FDA Liaison Update

ASTM F02 Spring Committee

April 14-16, 2021

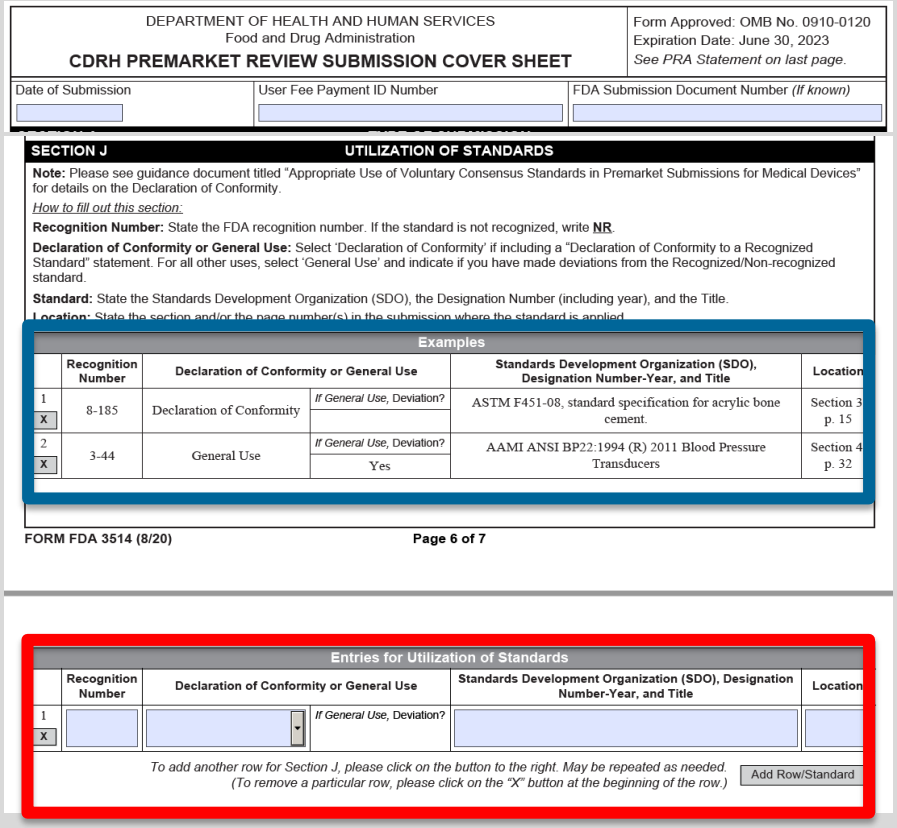
Topics

- Consensus Standards – Declaration of Conformance
- Accreditation Scheme for Conformity Assessment (ASCA) Update
- Ideas for Collaboration and Innovation

Use of Consensus Standards

- Voluntary
- Only mandatory if cited in regulation
  - Example: 21 CFR 801 cites ASTM D3492
- In any type of submission
- With a DOC (recognized standards only), “General Use” (any standards, recognized or not)

How to Cite Standards-Cover Sheet



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approved: OMB No. 0910-0120
Expiration Date: June 30, 2023
See PRA Statement on last page.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(If known)*

SECTION J **UTILIZATION OF STANDARDS**

Note: Please see guidance document titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" for details on the Declaration of Conformity.

How to fill out this section:

Recognition Number: State the FDA recognition number. If the standard is not recognized, write **NR**.

Declaration of Conformity or General Use: Select 'Declaration of Conformity' if including a "Declaration of Conformity to a Recognized Standard" statement. For all other uses, select 'General Use' and indicate if you have made deviations from the Recognized/Non-recognized standard.

Standard: State the Standards Development Organization (SDO), the Designation Number (including year), and the Title.

Location: State the section and/or the page number(s) in the submission where the standard is applied.

Examples

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X	8-185	Declaration of Conformity	*If General Use,* Deviation?	ASTM F451-08, standard specification for acrylic bone cement.	Section 3 p. 15
2 X	3-44	General Use	*If General Use,* Deviation? Yes	AAMI ANSI BP22:1994 (R) 2011 Blood Pressure Transducers	Section 4 p. 32

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Entries for Utilization of Standards

	Recognition Number	Declaration of Conformity or General Use		Standards Development Organization (SDO), Designation Number-Year, and Title	Location
1 X			*If General Use,* Deviation?		

To add another row for Section J, please click on the button to the right. May be repeated as needed.
(To remove a particular row, please click on the "X" button at the beginning of the row.)

Add Row/Standard

Form FDA 3514 Cover Sheet* Section J

- **Examples Section**
- **Entries for Utilization of Standards**

*** Download Form FDA 3514 "CDRH Premarket Review Submission Cover Sheet" at:**
www.fda.gov/media/72421/download

Declaration of Conformity (DOC)

What is a DOC?

- Attestation that device conforms with cited FDA-recognized standard
  - All normative requirements are met
  - All testing has been conducted
  - Testing is on finished device or final finished device
- If submitter 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 applicant/sponsor responsible for 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, cont'd

- Date and place of issuance of DOC
- Signature, printed name, and function of applicant/sponsor responsible for DOC
- Any limitation on validity of DOC (e.g., how long 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

- May cite any consensus standard
- Should include complete test reports
- Considerations:
  - If modifications not referenced or permitted in standard, should include complete test reports
  - When in doubt, ask FDA review team!

Supplemental Documentation

Supplemental Documentation

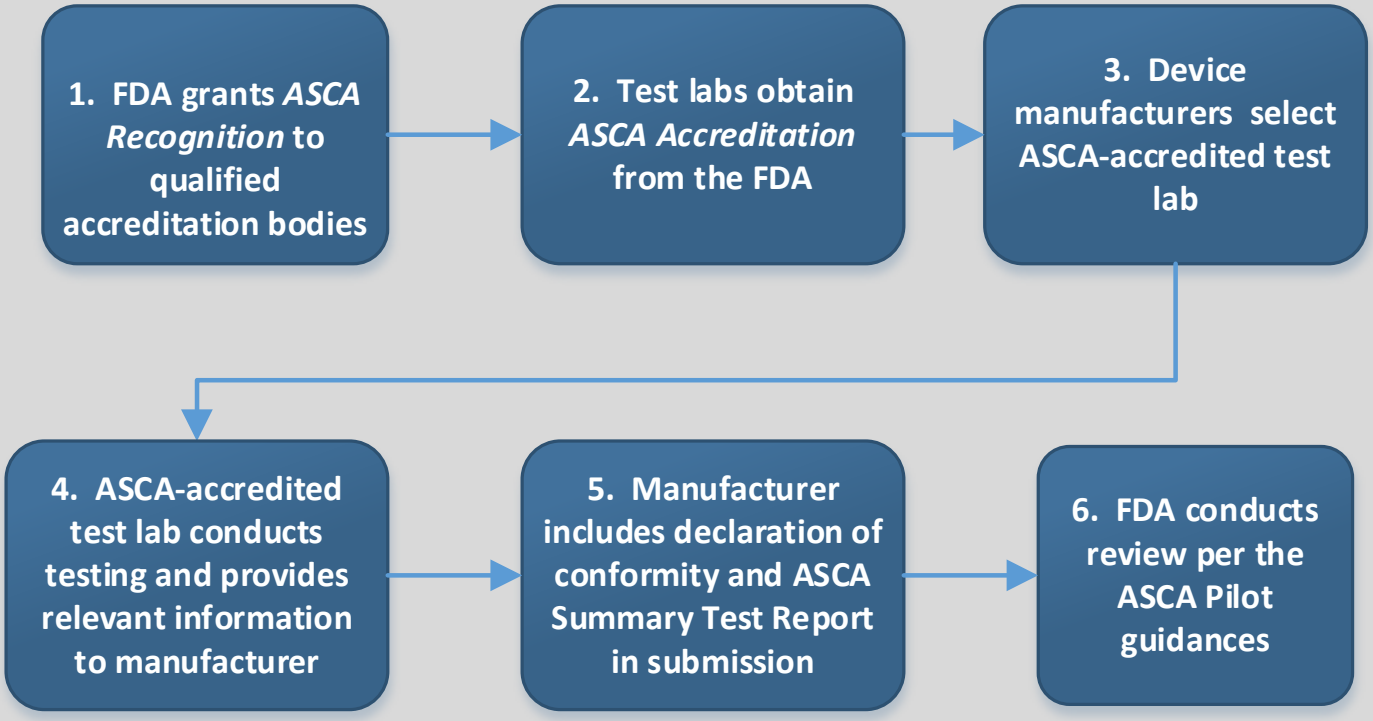
Standard Type		Complete Test Report Needed?	Supplemental Documentation Needed (ISO/IEC 17050-2)?
Design		No	No
Test Method	**Acceptance Criteria**		
Included	Not Included	No	Yes, Criteria/Summary Results
Not Included	Included	No	Yes
Included	Included	No	No
Not Included	Not included	Yes	Complete Test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

Accreditation Scheme for Conformity Assessment

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
- Leverages a well-established international conformity assessment infrastructure

How ASCA Works



ASCA Pilot Guidances

- **ASCA Pilot 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 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 *****

Timeline


Sept 2019:Draft guidance published
Sept 2020: Final guidances published
Nov 2020: Five accreditation bodies receive *ASCA Recognition*
Feb 2021: 60 test labs apply for *ASCA Accreditation*
Apr 2021: initial list of ASCA-accredited test labs; manufacturers may engage

ASCA Resources

- ASCA Final Guidance (https://fda.yorkcast.com/webcast/Play/6c970c8d9bb74801b43c93420d10aae51d)
- Standards and ASCA workshop (https://fda.yorkcast.com/webcast/Play/6c970c8d9bb74801b43c93420d10aae51d)
- Accredited Testing Laboratories (https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories)
- FDA Science Forum May 26-27, 2021 (https://www.fda.gov/science-research/about-science-research-fda/fda-science-forum)

Collaboration/Innovation

Need your feedback

- Where can standards collaboration be improved?

  IMDRF (International Med. Dev. Regulatory Forum)?
- Where can FDA help with standards innovation?
- Problems with regulatory interpretation?

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