices—Symbols to be used with medical device labels, labelling, and information to be supplied—Part 1: General requirements.	Withdrawn and replaced with newer version.
F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)			
19–34	19–41	ANSI/UL 61010–1 3rd Ed, dated May 12, 2012 with revision through July 19, 2019 Standard for Safety for Electrical Equipment For Measurement, Control and Laboratory Use; Part 1: General Requirements.	Withdrawn and replaced with newer version.
G. General Hospital/General Plastic Surgery (GH/GPS)			
6–365	6–464	ISO 11040–4 Third edition 2015–04–01 Prefilled syringes—Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling [Including AMENDMENT 1 (2020)].	Withdrawn and replaced with newer version.
6–451	6–465	USP–NF M76090_03_01 Sodium Chloride Irrigation	Withdrawn and replaced with newer version.
6–452	6–466	USP–NF M76070_03_01 Sodium Chloride Injection	Withdrawn and replaced with newer version.
6–453	6–467	USP–NF M80200_04_01 Nonabsorbable Surgical Suture	Withdrawn and replaced with newer version.
6–454	6–468	USP–NF M99670_02_01 <881> Tensile Strength	Withdrawn and replaced with newer version.
6–455	6–469	USP–NF M99650_02_01 <861> Sutures—Diameter	Withdrawn and replaced with newer version.
6–456	6–470	USP–NF M99660_03_01 <871> Sutures—Needle Attachment	Withdrawn and replaced with newer version.
6–457	6–471	USP–NF M88880_05_01 Sterile Water for Irrigation	Withdrawn and replaced with newer version.
6–458	6–472	USP–NF M36660_04_01 Heparin Lock Flush Solution.	Withdrawn and replaced with newer version.
6–459	6–473	USP–NF M80190_04_01 Absorbable Surgical Suture	Withdrawn and replaced with newer version.
H. In Vitro Diagnostics (IVD)			
No new entries at this time.			
I. Materials			
8–103	8–563	ASTM F1801–20 Standard Practice for Corrosion Fatigue Testing of Metallic Implant Materials.	Withdrawn and replaced with newer version.
8–121	8–564	ASTM F2005–21 Standard Terminology for Nickel-Titanium Shape Memory Alloys.	Withdrawn and replaced with newer version.
8–193	8–565	ASTM F2754/F2754M–21 Standard Test Method for Measurement of Camber Cast Helix and Direction of Helix of Coiled Wire.	Withdrawn and replaced with newer version.
8–346	8–566	ASTM F1813–21 Standard Specification for Wrought Titanium—12 Molybdenum—6 Zirconium—2 Iron Alloy for Surgical Implant (UNS R58120).	Withdrawn and replaced with newer version.
8–353	8–567	ASTM F86–21 Standard Practice for Surface Preparation and Marking of Metallic Surgical Implants.	Withdrawn and replaced with newer version.
8–355	8–568	ASTM F1586–21 Standard Specification for Wrought Nitrogen Strengthened 21 Chromium-10 Nickel-3 Manganese-2.5 Molybdenum Stainless Steel Bar for Surgical Implants (UNS S31675).	Withdrawn and replaced with newer version.
8–385	8–569	ASTM F648–21 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.	Withdrawn and replaced with newer version.
8–398	8–570	ASTM F1108–21 Standard Specification for Titanium-6Aluminum-4Vanadium Alloy Castings for Surgical Implants.	Withdrawn and replaced with newer version.
8–422	8–571	ASTM F2052–21 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment.	Withdrawn and replaced with newer version.
8–423	8–572	ASTM F2565–21 Standard Guide for Extensively Irradiation-Crosslinked Ultra-High Molecular Weight Polyethylene Fabricated Forms for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–424	8–573	ASTM F2695–12(2020) Standard Specification for Ultra-High Molecular Weight Polyethylene Powder Blended With Alpha-Tocopherol (Vitamin E) and Fabricated Forms for Surgical Implant Applications.	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
8–425	8–574	ASTM F2820–12(2021)e1 Standard Specification for Polyetherketoneketone (PEKK) Polymers for Surgical Implant Applications.	Withdrawn and replaced with newer version.
8–443	8–575	ASTM F3160–21 Standard Guide for Metallurgical Characterization of Absorbable Metallic Materials for Medical Implants.	Withdrawn and replaced with newer version.
8–450	8–576	ASTM F451–21 Standard Specification for Acrylic Bone Cement	Withdrawn and replaced with newer version.
8–456	8–577	ISO 13179–1 Second Edition 2021–09 Implants for surgery—Coatings on metallic surgical implants—Part 1: Plasma-sprayed coatings derived from titanium or titanium-6 aluminum-4 vanadium alloy powders.	Withdrawn and replaced with newer version. Title change.
8–460	8–578	ASTM F2848–21 Standard Specification for Medical-Grade Ultra-High-Molecular-Weight Polyethylene Yarns.	Withdrawn and replaced with newer version.
8–515	8–579	ISO 13779–3 Second Edition 2018–12 Implants for surgery—Hydroxyapatite—Part 3: Chemical analysis and characterization of crystallinity ratio and phase purity [Including AMENDMENT 1 (2021)].	Withdrawn and replaced with newer version.
J. Nanotechnology			
No new entries at this time.			
K. Neurology			
No new entries at this time.			
L. Obstetrics-Gynecology/Gastroenterology/Urology (OB-Gyn/G/Urology)			
No new entries at this time.			
M. Ophthalmic			
10–73	10–127	ANSI Z80.21–2020 American National Standard for Ophthalmics—Instruments—General-Purpose Clinical Visual Acuity Charts.	Withdrawn and replaced with newer version.
10–87	10–128	ASTM D882–18 Standard Test Method for Tensile Properties of Thin Plastic Sheeting.	Withdrawn and replaced with newer version.
10–88	10–129	ASTM D790–17 Standard Test Methods for Flexural Properties of Unreinforced and Reinforced Plastics and Electrical Insulating Materials.	Withdrawn and replaced with newer version.
10–102	10–130	ANSI Z80.36–2021 American National Standard for Ophthalmics—Light Hazard Protection for Ophthalmic Instruments.	Withdrawn and replaced with newer version.
N. Orthopedic			
11–239	11–385	ASTM F2345–21 Standard Test Methods for Determination of Cyclic Fatigue Strength of Ceramic Modular Femoral Heads.	Withdrawn and replaced with newer version.
11–266	11–386	ASTM F2665–21 Standard Specification for Total Ankle Replacement Prosthesis.	Withdrawn and replaced with newer version.
11–305	11–387	ASTM F1781–21 Standard Specification for Elastomeric Flexible Hinge Finger Total Joint Implants.	Withdrawn and replaced with newer version.
11–345	11–388	ASTM F1717–21 Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model.	Withdrawn and replaced with newer version.
11–359	11–389	ISO 7206–10 Second edition 2018–08 Implants for surgery—Partial and total hip-joint prostheses—Part 10: Determination of resistance to static load of modular femoral heads [Including AMENDMENT 1 (2021)].	Withdrawn and replaced with newer version.
O. Physical Medicine			
No new entries at this time.			
P. Radiology			
12–299	12–341	IEC 62563–1 Edition 1.2 2021–07 CONSOLIDATED VERSION Medical electrical equipment—Medical image display systems—Part 1: Evaluation methods.	Withdrawn and replaced with newer version.
12–300	12–342	NEMA DICOM PS 3.1—3.20 2021e Digital Imaging and Communications in Medicine (DICOM) Set.	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
Q. Software/Informatics			
13–46	.....	ASTM F2761–09 (2013) Medical Devices and Medical Systems—Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model.	Withdrawn. See 13–120.
R. Sterility			
14–424	14–563	ISO 13408–6 Second edition 2021–04 Aseptic processing of health care products—Part 6: Isolator systems.	Withdrawn and replaced with newer version.
14–555	14–564	USP–NF M98910_01_01 <161> Medical Devices-Bacterial Endotoxin and Pyrogen Tests.	Withdrawn and replaced with newer version.
14–556	14–565	USP–NF M98802_01_01 <62> Microbiological Examination of Nonsterile Products: Tests for Specified Microorganisms.	Withdrawn and replaced with newer version.
14–557	14–566	USP–NF M98795_02_01 <55> Biological Indicators—Resistance Performance Tests.	Withdrawn and replaced with newer version.
14–558	14–567	USP–NF M7414_01_01 <1229.5> Biological Indicators for Sterilization	Withdrawn and replaced with newer version.
14–559	14–568	USP–NF M98800_01_01 <61> Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests.	Withdrawn and replaced with newer version.
14–560	14–569	USP–NF M98810_01_01 <71> Sterility Tests	Withdrawn and replaced with newer version.
14–561	14–570	USP–NF M98830_02_01 <85> Bacterial Endotoxins Test	Withdrawn and replaced with newer version.
S. Tissue Engineering			
15–29	.....	ASTM F2259–10 (Reapproved 2012)e1 Standard Test Method for Determining the Chemical Composition and Sequence in Alginate by Proton Nuclear Magnetic Resonance (1H NMR) Spectroscopy.	Withdrawn.

[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: 057. 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		
No new entries at this time.		
B. Biocompatibility		
No new entries at this time.		
C. Cardiovascular		
3–176	Cardiovascular implants and artificial organs—Cannulae for extracorporeal circulation	ISO 18193 First edition 2021–08.
3–177	Standard Guide for Three-Point Bending of Balloon-Expandable Vascular Stents and Stent Systems.	ASTM F2606–08 (Reapproved 2021).
3–178	Standard Guide for Radial Loading of Balloon-Expandable and Self-Expanding Vascular Stents.	ASTM F3067–14 (Reapproved 2021).
3–179	Standard Guide for Design Verification Device Size and Sample Size Selection for Endovascular Devices.	ASTM F3172–15 (Reapproved 2021).
3–180	Standard Test Method for Stent and Endovascular Prosthesis Kink Resistance	ASTM F3505–21.
D. Dental/Ear, Nose, and Throat (ENT)		
4–285	Dental Abrasive Powders	ANSI/ADA Standard No. 37—1986 (R2020).
4–286	Dental Impression Trays	ANSI/ADA Standard No. 87—1995 (R2014).

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

Recognition No.	Title of standard [1]	Reference No. and date
4–287	Oral Rinses (Modified adoption of ISO 16408:2015, Dentistry Oral Care Products—Oral Rinses).	ANSI/ADA Standard No. 116—2020.
4–288	Dentistry—Mixing machines for dental amalgam	ISO 7488 Second edition 2018–04.
4–289	Dentistry—Intraoral spatulas	ISO 18556 First edition 2016–04.
4–290	Dentistry—Integrated dental floss and handles	ISO 28158 Second edition 2018–09.
4–291	Dentistry—Products for external tooth bleaching	ISO 28399 First edition 2011–01.
4–292	Dentistry—Screening method for erosion potential of oral rinses on dental hard tissues.	ISO 28888 First edition 2013–10.
	E. General I (Quality Systems/Risk Management) (QS/RM)	
	No new entries at this time.	
	F. General II (Electrical Safety/Electromagnetic Compatibility) (ES/EMC)	
19–42	Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 1: General requirements.	IEC 61326–1 Edition 3.0 2020–10.
19–43	Electrical equipment for measurement, control and laboratory use—EMC requirements—Part 2–6: Particular requirements—In vitro diagnostic (IVD) medical equipment.	IEC 61326–2–6 Edition 3.0 2020–10.
19–44	American National Standard—Recommended Practice for In Situ RF Immunity Evaluation of Electronic Devices and Systems.	ANSI/IEEE C63.24–2021.
	G. General Hospital/General Plastic Surgery (GH/GPS)	
6–474	Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities	ASTM F3352–19.
	H. In Vitro Diagnostics (IVD)	
7–309	Radiological protection—Performance criteria for laboratories using the cytokinesis block micronucleus (CBMN) assay in peripheral blood lymphocytes for biological dosimetry.	ISO 17099 First edition 2014–11–15.
7–310	Radiological protection—Performance criteria for service laboratories performing biological dosimetry by cytogenetics.	ISO 19238 Second edition 2014–02–01.
7–311	A Hierarchical Approach to Selecting Surrogate Samples for the Evaluation of In Vitro Medical Laboratory Tests.	CLSI EP39, 1st Edition
	I. Materials	
8–580	Eyewear display—Part 20–10: Fundamental measurement methods—Optical properties.	IEC 63145–20–10 Edition 1.0 2019–08.
8–581	Eyewear display—Part 20–20: Fundamental measurement methods—Image quality	IEC 63145–20–20 Edition 1.0 2019–09.
8–582	Eyewear display—Part 22–10: Specific measurement methods for AR type—Optical properties.	IEC 63145–22–10 Edition 1.0 2020–01.
	J. Nanotechnology	
18–19	Nanotechnologies—Measurements of particle size and shape distributions by scanning electron microscopy.	ISO 19749 First edition 2021–07.
18–20	Standard Guide for Visualization and Identification of Nanomaterials in Biological and Nonbiological Matrices Using Darkfield Microscopy/Hyperspectral Imaging (DFM/HSI) Analysis.	ASTM E3275–21.
	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	
11–390	Implants for surgery—Pre-clinical mechanical assessment of spinal implants and particular requirements—Part 2: Spinal intervertebral body fusion devices.	ISO 23089–2 First edition 2021–05.
11–391	Standard Practice for Evaluating Mobile Bearing Knee Tibial Baseplate Rotational Stops.	ASTM F2722–21.
11–392	Standard Test Method for Evaluating Mobile Bearing Knee Tibial Baseplate/Bearing Resistance to Dynamic Disassociation.	ASTM F2723–21.

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

Recognition No.	Title of standard [1]	Reference No. and date
11–393	Standard Test Method for Evaluating Mobile Bearing Knee Dislocation	ASTM F2724–21.
	O. Physical Medicine	
16–232	Medical electrical equipment—Part 2–78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation.	IEC 80601–2–78 Edition 1.0 2019–07.
	P. Radiology	
	No new entries at this time.	
	Q. Software/Informatics	
13–120	Medical Devices and Medical Systems—Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE)—Part 1: General requirements and conceptual model.	ANSI/AAMI 2700–1:2019.
	R. Sterility	
14–571	Sterilization of health care products—Biological indicators—Part 8: Method for validation of a reduced incubation time for a biological indicator.	ISO 11138–8 First edition 2021–07.
	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: April 18, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–08571 Filed 4–21–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

[OMB No. 0917–0040]

Request for Public Comment: 30-Day Information Collection: Request for Reinstatement of Indian Health Service Purchased/Referred Care Proof of Residency

AGENCY: Indian Health Service, HHS.

ACTION: Notice and request for comments; request for reinstatement.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) invites the general public to take this opportunity to comment on the reinstatement of the information collection, Office of Management and Budget (OMB) Control Number 0917–0040, titled, Purchased/Referred Care Proof of Residency. The IHS is requesting OMB to approve a reinstatement of this collection. Notice regarding the information collection was last published in the **Federal Register** on January 24, 2022, and allowed 60 days for public comment. The purpose of this notice is to announce the IHS's intent to reinstate this collection to OMB and to allow 30 days for public comment to be submitted directly to OMB. A copy of the supporting statement is available at *www.regulations.gov* (see Docket ID: IHS_FRDOC_0001).

DATES: Consideration will be given to all comments received by May 23, 2022.

ADDRESSES: *Direct Your Comments to OMB:* Send your comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Evonne Bennett, Information Collection Clearance Officer at: *Evonne.Bennett@ihs.gov* or 301–443–4750.

SUPPLEMENTARY INFORMATION: This previously approved information collection project was last published in the **Federal Register** on January 24, 2022, and allowed 60 days for public comment (87 FR 3562). No public comment was received in response to the notice. This notice announces our intent to reinstate this collection, which expired March 31, 2022; to submit this