Standards and Medical Device Regulatory Oversight

Scott A. Colburn, Director
FDA Standards and Conformity Assessment Program (S-CAP)
Topics

- FDA’s Standards and Conformity Assessment Program (S-CAP)
- Standards in device regulatory review
- Optimizing standards for regulatory purposes
- The Accreditation Scheme for Conformity Assessment (ASCA)
- Discussion
THE FDA’S STANDARDS AND CONFORMITY ASSESSMENT PROGRAM (S-CAP)
S-CAP Vision

The Standards and Conformity Assessment Program leads the medical device community in the enhancement and use of consensus standards in the design, development and evaluation of health technologies across their lifespans. S-CAP solves problems and anticipates opportunities to protect and promote public health through the use of high quality, regulatory-ready consensus standards.
S-CAP Mission

S-CAP drives the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles. S-CAP:

• Produces and implements clear policies and programs to optimize the appropriate use of standards in regulatory processes
• Anticipates the need for and leads development of national and international consensus standards
• Advances initiatives to enhance confidence in conformity assessment activities
• Fosters innovation and standardization in technologies that provide platforms for regulatory science to meet novel challenges
• Provides leadership in outreach and global harmonization
• Serves as a resource for CDRH staff, industry, other regulatory authorities and standards development organizations
Managing the Total Standards Life Cycle

Standards Development
- 17 internal advisory Specialty Task Groups (STGs) in 24 device/scientific areas
- ~400 CDRH staff participating in ~600 standards committees across 31 standards development organizations

Standards Conformity Assessment
- Enhance the use of declarations of conformity in device submissions
- ASCA program

Recognition Program
- >1400 recognized standards
- 5-10% annual increase in new standards development activities
- Average of 7 (range of 1-35) standards cited in each 510(k)
‘Recognition’: FDA’s formal identification of a standard after a determination that it is appropriate for manufacturers of products to declare conformance (with a declaration of conformity) to meet relevant requirements

- FDA may recognize all, part or none of the standard
- We will publish the decision rationale
- Recognition and non-recognition decisions updated regularly
  - Recognized Consensus Standards Database
  - Non-recognized Consensus Standards Database
- Withdrawal of recognized standards
Recognition Process

• Anyone may submit a request for recognition
• FDA formally acknowledges the request
• S-CAP considers the standard and convenes the appropriate Specialty Task Group
  – Formally reviews the standard and makes a recommendation to the program
• S-CAP recognizes the standard (or not)
• Complete or partial recognition
• Based upon scientific, technical or regulatory basis
FDA Recognized Consensus Standards Database

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm
Supplementary Information Sheets

• An SIS accompanies each recognized standard and includes:
  – Recognition number
  – Date of entry into Recognized Consensus Standards Database
  – SDO and designation number
  – US parallel adoption (if applicable)
  – Scope of standard
  – Extent of recognition (complete or partial)
  – Rationale for recognition or partial recognition
  – Transition period (if any)
  – Examples of applicable device product codes
  – Relevant guidance documents or other publications
  – Relevant FDA Specialty Task Group (STG)
  – Name of contact person
Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number: 056
FR Recognition Number: 4-278

Date of Entry: 06/07/2021

Standard
ISO 4823 Fifth edition 2021-02
Dentistry - Elastomeric Impression and bite registration materials

Scope/Abstract
This document specifies the requirements and their test methods for elastomeric impression and bite registration materials.

NOTE This document does not address possible biological hazards associated with the materials. Assessment of these hazards is addressed in ISO 7495 and the ISO 10993 series.

Extent of Recognition
Complete standard

Rationale for Recognition
This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

Transition Period
FDA recognition of ISO 4823 Fourth edition 2015-08 [Rec# 4-225] will be superseded by recognition of ISO 4823 Fifth edition 2021-02 [Rec# 4-278]. FDA will accept declarations of conformity, in support of premarket submissions, to [Rec# 4-225] until July 10, 2022. After this transition period, declarations of conformity to [Rec# 4-225] will not be accepted.

Public Law, CFR Citation(s) and Procode(s)*

<table>
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<tr>
<th>Regulation Number</th>
<th>Device Name</th>
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<tr>
<td>§872.3660</td>
<td>Material, Impression</td>
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FDA Technical Contacts
STANDARDS IN DEVICE REGULATORY REVIEW
FDA strongly encourages the use of recognized standards in premarket submissions.

Declarations of conformity (DOCs) may be used with recognized standards, reducing the amount of supporting data and information submitted to FDA.
Use of Consensus Standards

• Voluntary
  • Only mandatory if cited in regulation (‘incorporated by reference’)
• In any type of submission
• With a DOC (recognized standards only) or ‘General Use’ (any standards, recognized or not)
What is a Declaration of Conformity?

• Attestation that the device conforms with the cited FDA-recognized standard
  – All normative requirements are met
  – All testing has been conducted
  – Testing was performed on finished device or final finished device

• If the manufacturer declares conformity with a recognized standard, a DOC accompanies the submission
  – Use of DOC with a recognized standard generally reduces documentation needed in a submission
‘General Use’ of Standards

• Citing non-recognized standards
• Citing a recognized standard without submitting a DOC
• Citing a recognized standard where deviations have been made to the methodology

** Complete test reports are needed for these instances of ‘General Use’ **
Supplemental Documentation

• Supplemental documentation is needed when:
  – Standard features neither test method nor acceptance criteria
  – Modifications or adaptations have been made to recognized standard

• This supplemental documentation should be the complete test report

• Note: If standards are cited under ‘General Use’ additional documentation may be needed
## Supplemental Documentation

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Example: **NO** Supplemental Documentation Needed

- When the FDA-recognized standard is a design standard
- When there are **two** standards, (e.g., one a test method & one with acceptance criteria)
- When the standard includes **both** a test method and a pre-specified performance limit
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Example: Supplemental Information IS Needed

• When the standard describes a test method or procedure with **NO** prespecified limits/acceptance criteria or vice versa

• When the standard includes choices:
  – What is to be tested
  – How it is to be tested (method)
  – Describes a process, e.g., risk assessment, etc.
Supplemental Information: Complete Test Reports

- Standard has **neither** test method nor prespecified acceptance criteria
- A DOC is not provided, e.g., General Use
- Deviations or adaptations have been made to the recognized standard
OPTIMIZING STANDARDS FOR REGULATORY PURPOSES
International Medical Device Regulators Forum

Management Committee Members

Official Observers

Regional Harmonization Initiatives
Challenges to Regulatory-ready Standards

IMDRF Standards Working Group identified:

• *Poor participation by RAs* → can lead to the development of standards that do not include substance and language that are useful for regulatory purposes

• *Unbalanced representation* → can result in some groups’ disproportionate voice in and impact on standards development

• *Content of standards can be too flexible* → can render standards less useful as they may not adequately identify minimum requirements for quality, safety and/or effectiveness/performance.
Optimizing Standards for Regulatory Use (Guidance)

Key Recommendations

• Standards must be improved for regulatory use

• IMDRF members should participate – as early as possible – in standards development
Optimizing Standards

Standards should feature:

• Strong rationale that:
  • Explains the general requirements and identifies test methods and/or other means of demonstrating compliance
  • Demonstrates how conformance to the standard achieves its goal of satisfying the associated Essential Principles

• Summary of the type of stakeholder groups involved in the drafting and editing of the standard

• Identification of risk and direction on how to address it

• Clear scope

• Terms and definitions established and accepted in other standards

• Means to assess clinical performance (if applicable) as part of the normative requirements
Optimizing Standards

Standards should feature (continued):

• Clear and quantitative acceptance criteria
• Explanation of how conformance can be met if no acceptance criteria are included
• If acceptance criteria are not mandatory, justification for why, and how to demonstrate conformance to the standard
• Well-accepted and verified test methods (including for new or unfamiliar methods)
• Transparent and clear (e.g., ‘track changes’) revisions
• An annex or table that cross references the standard’s clauses to the IMDRF Essential Principles
THE ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)
What is the ASCA Pilot?

• Voluntary program

• Leverages a well-established international conformity assessment infrastructure

• Capitalizes on voluntary consensus standards in device development and review

• Puts “standards to work” on both individual and international levels
ASCA Goal: Streamline conformity assessment in Premarket review

• Reduces time needed for the review of conformity assessment submission elements
  • Less need for Additional Information questions, internal consultations and complete test report review

• Removes the guesswork about supplemental documentation needs
  • Provides templates for declarations of conformity and Summary Test Reports
  • Identifies the minimum documentation needed to accompany a declaration of conformity

• Brings together regulatory and conformity assessment communities on behalf of improving testing

• Contributes to global harmonization
1. FDA grants ASCA Recognition to qualified accreditation bodies
2. Test labs obtain ASCA Accreditation from the FDA
3. Device manufacturers select ASCA-accredited test lab
4. ASCA-accredited test lab conducts testing and provides relevant information to manufacturer
5. Manufacturer includes declaration of conformity and ASCA Summary Test Report in submission
6. FDA conducts review per the ASCA Pilot guidances
# ASCA Pilot Standards: Biocompatibility

<table>
<thead>
<tr>
<th>FDA Recognized Consensus Standard</th>
<th>Test Method(s)</th>
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<tbody>
<tr>
<td>ISO 10993-4</td>
<td>Complement Activation using a U.S. marketed ELISA kit</td>
</tr>
<tr>
<td>ISO 10993-4 and ASTM F756</td>
<td>Direct and Indirect Hemolysis</td>
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<tr>
<td>ISO 10993-5</td>
<td>MEM Elution Cytotoxicity</td>
</tr>
<tr>
<td>ISO 10993-10</td>
<td>Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization</td>
</tr>
<tr>
<td>ISO 10993-10 and ASTM F720</td>
<td>Guinea Pig Maximization Sensitization</td>
</tr>
<tr>
<td>ISO 10993-11</td>
<td>Acute Systemic Toxicity</td>
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<tr>
<td>ISO 10993-11 and USP 151</td>
<td>Material-Mediated Pyrogenicity</td>
</tr>
<tr>
<td>ISO 10993-12</td>
<td>Sample preparation for all test types</td>
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ASCA Pilot Standards: Basic Safety and Essential Performance

<table>
<thead>
<tr>
<th>Standard</th>
<th>Standard Title</th>
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<tr>
<td>60601-1</td>
<td>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601-80601 series)</td>
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<tr>
<td>IEC 61010-1</td>
<td>Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with the FDA-recognized particular standards in the IEC 61010 series)</td>
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ASCA Pilot Guidances

• Program guidance
  – Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

• Standards-specific guidances
  – Biocompatibility Testing of Medical Devices
  – Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment
### ASCA Pilot

**Premarket Submission Elements**

#### Cover Letter
- States that submission is for ASCA Pilot
- Name, location and IDs of test lab(s)
- FDA-recognized consensus standard(s) and test methods used

#### Declaration of Conformity (DOC)
- Manufacturer’s responsibility
- ASCA Accreditation status for the test lab
- See suggested content in guidance

#### ASCA Summary Test Report
- See standards-specific ASCA Pilot guidance documents for examples

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**Device manufacturers are responsible for documenting how testing supports premarket authorization, even for ASCA Pilot submissions**

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DISCUSSION
US Standards Resources

- **Standards & Conformity Assessment Program**
  www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro

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

- **Recognition and Withdrawal of Voluntary Consensus Standards guidance**

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
ASCA Resources

• ASCA Pilot web page

• ASCA Pilot program guidance

• ASCA Standards-specific guidances
  
  – Basic Safety and Essential Performance standards-specific guidance:

  – Biocompatibility standards-specific guidance:

• Ask ASCA! ASCA@FDA.HHS.GOV