Appropriate Use of Voluntary Consensus Standards and the Accreditation Scheme for Conformity Assessment Program

FDA Small Business
Regulatory Education for Industry (REdI)
Boston, MA
May 29, 2019

Scott Colburn
Director
Standards and Conformity Assessment Program
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Sharon Lappalainen
Deputy Director
Standards and Conformity Assessment Program
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Describe the purpose and elements of a declaration of conformity
- Describe supporting documentation needed to support a declaration of conformity
- Decide whether to use a standard in “general use”
- Describe the purpose of the Accreditation Scheme for Conformity Assessment [ASCA] Pilot Program

Standards Guidance

- Incorporates requirements from 21st Century Cures Act
- Clarified deviations to standards
- Explained position on use of promissory statements
- Eliminated use of FDA Form 3654

21st Century Cures

- Modified Section 514(c) of FD&C Act
  - Clarified how FDA will process requests for recognition
- Added 60-day timeframe for FDA review of requests for recognition
- Required FDA to publish basis for recognition
- Required training for FDA staff on standards

Declaration of Conformity (DOC)

- Attestation that device **is** in conformity
- Reduces amount of supporting data and information

Declaration of Conformity (DOC)

What does this mean?

- All normative requirements are met
- Testing was conducted **before** premarket submission
- Testing was conducted on **finished or final finished** device

DOC Elements:
from ISO/IEC 17050-1

1. Name and address of sponsor
2. Product/device identification
3. Statement of conformity (not compliance)
4. List of standards applicable, including options selected

DOC Elements:
from ISO/IEC 17050-1

5. **FDA recognition number for each standard**
6. Date and place of issuance
7. Signature, printed name, and function of applicant
8. Limitations on validity of DOC

Examples of Declarations of Conformity

Example #1

I certify that, in my capacity as CEO of XYZ, Inc., that the subject of this Traditional 510(k), the ABC Monitor, conforms with the following FDA-recognized standards:

- [Rec. Number 19-4] ANSI/AAMI ES60601-1 Medical electrical equipment – Part 1: General requirements for safety and essential performance
- [Rec. Number 19-1] ANSI/AAMI IEC 60601-1-2 Medical electrical equipment – Part 1-2 General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- [Rec. Number 12-293] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

All requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from each applicable standard were applied, and there were no differences between the tested device and the device to be marketed.

All tests were performed by [insert Testing Lab, and address if applicable].

Signed Date Address

Example #2

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as CEO of XYZ, Inc., that the subject of this Traditional 510(k), the ABC Monitor, conforms with the following FDA-recognized standard:

> [Rec. Number 12-293] IEC 60601-2-37 Medical electrical equipment – Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment

All *normative* requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from the standard were applied, and there were no differences between the tested device and the device to be marketed.

All tests were performed by [insert Testing Lab, and address if applicable].

Signed Date Address

What Is a Finished Device?

Finished Device under 21 CFR 820.3(l)

"Any device or accessory to any device that is suitable for use or capable of functioning, whether or not it is packaged, labeled, or sterilized."

Final Finished Device

Any device that includes all manufacturing processes for the "to be marketed" device, including packaging and sterilization, if applicable.

ISO/IEC 17050-2 Supporting Documentation

- Description of what was tested
- Conformity assessment results, including:
  - Test method (if not described in standard)
  - Good Laboratory Practices or Quality System Regulations were followed
  - Results of testing (if not described in standard)
  - Conclusions: choices, selections, adaptations, modifications, concessions that were made in accordance with how standard was designed

Supplementary Information Sheet (SIS)
or
Supporting Documentation

SIS or Supporting Documentation

Supplementary Information Sheet

- CDRH's determination of how FDA-recognized standard may be used to satisfy a portion of the FD&C Act
- Example: Describes a complete recognition or sections that are excluded from FDA's recognition

Supporting Documentation

- Describes how medical device conforms to FDA-recognized standard
- Example: Describes acceptance criteria to demonstrate essential performance of medical device

Supporting Documentation - Yes

- Standard has test method, but **NO** acceptance criteria
- Standard has acceptance criteria, but **NO** test method
- Standard has choices:
  - What is tested
  - How it is tested (method)

Supporting Documentation - No

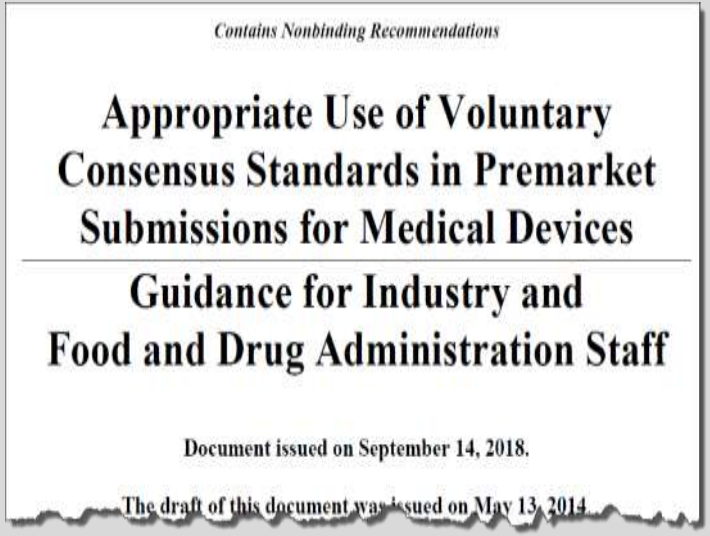
- Standard includes **both** test method **and** acceptance criteria, or
- More than one standard:
  - one has test method; another has acceptance criteria, or
- Design standard

Complete Test Reports Requested

When standard:

- Has **no** test method **or** acceptance criteria
- Is a process (risk assessment)

“Appropriate Use” Guidance outlines current premarket review considerations for Declarations of Conformity.



Contains Nonbinding Recommendations

Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on September 14, 2018.

The draft of this document was issued on May 13, 2014.

Table 1. FDA Review of Declarations of Conformity and Supplemental Documentation[12]

Type of Consensus Standard for which a DOC might be provided in a premarket submission		Should submission include complete test report?	Should submission include supplemental documentation per ISO/IEC 17050-2?
Design Standard		No	No
Standard Includes—			
Test Method(s) or Procedure(s)	*Acceptance Criteria*		
Included	Not included	No	Yes, criteria/ summary results
Not included	Included	No	Yes
Included	Included	No	No
Not included	Not Included	Yes	Yes, complete test report

FDA DOC Review Checklist

- ISO/IEC 17050-1 elements (or equivalent ☺)

- Then, FD&C Act Elements
  - Standard **is** FDA-recognized
  - No deviations to normative requirements
  - Standard is applicable to product
  - Supporting documentation, if necessary, per ISO 17050-2 or equivalent
  - Data and information demonstrate conformance
  - DOC **does not** include promissory statement

Why FDA can rely on a DOC

- Section 301(x) of the FD&C Act
- Section 501(e)(2) of the FD&C Act
- Section 301(q)(2) of the FD&C Act
- 21 CFR Part 58 Good Laboratory Practices
- 21 CFR Part 820 Quality System Regulations
  - Design validation, 21 CFR 820.30(g)
  - Process validation, 21 CFR 820.75(b)
- Laboratory accreditation under:
  - ISO/IEC 17025 General requirements for the competence of testing and calibration laboratories
  - ISO/IEC 17043 Conformity assessment – General requirements for proficiency testing
  - Other ISO/IEC 17000 series as appropriate

General Use Option

- Deviations
- Standard not recognized
- Older version of standard

Tell us more!

Or,
Promissory Statements

This means…Complete Test Reports

When Standards Change

Before Review	During Review	After Review
Guidance encourages Q-Sub interactions	FDA will continue to review based on previously recognized version	Changes to standards are not retroactive
Provide a strategy that addresses differences between older and current version	If new revision addresses new safety or effectiveness issue relevant to the final decision, FDA may ask submitter to either meet new requirement, or provide alternative data/information with a rationale.	Do not affect status of clearance or approval
Focus is on safety and/or effectiveness		Superseded standards that FDA has withdrawn may not be used with a DOC
		If Submitter received clearance based on DOC, but standard is withdrawn, device remains legally marketed.

Transitions

- Transition for new versions standards
- Specific amount of time
- Located in SIS
- Standards that impact QSR will receive a 2-3 year transition
- Will follow ISO implementation/withdrawal dates

Why? Because… It Allows for

- Continued testing & develop without additional retesting
- Time to revalidate processes under 21 CFR 820.75(b)
- Testing laboratories time to validate new test methods per ISO 17025

Promissory Notes

- Statement that device is not yet known to be in conformance
  - but **will** conform before marketing

- Used in certain situations, examples: installation, chronic or long-term testing, extension of expiration dating, post-market testing

- Not accompanied with a DOC

Intent to Recognize

FDA-recognized database, updated January 14, 2019

Followed by

FR Publication, March 14, 2019 (List #051)

Accreditation Scheme for Conformity Assessment

Pilot Program

(ASCA)

Enhanced Use of Consensus Standards

What is ASCA?

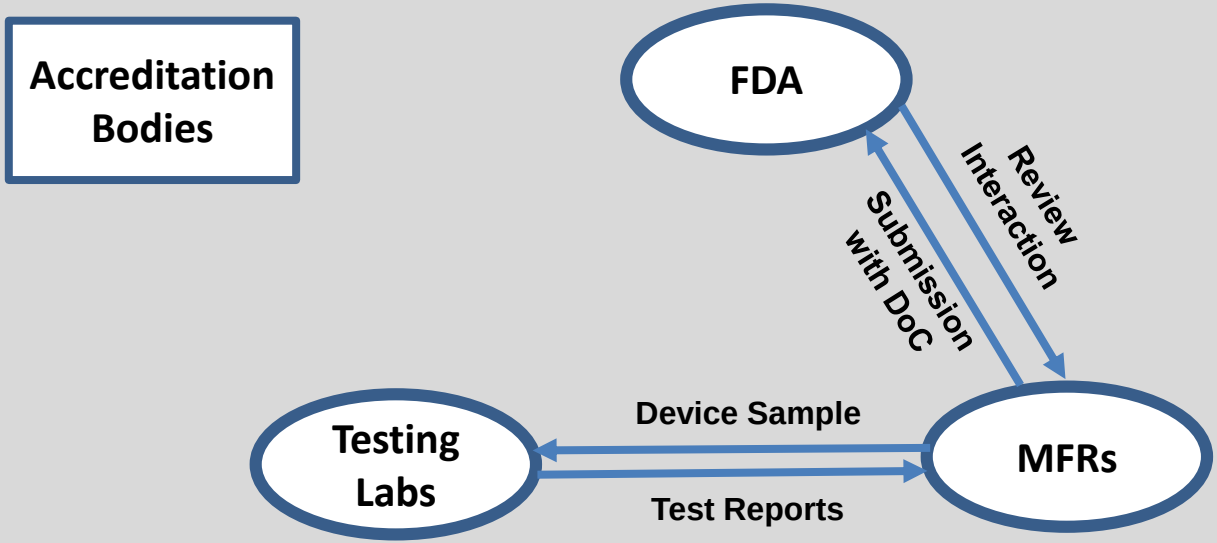
MDUFA IV- voluntary conformity assessment program to improve the premarket regulatory process

- Uses FDA-accepted accreditation bodies to accredit test labs to certain recognized standards
- Standardized test reports from device sponsors will enhance consistency and predictability towards premarket review

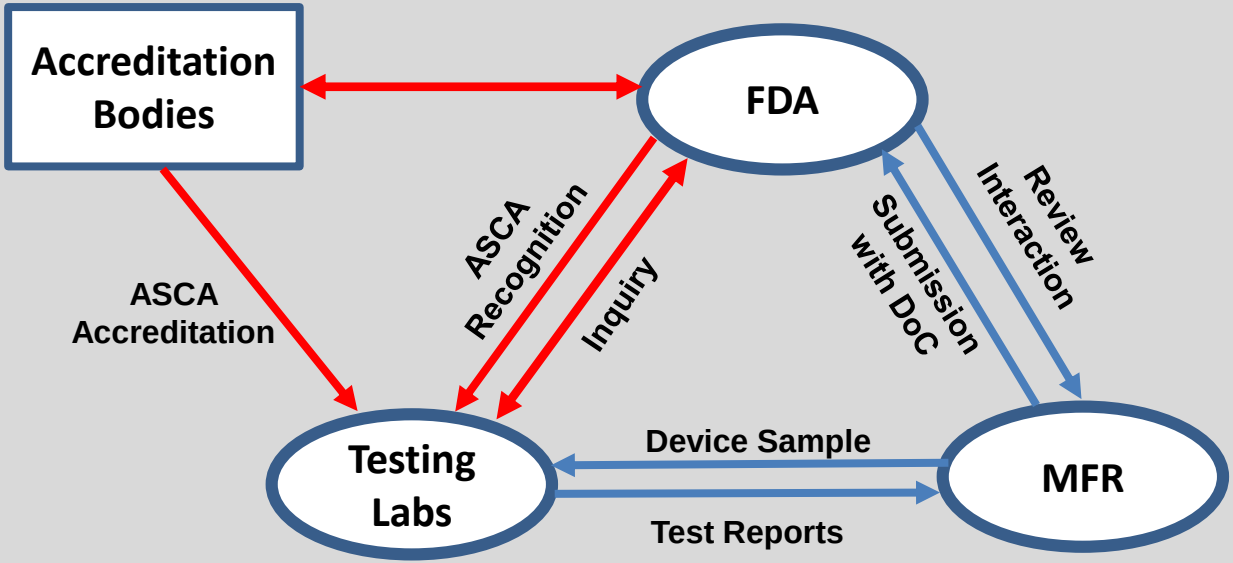
ASCA Goals

- **Enhance FDA's confidence**
  - Competence of testing laboratories
  - Test methods and results
- **Increase consistency and predictability**
  - FDA's approach to judging conformance to standards in product review
  - Reduced need for consultations, complete test report review and requests for additional information
  - DoCs will demonstrate appropriate use of the standard for regulatory review

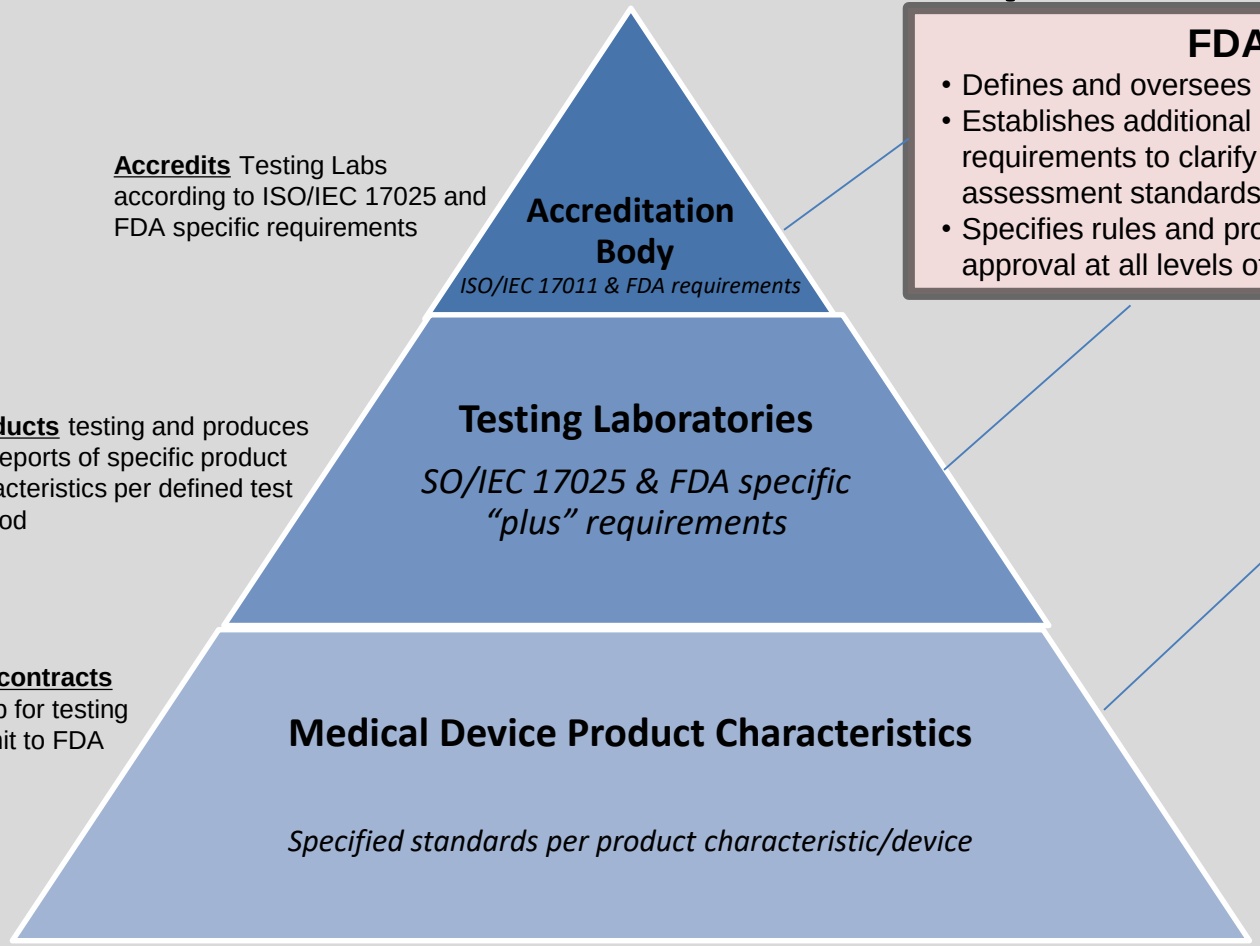
Pre-ASCA Stakeholders



ASCA Community of Stakeholders



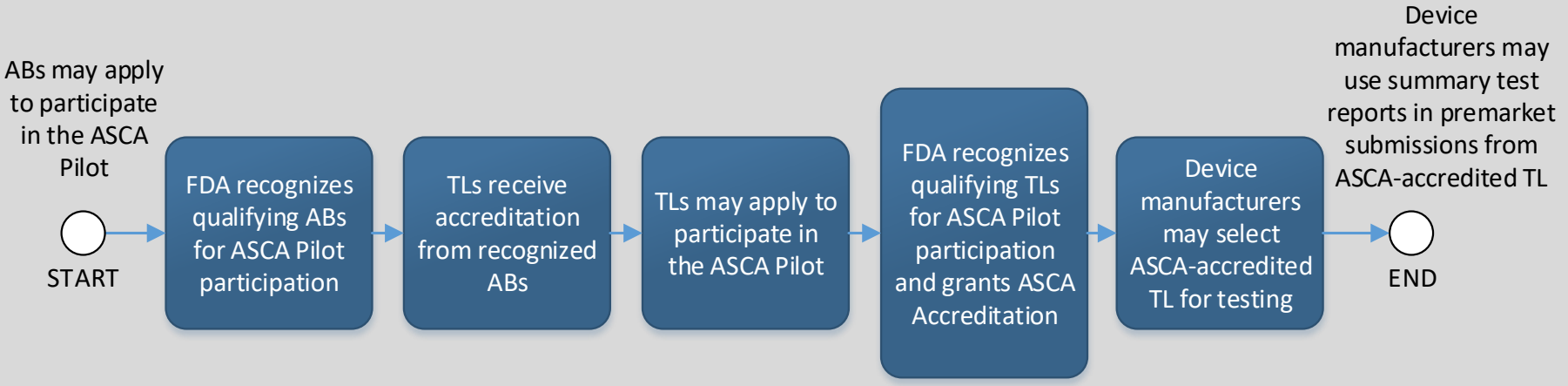
ASCA Pilot –Relationships



FDA

- Defines and oversees pilot
- Establishes additional specific program requirements to clarify ISO/IEC conformity assessment standards
- Specifies rules and procedures for approval at all levels of the program

ASCA Conformity Assessment Scheme



Resources

- National Institute of Standards and Technology:
  www.nist.gov/standardsgov/index.cfm

- Standards and 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

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

Resources

- Device Advice: Comprehensive Regulatory Assistance
  www.fda.gov/DeviceAdvice

- CDRH Learn:
  www.fda.gov/training-and-continuing-education/cdrh-learn

Summary

- Overview of the Appropriate Use of Voluntary Consensus Standards
  - FDA includes elements & supporting documentation to support a declaration of conformity
  - FDA standards may also be used in “general use”
  - Transition between versions of standards
- Accreditation Scheme for Conformity Assessment Pilot

Questions?

Your Call To Action

1. Understand the role that standards may have in your future regulatory submissions.

2. Be aware of standards, and changes to them, that apply to your medical device.

3. Improve relationship with testing houses in understanding the reports of testing to support regulatory submission needs.


FDA
U.S. FOOD & DRUG
ADMINISTRATION