U.S. FOOD & DRUG ADMINISTRATION

Standards and Medical Device Regulatory Oversight

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Topics

- Consensus standards
- US FDA's Standards and Conformity Assessment Program (S-CAP)
- Standards in device regulatory review
- The Accreditation Scheme for Conformity Assessment (ASCA)
- Participating in standards development

CONSENSUS STANDARDS

Technical Definition

'A standard is a document, established by a consensus of subject matter experts and approved by a recognized body that provides guidance on the design, use or performance of materials, products, processes, services, systems or persons.'

(https://www.iso.org/sites/ConsumersStandards/1_standards.html)

Less Technical Definition

'Standards are the distilled wisdom of people with expertise in their subject matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators.'

*(*https://www.iso.org/standards.html)

Value of Standards

- Promote international trade
- Encourage innovation and competition among product developers
- More efficient to rely upon consensus-driven standards rather than lengthy legal or rule-making approaches
- Reduce burdens on device companies by harmonizing expectations across international jurisdictions

Value of Standards for Devices

Enhance regulatory science	Promote quality	Improve patient access

Science-based, least burdensome regulatory approach

Global Authority

- Universal support for consensus standards
- Technical Barriers to Trade treaty
  - Promotes international competition
  - Encourages reliance upon international consensus standards

US Authority

- US Standards Strategy
  - Promotes US ‘competitiveness, innovation, health and safety, and global trade’
  - Directs how the US should develop and use standards
  - Encourages global harmonization

Standards Laws, Directives & Policies

Congress — NTTAA of 1995

- *Use consensus technical standards when possible*
- *Participate in voluntary consensus standards bodies*
- *Administered by NIST*

Executive Branch — OMB Circular A-119

- *Federal government strategy for participating in the development & use of VCS and CA activities*

FDA — Regulation 21CFR 10.95 → Policy 60 FR 53078 → Staff Manual Guide SMG 9100.1

- *Outside activities*
- *International harmonization*
- *Standards management & participation*

luntary consensus standards

FDA Guidance

FDA utilizes formal ‘guidance’ to interpret federal policies

- Guidances represent FDA’s current thinking on a regulatory topic or issue
- Guidance documents receive public comment
- Compliance is voluntary; however, manufacturers must be prepared to demonstrate the value of a different approach
- *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*
- *Recognition and Withdrawal of Voluntary Consensus Standards*

Standards Development Organizations (SDOs)

- SDOs write and publish standards
  - Consensus standards
    - Adhere to consensus principles
    - Crowd-sourced
    - Transparent, inclusive processes
  - Industry standards
  - Consortium standards

ISO

- International Organization for Standardization
- A worldwide federation of 165 national standards bodies
- Established in 1947
- Based in Geneva, Switzerland

IEC

- International Electrotechnical Commission
- Total of 88 national committees
- Develops international standards for all electrical, electronic and related technologies
- Founded in 1906
- Based in Geneva, Switzerland

Device Standards

- Horizontal (cross-cutting)
  - ISO 14971: Risk management
  - ISO 10993: Biocompatibility
- Vertical (device-specific)
  - ISO 10555: Sterile and single use of catheters
  - ISO 11318: Cardiac defibrillators

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

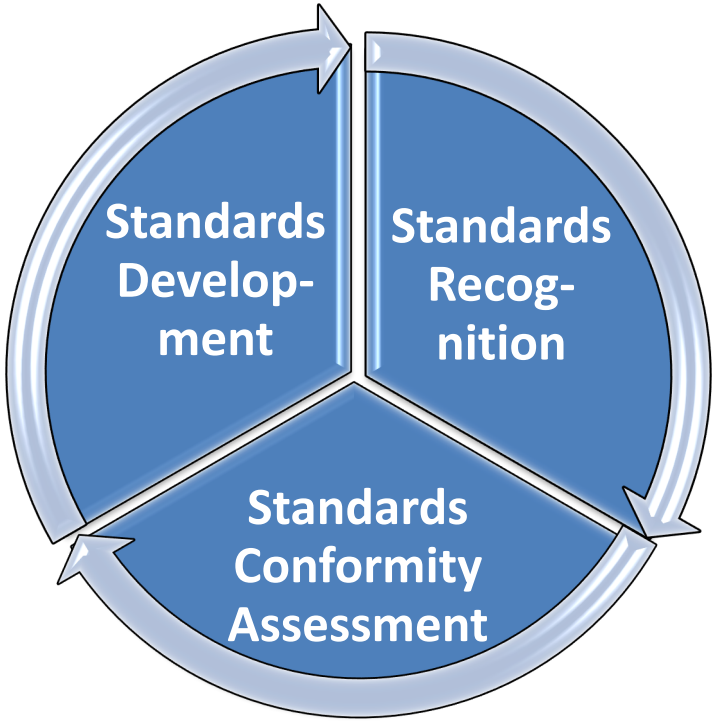
S-CAP drives the development, recognition, and appropriate use of regulatory-ready standards for medical devices throughout their lifecycles. S-CAP:

- 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 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



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)

Standards Conformity Assessment

- Enhance the use of declarations of conformity in device submissions
- ASCA Pilot program

Standards Recognition Program

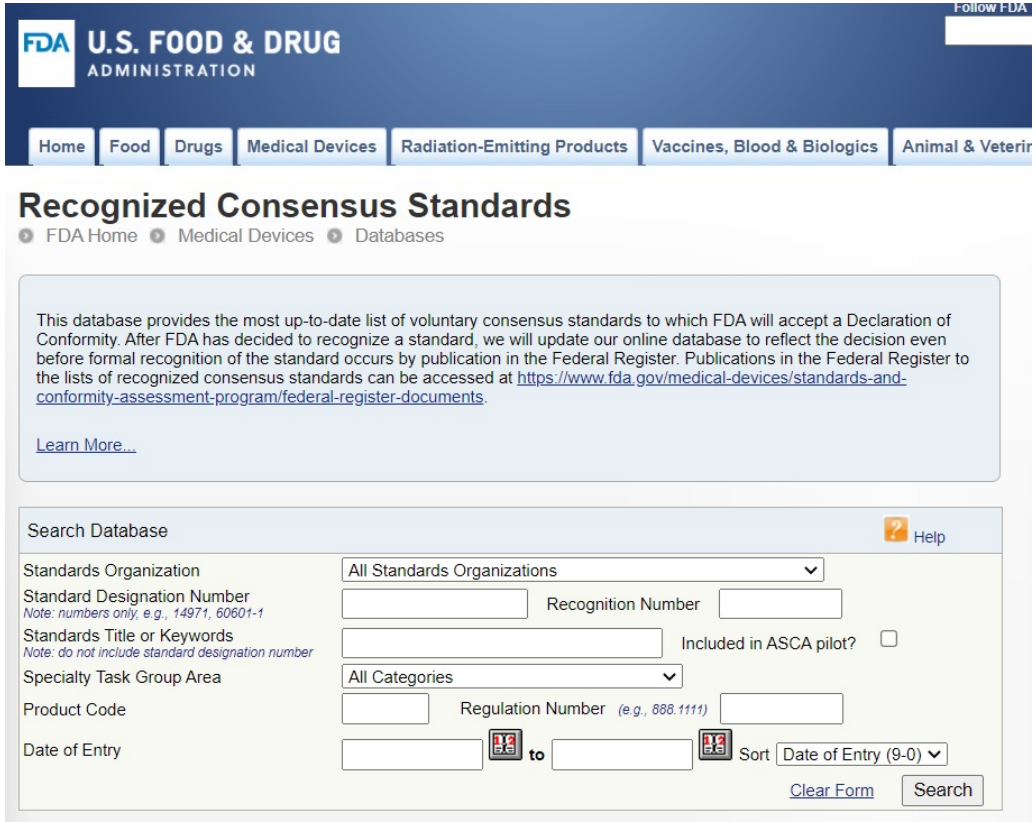
'Recognition': FDA's formal identification of a standard after a determination that it is appropriate for manufacturers of products to declare conformance (with a declaration of conformity) to meet relevant requirements

- 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 Decision 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

- A Supplementary Information Sheet (SIS) accompanies each recognized standard, which 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

SIS Example

ISO 4823:2021

Part B: Supplementary Information Sheet (SIS)

FR Recognition List Number 056 **Date of Entry** 06/07/2021

FR Recognition Number 4-278

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 7405 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)*

Regulation Number	Device Name	Device Class	Product Code
§872.3660	Material, Impression	Class 2	ELW

FDA Technical Contacts

STANDARDS IN DEVICE REGULATORY REVIEW

Using FDA-Recognized Standards

- 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
  - PMA, 510(k), etc.
- 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

Elements of a DOC

- Name and address of person responsible for the DOC
- Product/device identification
- Statement of conformity
- List of standards to which DOC applies
- FDA recognition number for each standard

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

Elements of a DOC, continued

- Date and place of issuance of DOC
- Signature, printed name, and function of applicant/sponsor responsible for DOC
- Any limitation on validity of DOC (for example, how long the declaration is valid, what was tested, or concessions made about testing outcomes)
- Supplemental documentation per ISO 17050-2 or equivalent

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

‘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 has neither test method nor prespecified acceptance criteria
  - Modifications or adaptations have been made to recognized standard
- This supplemental documentation should be the complete test report
- Note: If used under ‘General Use’ additional documentation may be needed

Supplemental Documentation

Standard Type		Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Design		No	No
Test Method	**Acceptance Criteria**		
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Standard Type	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Design	No	No

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

Supplemental Documentation

Test Method	Acceptance Criteria	Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test Report

THE ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

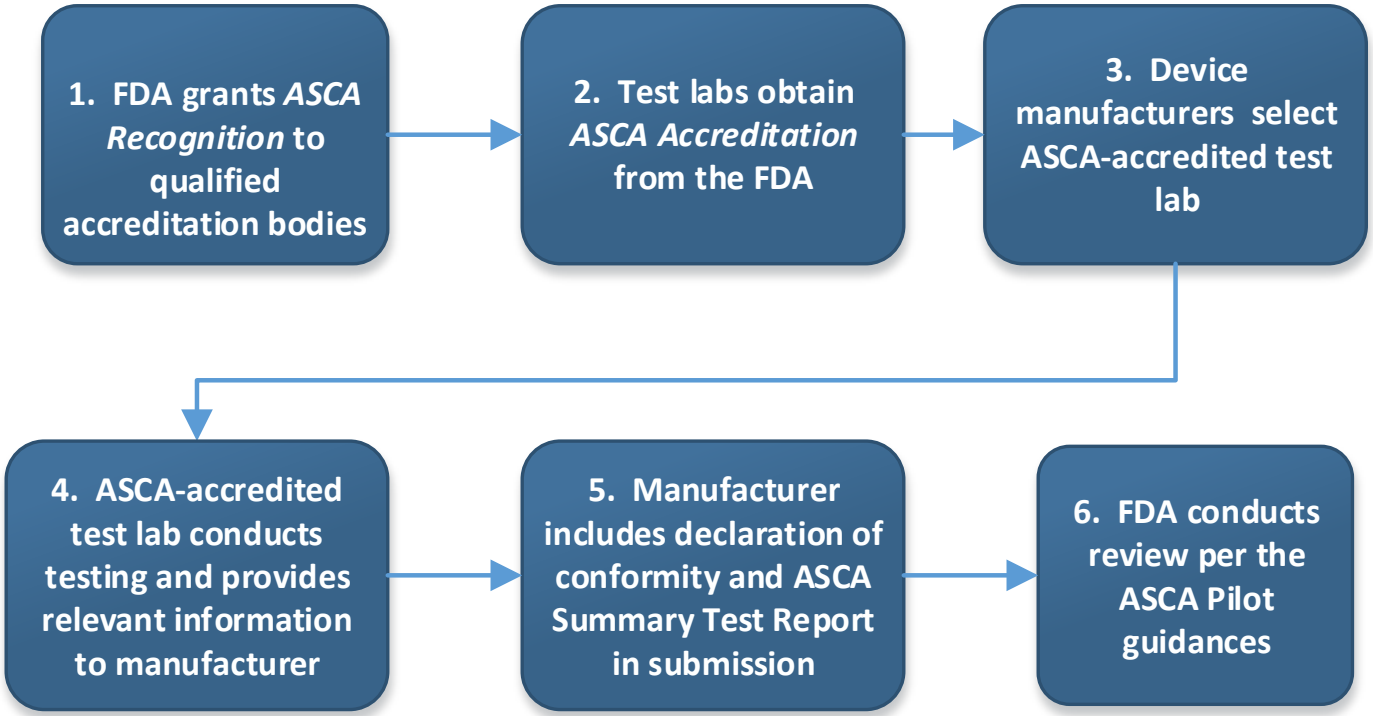
What is the ASCA Pilot?

- 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

Why ASCA?

- Enhances FDA's confidence in test methods and results
- Decreases need for additional information related to conformance with a standard
- Promotes consistency, predictability, and efficiency in medical device review
- Least burdensome approach to conformity assessment
- Patients have access to safe, effective, and high-quality medical devices

How ASCA Works



ASCA Pilot Standards: Biocompatibility

FDA Recognized Consensus Standard	Test Method(s)
ISO 10993-4	Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10	Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization
ISO 10993-10 and ASTM F720	Guinea Pig Maximization Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

***** Please see the Biocompatibility standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information *****

ASCA Pilot Standards: Basic Safety and Essential Performance

Standard	Standard Title
ANSI/AAMI 60601-1	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 family)
IEC 61010-1	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 family)

***** Please see the Basic Safety and Essential Performance standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information *****

ASCA Pilot Guidances

- Program
  - Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
- Standards-Specific
  - 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

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

PARTICIPATING IN STANDARDS DEVELOPMENT

International Medical Device Regulators Forum

World Health Organization

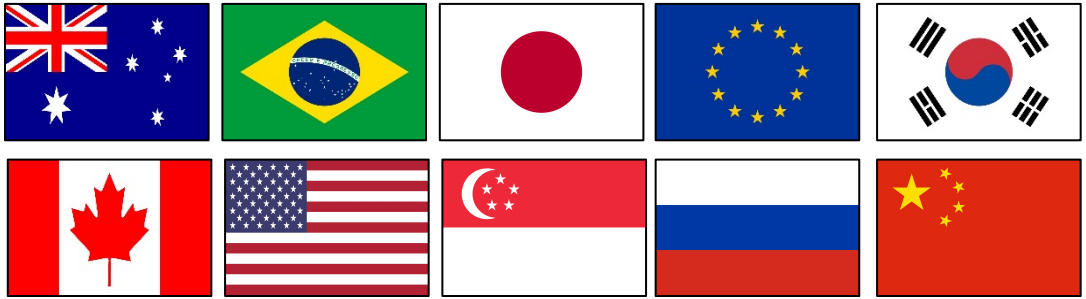
Official Observers

APEC
Asia-Pacific Economic Cooperation

AHWP
ASIAN HARMONIZATION WORKING PARTY

Pan American Health Organization

Regional Harmonization Initiatives



Management Committee Members

IMDRF International Medical Device Regulators Forum

IMDRF Goals

Goals

- Accelerate international medical device regulatory harmonization and convergence building on the work of the Global Harmonization Task Force
- Address common public health regulatory challenges to convergence due to the globalization of medical device production and the emergence of new technologies
- Accelerate innovation by clear and practical regulatory expectations

IMDRF International Medical Device Regulators Forum

Current IMDRF Working Groups

1. Good Regulatory Review Practices (GRRP)
2. Regulated Product Submission (RPS)
3. Cybersecurity
4. Personalized Medical Devices
5. Artificial Intelligence
6. Adverse Event Terminology
7. *Clinical Evaluation*
8. *IVDs*

*WGs are comprised of regulators only or regulators and stakeholders depending on the topic.

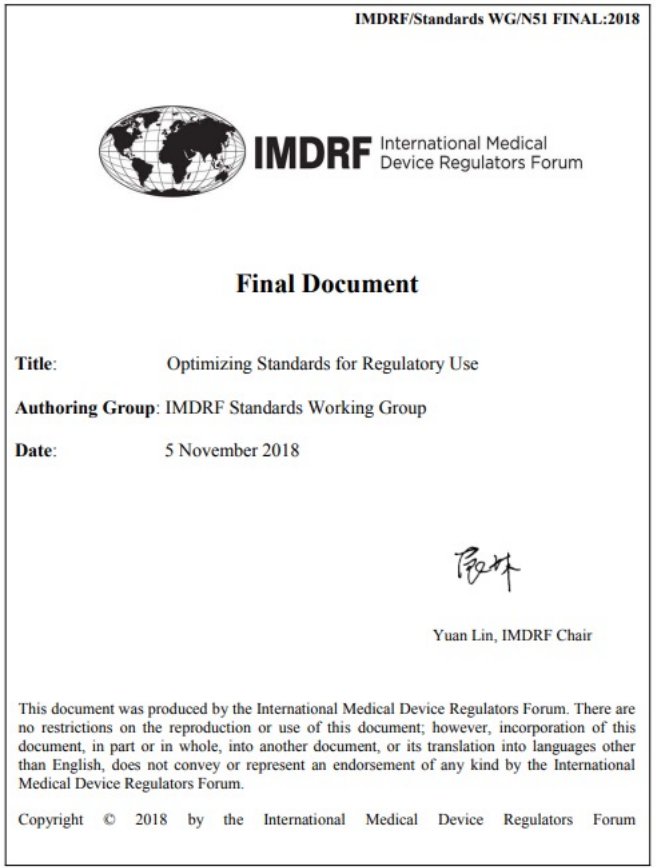
Challenges to Regulatory-ready Standards

- *Poor participation by RAs* → can lead to the development of standards that do not include substance and language that ar 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



IMDRF/Standards WG/N51 FINAL:2018

IMDRF International Medical Device Regulators Forum

Final Document

Title: Optimizing Standards for Regulatory Use

Authoring Group: IMDRF Standards Working Group

Date: 5 November 2018

Yuan Lin, IMDRF Chair

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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

Enhancing Participation

- Regulatory Authorities should build a strong standards program that encourages contributions to standards development
- Engagement with SDOs is essential
  - —Through national bodies and mirror committees
  - —On SDO Technical Committees
- Contribute regulatory perspective
- Consider leadership roles

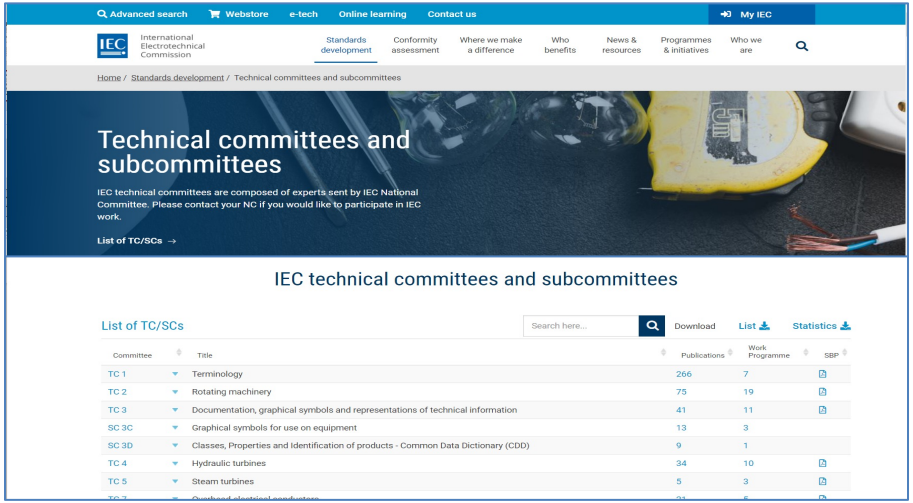
Join the Standards Conversation

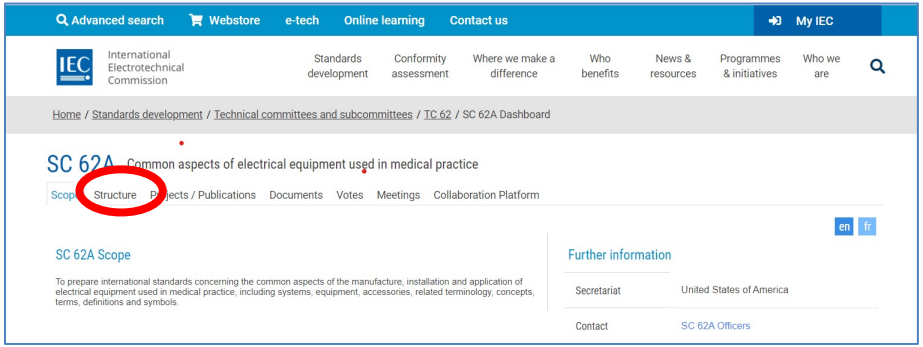
- Nations (through their ‘national bodies’ or ‘national committees’) are ISO and IEC members; they appoint individuals to represent them
- National bodies are responsible for ISO and IEC work within their countries
- National bodies appoint national or ‘mirror’ committees (called TAGs in the US) whose work mirrors that of the ISO and IEC bodies
  - Develop consensus on issues
  - Review proposals and documents
  - Comment on new standards
- Regulators should participate at both the national (for example, national bodies or mirror committees) and the international levels (ISO and IEC committees)
  - Goal: build regulatory interests into the standards (e.g., test methods, acceptance criteria)
  - Submit effective comments

How to contact an **IEC** national committee:

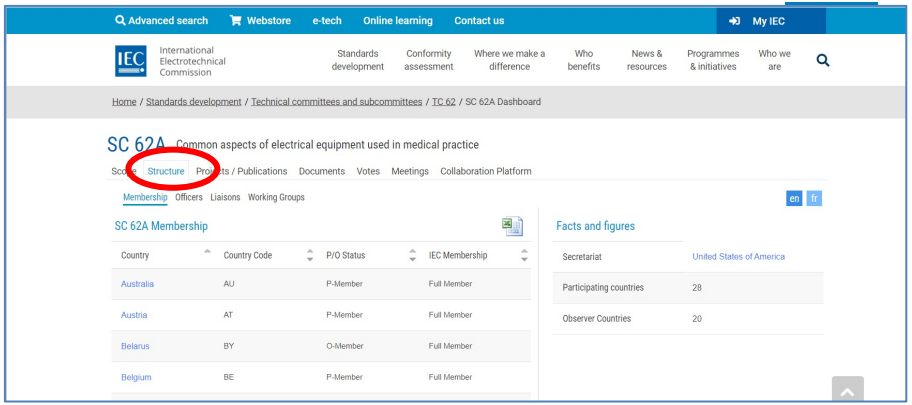
1. Click on this link: https://www.iec.ch/technical-committees-and-subcommittees#tclist

2. Scroll to the committee of interest and click on the ‘Structure’ tab

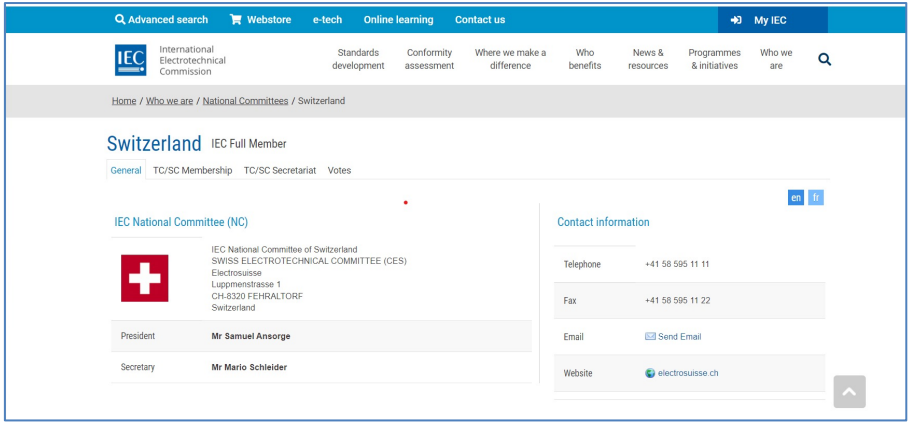




3. Next, click on the country whose national committee information you seek



4. The contact information for that country's national committee representative appears



How to contact an **ISO** national body:

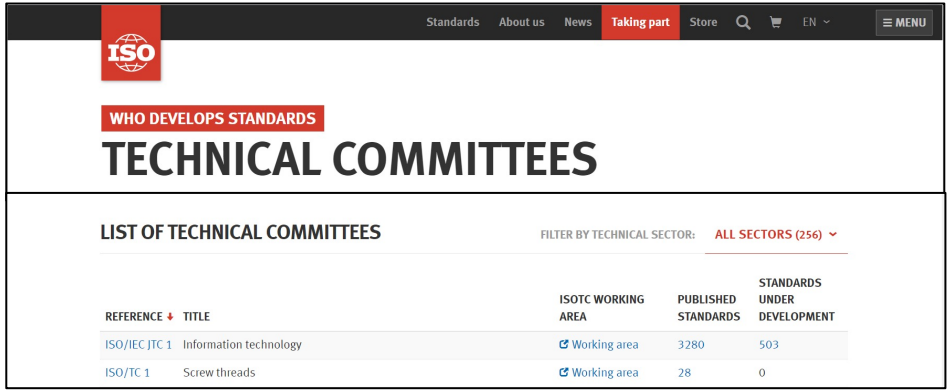
1. Go to https://www.iso.org/technical-committees.html

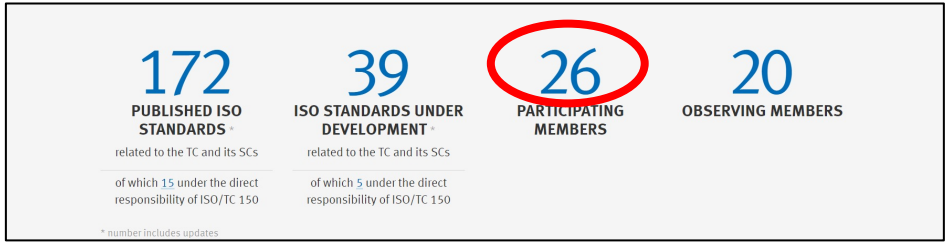
2. Scroll down to select the committee you are interested in

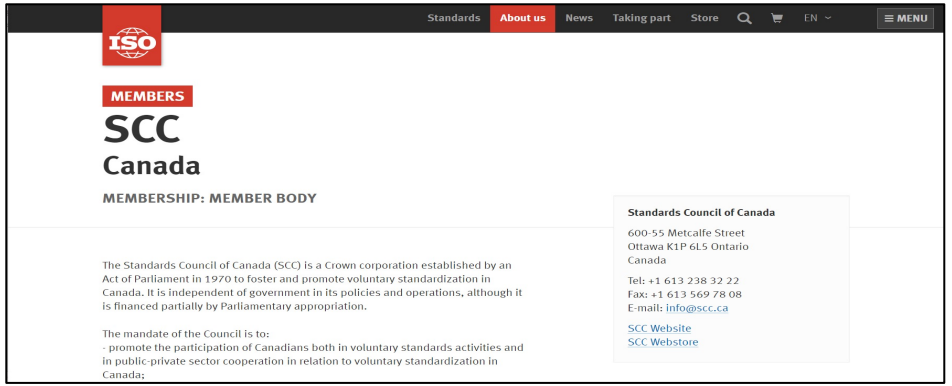
3. Click on the number above the words “Participating Members”

4. Choose the country

5. Contact information will be available







How to Get Involved (continued)

- If your country is not a member and wishes to join, write the SDOs at:
  - info@iec.ch
  - Central@iso.org

International Resources

- **IMDRF *Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices: 2018***
  http://imdrf.org/docs/imdrf/final/technical/imdrf-tech-181031-grrp-essential-principles-n47.pdf
- **IMDRF *Optimizing Standards for Regulatory Use* guidance:**
  http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-181105-optimizing-standards-n51.pdf
- **International Electrotechnical Commission (IEC)**
  http://www.iec.ch/about/activities/standards.htm?ref=home
- **International Organization for Standardization (ISO)**
  https://iso.ch/home.html
- **ISO Conformity Assessment tools to support public policy: the CASCO Toolbox**
  https://www.iso.org/sites/cascoregulators/02_casco_toolbox.html
- **ISO/IEC Directives Parts 1 (Ed. 13, 2017) and 2 (Ed. 7, 2016)**
  https://www.iec.ch/members_experts/refdocs/iec/isoiecdir-1-consolidatedIECsup%7Bed13.0%7Den.pdf
  https://www.iso.org/sites/directives/current/part2/index.xhtml
- **Asian Harmonization Working Group Playbook (see in particular Chapter 7)**
  http://www.ahwp.info/sites/default/files/ahwp-files/4_Technical_Committee/AHWP%20Playbook%20for%20Implementation%20of%20MD%20Reg%20Framework.pdf

International Resources, cont'd

- **ISO/IEC Guide 59, ISO and IEC recommended practices for standardization by national bodies 2019**
  https://www.iso.org/standard/71917.html
- **ISO/IEC Guide 63:2012 Guide to the development and inclusion of safety aspects in International Standards for medical devices**
  https://www.iso.org/standard/50729.html
- **ISO/IEC 17007:2009, Conformity assessment – Guidance for drafting normative documents suitable for use for conformity assessment**
  https://www.iso.org/standard/42635.html
- **ISO/IEC 17050-1:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 1: General Requirements**
  https://www.iso.org/standard/29373.html#:~:text=ISO%2FIEC%2017050%2D1%3A2004%20specifies%20general%20requirements%20for,irrespective%20of%20the%20sector%20involved.
- **ISO/IEC 17050-2:2004 Conformity Assessment – Supplier's Declaration of Conformity – Part 2: Supplemental Information**
  https://www.iso.org/standard/35516.html
- **ISO 14971:2019 Medical devices – Application of risk management to medical devices**
  https://www.iso.org/standard/72704.html
- **Society for Standards Professionals**
  https://www.ses-standards.org/page/A2?
- **World Health Organization WHO Global Model Regulatory Framework for Medical Devices including in vitro diagnostic medical devices 2017**
  https://apps.who.int/iris/handle/10665/255177
- **World Trade Organization Agreement on Technical Barriers to Trade 1994**
  https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm

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**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards

- **Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices guidance**
  www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

ASCA Resources

- **ASCA Pilot web page**
  www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
- **ASCA Pilot program guidance**
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and
  - **Biocompatibility standards-specific guidance:** https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme
- **Ask ASCA! ASCA@FDA.HHS.GOV**

Industry Education: Three Resources for You

1. **CDRH Learn: Multi-Media Industry Education**
   - Over 200 modules
   - Videos, audio recordings, power point presentations, software-based "how to" modules
   - Mobile-friendly: access CDRH Learn on your portable devices

   www.fda.gov/CDRHLearn

2. **Device Advice: Text-Based Education**
   - Comprehensive regulatory information on premarket and postmarket topics

   www.fda.gov/DeviceAdvice

3. **Division of Industry and Consumer Education (DICE)**
   - Contact DICE if you have a question
   - Email: DICE@fda.hhs.gov
   - Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
   - Web: www.fda.gov/DICE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