Standards and Conformity Assessment Program

Introduction

The Standards and Conformity Assessment Program supports the FDA's mission of protecting and promoting public health through the development, recognition and use of voluntary consensus standards in regulating medical devices, radiation-emitting products and emerging technologies. The Center for Devices and Radiological Health (CDRH) is committed to making safe and effective medical devices available to patients in an efficient and least burdensome manner. An important element of our regulatory framework is a robust standards program. CDRH encourages medical device sponsors to use FDA-recognized voluntary consensus standards in their submissions, as conformity to relevant standards streamlines regulatory review and fosters quality.

What is a Voluntary Consensus Standard?

A standard is any '...document, established by consensus that provides rules, guidelines or characteristics for activities or their results.' (ANSI (https://www.ansi.org/about_ansi/faqs/faqs?menuid=1) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) definition). A voluntary consensus standard is one that is developed or adopted by Standards Developing Organizations (SDOs), both domestic and international, according to strict consensus principles. Consensus standards contribute to regulatory quality because consensus-based SDOs must demonstrate adherence to the tenets of transparency, openness to participation by interested stakeholders, balance of representation, and due process, among other principles. For more information about consensus standards and their use in federal agencies, see *OMB Circular A-119:* (https://www.federalregister.gov/documents/2016/01/27/2016-01606/revision-of-omb-circular-no-a-119-federal-participation-in-the-development-and-use-of-voluntary) *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* and*ANSI Essential Requirements: Due Process requirements for American National Standards* (https://share.ansi.org/Shared%20Documents/Standards%20Activities/American%20National%20Standards/Procedures%2C%20Guides%2C%20Essential-Requirements-2018.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

What is Conformity Assessment?

Rigorous conformity assessment is an integral part of a strong regulatory framework incorporating the appropriate use of consensus standards. OMB defines conformity assessment as '... a demonstration, whether directly or indirectly, that specified requirements relating to a product, process, system, person, or body are fulfilled. Conformity assessment includes sampling and testing, inspection, supplier's declaration of conformity, certification, and management system assessment and registration. Conformity assessment also includes accreditation of the competence of those activities.'

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How Consensus Standards Can Be Used in Premarket Submissions

While manufacturers are encouraged to use FDA-recognized consensus standards in their premarket submissions, conformance is voluntary, unless a standard is incorporated by reference into regulation see the Standards (Medical Devices) Federal Register Documents (/medical-devices/standards-and-conformity-assessment-program-medical-devices/federal-register-documents).

Demonstrating conformity with FDA-recognized standards facilitates the premarket review process—including for any Premarket Notifications (510(k)s), De Novorequests, Investigational Device Exemption (IDE) applications, Premarket Approval (PMA) applications, Product Development Protocols (PDP), Humanitarian Device Exemption (HDE) applications, Investigational New Drug (IND) Applications, and Biologics License Applications (BLA) for those devices that are regulated by the Center for Biologics Evaluation and Research (CBER) as biological products under section 351 of the Public Health Service Act.. Standards are particularly useful when an FDA-recognized consensus standard exists that serves as a complete performance standard for a specific medical device. Conformity with other more general (i.e., device-specific standards that may not encompass all aspects of device performance) can also streamline the premarket review process.

Applicants should clearly identify their appropriate use of standards in premarket submissions; they may identify any referenced standards in their CDRH Premarket Review Submission Cover Sheet (Form FDA 3514 (/media/72421/download)). If a manufacturer elects to conform to one or more FDA-recognized consensus standards to satisfy part of a premarket review requirement, the manufacturer must submit a "Declaration of Conformity" to the standard(s) (221 U.S.C. 360d(c)(1)(B)). For further information, refer to the Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance document.

How to Find FDA Recognized and Non-Recognized Standards

Standards that have been recognized by the FDA (either wholly or in part) are maintained and are searchable in the FDA's Recognized Consensus Standards database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm). Standards for which a non-recognition determination has been made are listed in the Non-Recognized Standards database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm). A manufacturer may not declare conformity to a non-recognized standard. The historical record of all FDA's recognition determinations (i.e., recognized wholly, in part, or not) is provided on the Federal Register Documents (/medical-devices/standards-and-conformity-assessment-program-medical-devices/federal-register-documents) webpage.

For further information on standards, their use, and their recognition, refer to the standards modules provided in CDRH Learn (/training-and-continuing-education/cdrh-learn) (under the heading "How to Study and Market Your Device").

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FDA Standards Recognition Process

FDA may recognize all, part, or none of a standard established by a national or international SDO. Any interested party may submit a request for recognition.

In addition, the 21st Century Cures Act of 2016 (https://www.congress.gov/bill/114th-congress/house-bill/34/text) (Pub. L. 114-255) modified Section 514(c) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to clarify how the FDA will process requests for recognition of voluntary consensus standards. Specific changes included:

a. adding a 60-day timeframe for FDA's response to standards recognition requests,

b. directing the FDA to issue a response in writing, and,

c. directing the FDA to publish on its website its rationale for recognition of all, part, or none of a standard.

What is FDA Recognition?

Recognition is the process whereby FDA identifies standards to which manufacturers of medical devices may submit a Declaration of Conformity to demonstrate they have met relevant requirements in the FD&C Act.

In general, the FDA actively assesses the impact of new consensus standards and revisions of existing standards on the premarket review process and recognizes these standards, as appropriate. As FDA determines that new or revised standards are appropriate for meeting requirements under the FD&C Act for medical devices, we will update the standards database on FDA's website. Once we have decided to recognize a standard, we will issue a recognition number and provide supplemental information in the database. To recognize such standards, we will periodically publish a recognition list in the Federal Register. FDA usually performs the activity at least twice annually. Superseded standards that the FDA has withdrawn from the list of recognized standards cannot be used in a Declaration of Conformity.

Submitting a Request for Recognition

A request for recognition of a standard should contain the following information:

1. Name and electronic or mailing address of the requester
2. Title of the standard
3. Any standard reference or designation number and date
4. Proposed list of devices for which a declaration of conformity should routinely apply
5. Basis for supporting the recognition request, for example the scientific, technical, regulatory, or other basis for the request
6. A brief identification of the testing or performance or other characteristics of the device(s) or process(es) that would be addressed by a Declaration of Conformity.

Submit one paper copy by mail to the CDRH Standards Program at the address below or electronically to: CDRHStandardsStaff@fda.hhs.gov (mailto:CDRHStandardsStaff@fda.hhs.gov).

Standards and Conformity Assessment Program
Office of the Center Director
Center for Devices and Radiological Health
10903 New Hampshire Avenue
WO66-5514
Silver Spring, MD 20993-0002

Review Timeline

FDA's goal is to make a decision on recognition (complete or partial) or non-recognition no later than 60 calendar days from the date the request was received.

Response to Request for Recognition

FDA's goal is to make a decision on recognition (complete or partial) or non-recognition no later than 60 calendar days from the date the request was received. When such a decision is made, the Agency will issue the decision letter to the submitter by mail using the mailing address provided or electronically using the email address provided. We will announce the decision to recognize the standard (completely or partially) with a subsequent notice in the Federal Register.

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Recognized Consensus Standards Database

Standards recognized by the FDA (either wholly, or in part) are maintained and are searchable in the FDA's Recognized Consensus Standards database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm).

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Federal Register Documents

This webpage (/medical-devices/standards-and-conformity-assessment-program-medical-devices/federal-register-documents) contains a record of all Federal Register (FR) notices announcing recognized standards, modifications to existing recognitions, corrections, and withdrawal of standards, as required under 514(c) of the FD&C Act.

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Non-Recognized Standards

What is a FDA Non-Recognized Standard?

A non-recognized standard is a standard that the FDA has determined does not satisfy or would not be helpful in satisfying a portion of the FD&C Act (which includes the FDA Modernization Act of 1997 (FDAMA) and 21st Century Cures Act of 2016) or regulations.

Reasons for FDA Non-Recognition

A non-recognition determination is communicated to the applicant of the request along with an explanation of the technical, scientific, regulatory, or other basis for the decision.

List of FDA Non-Recognized Standards

A summary listing of those standards that have received a non-recognition determination can be found in the FDA's Non-Recognized Standards Database (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/nr_results.cfm).

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Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

CDRH is expanding its standards program to include an accreditation initiative that is intended to improve the device review process by enhancing product reviewers' confidence in conformance documentation from manufacturers. The ASCA pilot program, endorsed and funded as part of the Medical Device User Fee Amendments 2017 (MDUFA IV), aims to streamline the conformity assessment of medical device submissions when certain FDA recognized standards are used. Capitalizing on the increasingly prominent role that standards can play in regulatory science and practice, the FDA intends to recognize accredited test labs (including in-house and third party) to produce standardized test reports for device sponsors.

The intended outcome of the ASCA pilot is directed towards improving consistency and predictability of FDA's approach to assessing conformance to standards in device submission reviews by enhancing FDA's confidence in the test labs' competence, and thereby in the test methods and results. The need for consultations, complete test report review and additional information are expected to decrease as FDA's confidence in the test labs' capabilities grows and both FDA and manufacturers should benefit from the use of uniform Declarations of Conformity. For information about ASCA please see the Accreditation Scheme for Conformity Assessment (ASCA) page (/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca).

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Other Standards and Conformity Assessment Program Activities

International Medical Device Regulators Forum (IMDRF): CDRH serves as the Chair for the Standards Working Group within the International Medical Device Regulators Forum (IMDRF). (http://www.imdrf.org/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) This group contributes to IMDRF's mission to converge regulatory processes across international jurisdictions by advancing the use of consensus standards globally. This effort includes publishing recommendations on how to write standards that are appropriate for regulatory use and how regulators can contribute effectively to the standards development process.

Participation in Standards Development Organization (SDO)Activities: CDRH is actively engaged in collaborations with national and international consensus SDOs. CDRH staff participate as experts and leaders to various committees to ensure that published standards are suitable and useful for regulatory purposes.

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Resources for Standards and Conformity Assessment Program

- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices (/media/71983/download) **(guidance)**
- CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards (/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-standard-operating-procedures-identification-and-evaluation-candidate-consensus-standards) **(guidance)**
- CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) (/media/72421/download) **(form)**
- Industry: X-ray Imaging Devices (/radiation-emitting-products/medical-x-ray-imaging/information-industry-x-ray-imaging-devices) **(webpage)**
- CDRH Learn (/training-and-continuing-education/cdrh-learn)**Standards Modules (under heading "How to Study and Market Your Device")**

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Contact Us

For **standards-specific questions**, please contact the CDRH Standards Management Staff at: CDRHStandardsStaff@fda.hhs.gov (mailto:CDRHStandardsStaff@fda.hhs.gov)

For **ASCA-specific questions**, please contact CDRH at: ASCA@fda.hhs.gov (mailto:ASCA@fda.hhs.gov)

For **general regulatory information,** please contact the Division of Industry and Consumer Education (DICE) (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) by phone at:(800) 638-2041 or (301) 796-7100 or by email at: DICE@fda.hhs.gov (mailto:DICE@fda.hhs.gov)

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