FDA U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

Welcome to Today's FDA/CDRH Webinar

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Recognition and Withdrawal of Voluntary Consensus Standards – Final Guidance

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Center for Devices and Radiological Health (CDRH)

U.S. Food and Drug Administration

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Agenda

- S-CAP Overview
- Draft guidance comments
- Final guidance
- Questions and answers

Using FDA-Recognized Standards

- S-CAP supports CDRH's mission by driving the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles
- FDA encourages the voluntary use of recognized standards in premarket submissions
  - Can increase predictability, streamline premarket review, provide clearer regulatory expectations, and facilitate market entry for safe and effective medical products
  - Declarations of Conformity may be used with recognized standards, reducing the amount of supporting data and information submitted to FDA
- *'Recognition':* FDA's formal identification of a standard after a determination that it is appropriate for manufacturers of products to declare conformance to meet relevant requirements

S-CAP core priorities

- Standards Recognition Program
- Encouraging the appropriate use of standards
- Active participation in national and international standards development

The numbers

- 17 internal advisory Specialty Task Groups (STGs) in 23 device/scientific areas
- ~ 400 CDRH staff participating in ~ 600 national and international standards committees across 29 Standards Developing Organizations
- ~1400 currently recognized standards (90%+ complete recognitions)
- 5-10% typical increase in requests for new standards development activities each year
- Average of 7 (range of 1-35) standards cited in each 510(k) submission

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Comments on the Draft Guidance

- Emphasized:
  - Need for a least burdensome, clear and transparent approach to standards recognition
- Requested clarity on:
  - Transition periods
  - Inclusion of basis for recognition and updates to the Supplemental Information Sheets
  - The distinction between when a standard may be used in a submission (upon inclusion in the Consensus Standards Recognition Database) versus when it is formally recognized (upon publication in the *Federal Register*)

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Final Guidance

The final guidance outlines:

- Who may submit a request for recognition (See Section IV.B)
- FDA's intent to respond in writing with the decision and its rationale within 60 calendar days: recognize all, part or none of the standard (See Section IV.C)
- FDA's obligation to publish recognition and non-recognition decisions (See Sections IV.C and IV.D)
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database

Final Guidance

- The guidance also addresses:
  - Consensus standards' value and utility in device submissions (See Section IV)
  - Elements of a request for recognition (See Section IV.B)
  - Supplementary Information Sheet update, including recognition rationale for all or part of a recognition of a standard (See Section V)
  - Updating the Recognized Consensus Standards Database (See Section IV.E)
  - Official recognition: upon publication in the *Federal Register* (See Section IV.E)
  - Withdrawal of recognized standards (See Section VI)
    - Possible transition periods

Elements in the Request for Recognition

1. Requester's name and electronic or mailing address
2. Title of the standard
3. Reference number and date (of the standard)
4. Proposed list of product types for which a Declaration of Conformity should routinely apply
5. Basis for recognition, e.g., including the scientific, technical, regulatory or other basis
6. Brief identification of the testing or performance or other characteristics that a DOC would address

Recognition Decision Process

- FDA formally acknowledges the request
- S-CAP considers the standard
- S-CAP convenes the appropriate Specialty Task Group to formally review the standard and make a recommendation to the program
  - Recognize or not recognize
  - Complete or partial recognition
- Based upon:
  - Scientific, technical, regulatory or other basis

Recognition Decisions

- Recognition decision within 60 calendar days
- Decision, including rationale, sent to requester
- Pending recognition: FDA's determination (partial or complete) appears in the FDA Consensus Standards Recognition Database
- Official recognition: publication in the *Federal Register*
- Non-recognitions listed in the Non-recognized Standards Database

**** Manufacturers may submit declarations of conformity within their premarket submission when a standard appears in the Standards Recognition Database ****

Supplementary Information

- Each recognized standard includes a Supplemental Information Sheet (SIS), which includes:
  - Recognition number
  - Date of entry
  - SDO & designation number
  - US identical adoption (if applicable)
  - Scope of standard
  - Extent of recognition (complete or partial)
  - Rationale for recognition
  - Transition period (if any)
  - Relevant FDA Specialty Task Group (STG)

Withdrawal of Recognition

- Standard is replaced by a newer version (superseded)
- Standard is no longer appropriate for meeting a requirement

****See the *Appropriate Use of Voluntary Consensus Standards* guidance for additional information****

Transition Periods

- When appropriate, CDRH may implement a transition period for revised standards
- CDRH considers:
  - Public health impact of delaying the use of a revised standard
  - Difficulties manufacturers face in implementing new changes
- Allows the submitter time to:
  - Continue to test and develop without additional retesting
  - Validate new test methods
- Located in the SIS below the “Rationale for Recognition” section

Thank You

Questions?

Division of Industry and Consumer Education:
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Slide Presentation, Transcript and Webinar Recording will be available at:

http://www.fda.gov/training/cdrhlearn Under the Heading: How to Study and Market Your Device; Sub heading: Standards

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Resources

Standards and Conformity Assessment Program:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm#intro

Recognition and Withdrawal of Voluntary Consensus Standards (final guidance)
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

FDA Recognized Consensus Standards Database:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices:
https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf

Device Advice: Comprehensive Regulatory Assistance:
https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

CDRH Learn: https://www.fda.gov/training/cdrhlearn/default.htm