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The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program Draft Guidance Webinar

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Office of Strategic Partnership and Technology Innovation
Center for Devices and Radiological Health

October 28, 2019

Agenda

- Objectives
- Background
- ASCA Pilot Program
  - Roles and responsibilities
  - Selected device standards
  - Pilot participation
  - Program specifications
  - Premarket review considerations
- Stakeholder Information
  - Important events
  - Commenting period

Objectives

- Understand **why** the ASCA Pilot is being developed
- Understand **how** the ASCA Pilot is being developed
- Understand **what** the ASCA Pilot will be, including:
  - Roles and responsibilities of all stakeholders
  - How to participate
  - Impact on premarket review
  - Implementation timeline

Background

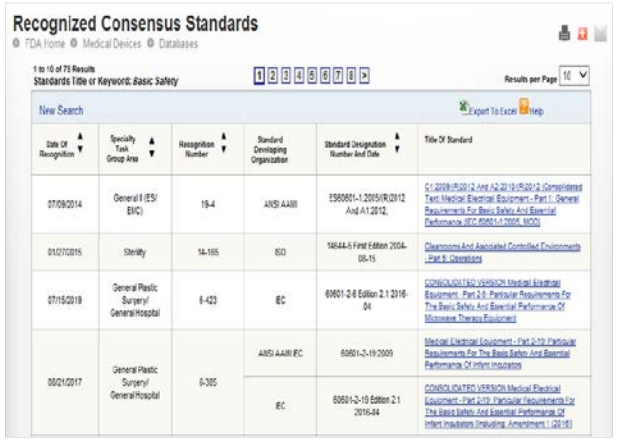
- During negotiations for the Medical Device User Fee Amendments of 2017 (MDUFA IV), the FDA & Industry agreed to establish a conformity assessment accreditation scheme for testing laboratories that evaluate medical devices according to certain FDA-recognized standards

- The FDA Reauthorization Act of 2017 (FDARA) amended section 514 of the FD&C Act by adding a new subsection (d) titled, “Pilot Accreditation Scheme for Conformity Assessment”

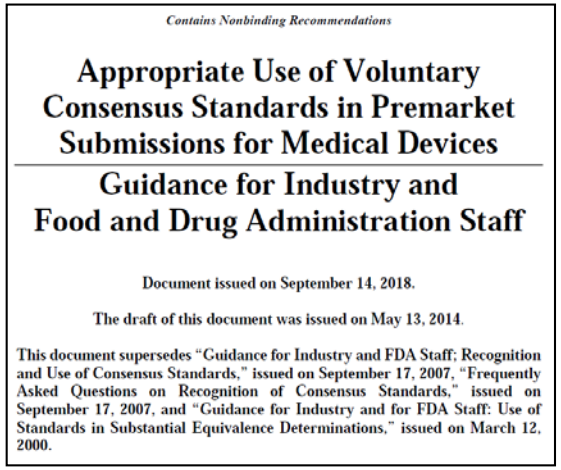
- **Draft guidance is distributed for comment purposes only. Program will be operationalized upon publication of final guidance.**

Why Is the ASCA Pilot Being Developed?

- Evidence of conformity to one or more of FDA-recognized standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and/or effectiveness



- For manufacturers and the FDA to benefit from the efficiency, the FDA must have confidence in the declaration of conformity (DOC) submitted by device manufacturers in their premarket submissions. (See the FDA guidance: [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices])



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.

This document supersedes "Guidance for Industry and FDA Staff; Recognition and Use of Consensus Standards," issued on September 17, 2007, "Frequently Asked Questions on Recognition of Consensus Standards," issued on September 17, 2007, and "Guidance for Industry and for FDA Staff: Use of Standards in Substantial Equivalence Determinations," issued on March 12, 2000.

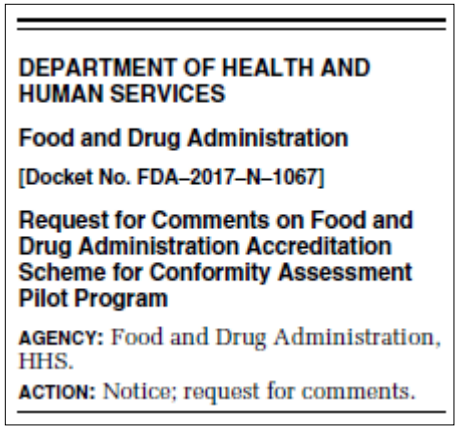
- In practice, the reliability of the determination in the DOC varies depending on the specific laboratory performing the testing and the standard being used. In some instances, this results in the need for the FDA to request additional information, review complete test reports, or repeat testing causing delays and additional costs.

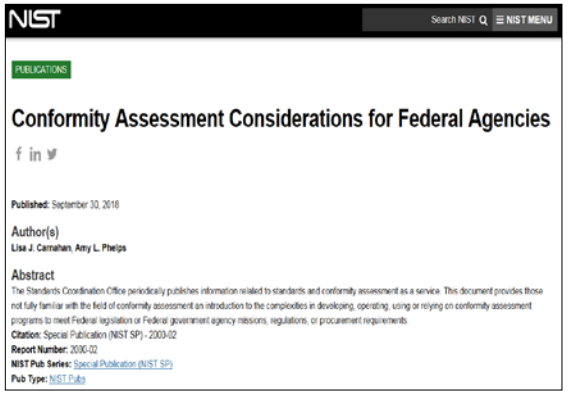
Why Is the ASCA Pilot Being Developed?

The ASCA Pilot Program capitalizes on the relevance of consensus standards in device development and regulatory review as well as the existence of a well-established international conformity assessment infrastructure. The ASCA Pilot Program aims to **improve efficiency** of the premarket review process by **building confidence** in the Declaration of Conformity through the utilization of accredited testing laboratories.

How Is the ASCA Pilot Being Developed?

- Concept of ASCA Pilot Program emerged from discussions between device manufacturers and the FDA.
- The FDA published a *Federal Register* notice in May 2017 requesting comments on a set of questions designed to gain insight regarding development and overall design of ASCA Pilot Program.
- The FDA held public workshop titled “Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards,” May 22-23, 2018.
- A conformity assessment expert from the National Institute of Standards and Technology is working with CDRH to develop ASCA Pilot Program.





What is Conformity Assessment?

- **Conformity Assessment** is a demonstration that specified requirements relating to a product, process, system, person or body are fulfilled. (ISO/IEC 17000: 2004)

- **Conformity Assessment Body** is a body that performs conformity assessment services such as a testing laboratory; note that an accreditation body is not a conformity assessment body. (ISO/IEC 17000: 2004)

- **Conformity Assessment Scheme** is a conformity assessment system related to specified objects of conformity assessment, to which the same specified requirements, specific rules and procedures apply. (ISO/IEC 17000: 2004)

What is Accreditation?

- **Accreditation** is a third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks (ISO/IEC 17000: 2004)

- **Accreditation Body** is an authoritative body that performs accreditation (ISO/IEC 17000: 2004)

- **Third-party Attestation** is an issue of statement, based on a decision following review, that fulfillment of specific requirements has been demonstrated. (ISO/IEC 17000: 2004)

What Will the ASCA Pilot Be?

This will be a **voluntary** program for all external stakeholders: accreditation bodies, testing laboratories, and device manufacturers.

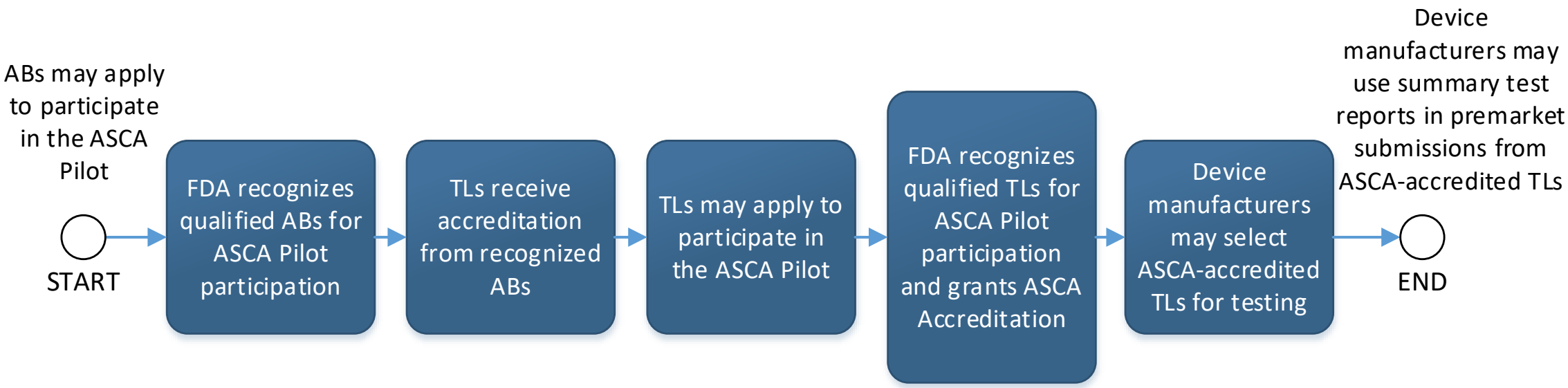
The FDA intends to:

- leverage the existing relationships between accreditation bodies and testing laboratories.
- rely on recognized accreditation bodies to accredit testing laboratories using the specific conformity assessment scheme outlined in this guidance.
- generally accept the testing laboratory's determinations that a device conforms with the specified standards based on the increased confidence in the testing laboratory's determination.

The FDA does not intend to:

- question the validity of methods and outcomes from ASCA-accredited testing laboratories except as part of periodic audits, if the summary test report indicates an issue with the testing or device, or if the FDA becomes aware of information materially bearing on the safety or effectiveness of the device.

What Will the ASCA Pilot Be?



As proposed

AB = Accreditation Body
TL = Testing Laboratory

Recognition vs Accreditation

Recognition

As proposed:

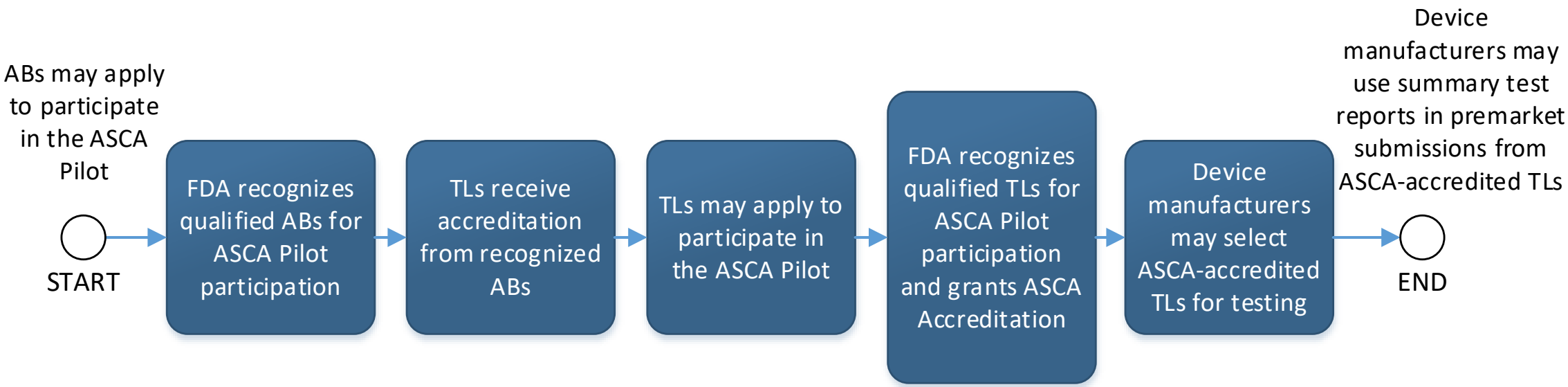
- The FDA would recognize accreditation bodies and testing laboratories as participating in the ASCA Pilot Program.
- Recognized accreditation bodies and testing laboratories would receive training from, regularly communicate with, and be periodically audited by the FDA.
- The FDA would recognize any qualified applicant organization that agrees to the terms of participation.
- Scope of recognition would refer to the standards and test methods for which competence in accreditation or testing has been demonstrated to the FDA for the purposes of the Pilot Program.

Accreditation

As proposed:

- The FDA would use the term “accreditation” for a testing laboratory in two different contexts.
- Accreditation by an accreditation body:
  - Accreditation bodies accredit testing laboratories to the specifications of ISO/IEC 17025 and ASCA program specifications.
- *ASCA Accreditation* by the FDA:
  - This would be the FDA’s acceptance of accreditation to ISO/IEC 17025 and the ASCA program specifications by a recognized accreditation body.
  - This would exist only within the ASCA Pilot Program and only testing laboratories recognized by the FDA as participating in the ASCA Pilot Program may receive *ASCA Accreditation.*
  - The FDA intends to generally accept testing results from an ASCA-accredited testing laboratory in premarket submissions without further interaction concerning test methods except in specific circumstances.

What Will the ASCA Pilot Be?



As proposed

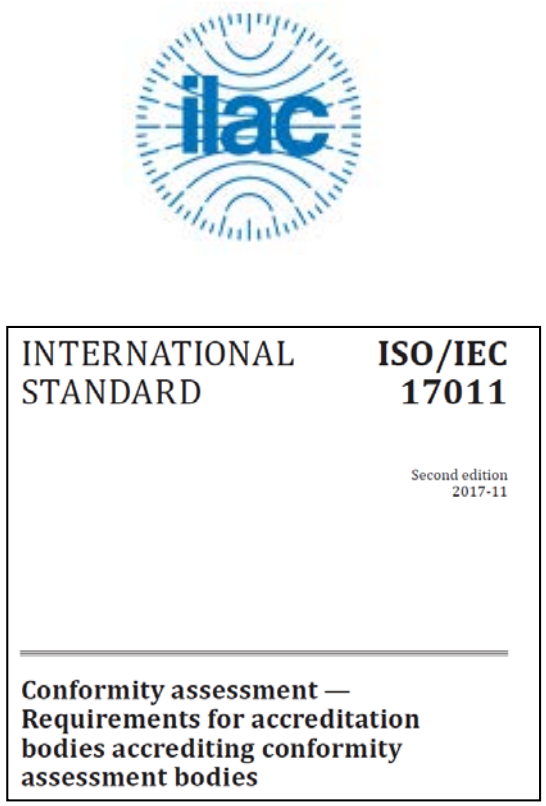
AB = Accreditation Body
TL = Testing Laboratory

How would the ASCA Pilot leverage existing conformity assessment resources?

The FDA intends to maximize the use of existing frameworks and arrangements for the ASCA Pilot.

Existing Framework:

- International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)
  - ILAC is an international organization for accreditation bodies that accredit conformity assessment bodies such as testing laboratories.
  - Accreditation bodies that are signatories to the ILAC MRA are peer evaluated to ISO/IEC 17011 to demonstrate their competence.
  - ISO/IEC 17011 includes specifications for accreditation bodies.



In the ASCA Pilot Program:

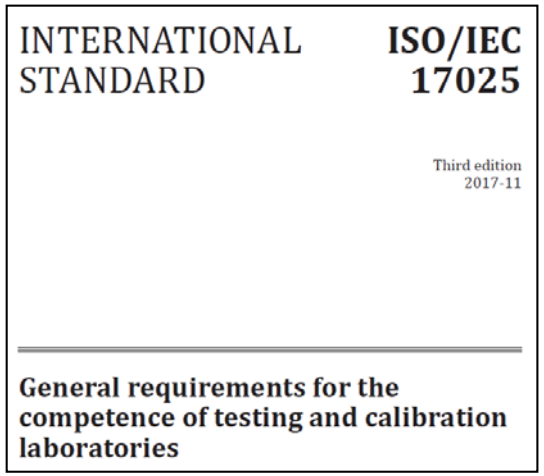
- ILAC MRA signatory status would be a qualification for accreditation body participation.
- The FDA intends to leverage ILAC MRA policies and procedures, including peer evaluations.
- The FDA intends to leverage ISO/IEC 17011 policies and procedures including testing laboratory assessments.

How would the ASCA Pilot leverage existing conformity assessment resources?

The FDA intends to maximize the use of existing frameworks and arrangements for the ASCA Pilot Program.

Existing Framework:

- ISO/IEC 17025 contains specifications for laboratories to operate competently and generate valid results.


INTERNATIONAL STANDARD

ISO/IEC 17025

Third edition
2017-11

General requirements for the competence of testing and calibration laboratories

In the ASCA Pilot:

- Accreditation bodies would use ISO/IEC 17025 plus ASCA program specifications to accredit testing laboratories.
- The FDA intends to leverage the policies and procedures of ISO/IEC 17025, including annual internal audits conducted by testing laboratories.

Which device standards is the FDA considering?

The FDA identified standards for the ASCA Pilot Program based on input at the public workshop and in response to the *Federal Register* notice. In accordance with the MDUFA IV commitment letter, these standards include both cross-cutting (horizontal) and device-specific (vertical) standards, are of public health significance, and have or are able to provide the means for establishing acceptance.

Basic Safety and Essential Performance of medical electrical equipment, medical electrical systems, and laboratory equipment	
ANSI/AAMI ES60601-1	Medical electrical equipment—Part 1: General requirements for basic safety and essential performance **(along with the FDA-recognized collateral and particular standards in the 60601 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 61010 family**)

Biological Evaluation of Medical Devices	
Standard	Tests
ISO 10993-4*	Complement Activation
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10	Dermal Irritation, Intracutaneous Reactivity Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediate Pyrogenicity
ISO 10993-12	Sample preparation for all test types

* See also ISO/TS 10993-20 for information on when complement activation should be considered for anaphylaxis (Table 2, Hypersensitivity Column)

Proposed ASCA Program Specifications

IEC/ISO 17025 served as foundation for ASCA Program Specifications found in Appendix A and B of the draft guidance. The working group consisted of technical experts and personnel from the FDA and NIST.

ISO/IEC 17025: General requirements for the competence of testing and calibration laboratories, 3rd Edition (2017)

7.2 Selection, verification and validation of methods

7.2.1 Selection and verification of methods

7.2.1.1 The laboratory shall use appropriate methods and procedures for all laboratory activities and, where appropriate, for evaluation of the measurement uncertainty as well as statistical techniques for analysis of data.

NOTE "Method" as used in this document can be considered synonymous with the term "measurement procedure" as defined in ISO/IEC Guide 99.

7.2.1.2 All methods, procedures and supporting documentation, such as instructions, standards, manuals and reference data relevant to the laboratory activities, shall be kept up to date and shall be made readily available to personnel (see 8.3).

7.2.1.3 The laboratory shall ensure that it uses the latest valid version of a method unless it is not appropriate or possible to do so. When necessary, the application of the method shall be supplemented with additional details to ensure consistent application.

NOTE International, regional or national standards or other recognized specifications that contain sufficient and concise information on how to perform laboratory activities do not need to be supplemented or rewritten as internal procedures if these standards are written in a way that they can be used by the operating personnel in a laboratory. It can be necessary to provide additional documentation for optional steps in the method or additional details.

7.2.1.4 When the customer does not specify the method to be used, the laboratory shall select an appropriate method and inform the customer of the method chosen. Methods published either in international, regional or national standards, or by reputable technical organizations, or in relevant

Appendix A: ASCA Program Specifications for the Biological Evaluation of Medical Devices

7.2 Selection, verification and validation of methods

a) The applicant organization agrees that its management system will include procedures governing the development, maintenance, and use of test procedures (including associated documents such as test data forms and checklists). These management system procedures include steps for:
   - Identifying the personnel responsible for developing, reviewing, and maintaining these documents
   - Specifying the frequency of review by technical personnel and management
   - Ensuring consistency with applicable standard(s)
   - Ensuring test modifications are reviewed by personnel who are competent to the applicable standard(s)
   - Identifying the types of modifications that do not need to be reviewed for confirmation prior to implementation. The applicant organization further agrees that changes to any procedures regarding the following will be confirmed with FDA and its Accreditation Body prior to implementation:
     - Changes to sample for retesting to achieve a "passing" result
     - pH adjustments
     - Sample filtration or other extract manipulation
     - Removal of documentation associated with color, turbidity or particles in the test extract, or swelling/degradation of the test article
     - Frequency of non-concurrent control testing
     - Changes to acceptance criteria outside the validated/qualified laboratory-specific limits (e.g., for complement activation where the standard methods do not specify acceptable limits)
     - Changes to data calculations and presentation, if applicable (e.g., hemolytic index, irritation index, complement activation plots)
     - Changes in the criteria for re-challenge or retesting

Appendix B: ASCA Program Specifications for the Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment

7.2 Selection, verification and validation of methods

a) The applicant organization agrees that its management system will include procedures governing the development, maintenance, and use of test procedures (including associated records in paper or electronic format such as test data forms and checklists). The applicant organization further agrees that these management system procedures will include steps for:
   - ensuring that test procedures are documented and reviewed prior to use;
   - identifying the personnel responsible for developing, reviewing, and maintaining test procedures;
   - ensuring that new and revised test procedures are reviewed by personnel who are competent and trained in the applicable standard(s); and
   - specifying the criteria for review.

b) The applicant organization agrees that test procedures will include or specify, as appropriate, the:
   - unique identification, including title, document number, revision, and effective date;
   - specific test equipment to use along with their required ratings;
   - warnings/caution statements to alert the operators of potential hazards;
   - normal and any unusual ambient conditions (including tolerances) for tests;
   - test data to be obtained and recorded;
   - objective acceptance criteria for results including the essential performance required to be maintained;
   - testing techniques required to ensure consistent results;
   - Instructions on equipment operation and on handling and preparation of test samples (including instructions on multiple sample marking, if applicable).

Proposed Roles and Responsibilities

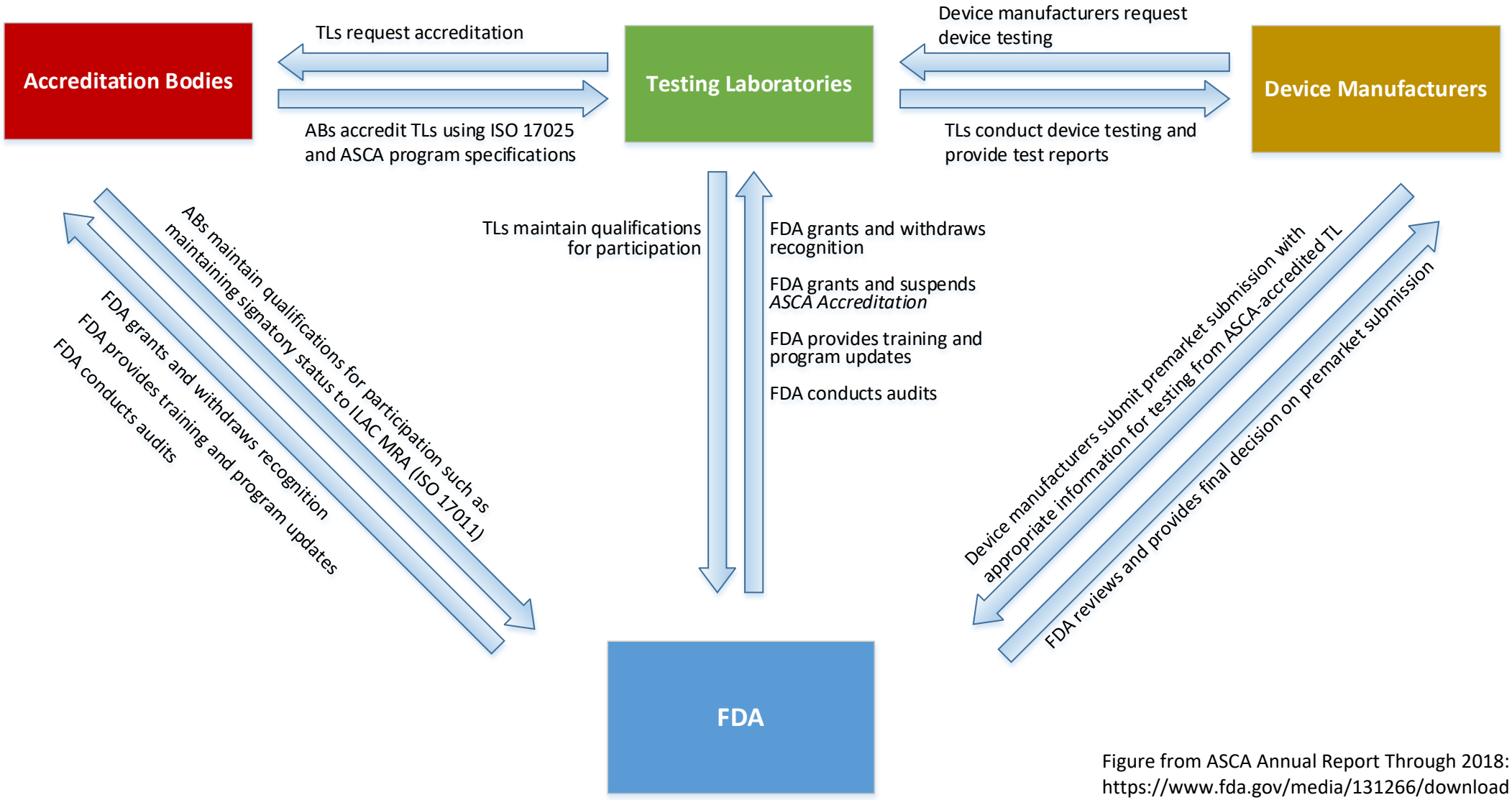


Figure from ASCA Annual Report Through 2018: https://www.fda.gov/media/131266/download

Proposed Participation Qualifications

Accreditation Body

- Signatory status to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA).
- Based in USA.
- Agree to terms and conditions described in Section D of Appendix C in the guidance
  - Ex: commit to the FDA training, maintain scope of ILAC signatory status, etc.

Testing Laboratory

- Requested scope of recognition is consistent with scope of accreditation provided by accreditation body recognized as participating in the ASCA Pilot Program.
- Agree to terms and conditions described in Section D of Appendix D in the guidance.
  - Ex: commit to the FDA training, allow the FDA to conduct audits upon request, etc.

Proposed Accreditation Body Application Content (*in Appendix C*)

A. Administrative Information

- Organization Name; Point of Contact

B. Scope of Recognition

- Requested scope of recognition from list of selected standards and/or test methods

C. Information in Support of Competence

- Proof of signatory status as ILAC MRA whose scope includes ISO/IEC 17025 and based in US
- Description of any current conformity assessment services offered
- Description of process to accredit testing laboratory to ISO/IEC 17025 and ASCA program specifications
- Description of approach to determine technical competency of testing laboratory
- Description of policy and processes concerning corrective actions

Proposed Accreditation Body Application Content (*in Appendix C*) (cont'd)

D. Signed Agreement

- Maintain ILAC MRA signatory status.
- Verify conformance with ISO/IEC 17025 and ASCA program specifications when accrediting testing laboratories.
- Provide all ASCA Pilot accreditation documentation.
- Allow the FDA to participate as observer during ILAC MRA peer evaluation.
- Allow the FDA to participate as observer during accreditation body's assessment of testing laboratory.
- Commit to all the FDA training.
- Establish and maintain appropriate communication with the FDA. Examples:
  - Notification of any changes that may impact Pilot participation.
  - Notification of any changes that impact participation of any testing laboratory that the accreditation body has accredited.
  - Annual status updates, such as any complaints, or number of suspensions issues by accreditation body to testing laboratory, etc.
- Establish and maintain policies and procedures that incorporate feedback from the FDA.
- Acknowledge that FDA maintains complete discretion regarding recognizing an accreditation body's participation in the ASCA Pilot. FDA may withdraw recognition at any time.
- Confirm, to your best knowledge, all information submitted to FDA is truthful and accurate and no material fact has been omitted.

Proposed Testing Laboratory Application Content (*in Appendix D*)

A. Administrative Information

- Organization Name; Point of Contact

B. Scope of Recognition

- Requested scope of recognition from list of selected standards and/or test methods

C. Information in Support of Competence

- Proof of testing laboratory accreditation that shows:
  - Accreditation is from an accreditation body participating in the ASCA Pilot.
  - Scope of recognition for the accreditation body includes the scope for which they accredited the testing laboratory.
  - Scope of accreditation provided by the accreditation body to the testing laboratory matches the testing laboratory's requested scope of recognition.
- Copy of the Index of SOPs and any relevant ASCA test-related documents applicable to any biological evaluation of medical device standards and/or test methods if included in scope of recognition.

Proposed Testing Laboratory Application Content (*in Appendix D*) (cont'd)

D. Signed Agreement

- Conduct testing in accordance with ISO/IEC 17025 and ASCA program specifications
- Abide by ASCA program specifications to achieve and maintain status as ASCA-accredited testing laboratory
- Allow the FDA to conduct audits upon request; audits may include observations of testing activities and documentation review
- Establish and maintain appropriate communication with the FDA. Examples:
  - Notification of any changes that may impact testing laboratory's Pilot participation.
  - Attendance at regularly scheduled teleconferences.
  - Annual reports of complaint handling.
- Commit to attending all the FDA training
- Ensure proprietary information is protected per client agreements
- Acknowledge that FDA maintains complete discretion regarding recognizing a testing laboratory's participation and ASCA-accreditation. FDA may withdraw recognition or ASCA-accreditation at any time.
- Confirm, to your best knowledge, all information submitted to FDA is truthful and accurate and no material fact has been omitted.

Proposed Application Process for Accreditation Bodies and Testing Laboratories

Please Note: Applications are not ready for receipt at this time.

1) **Submit your applications via email to ASCA@fda.hhs.gov.**
   - Accreditation Body Application Content: Appendix C in guidance.
   - Testing Laboratory Application Content: Appendix D in guidance.

2) **Applications will be reviewed within 60 calendar days**
   - This includes request and any interactive discussion.

3) **Decision of recognition will be e-mailed to applicant**
   - Scope and date of expiration will be included if recognition is granted.
   - To continue ASCA Pilot participation, accreditation body or testing laboratory may apply for renewal of recognition 6 months prior to expiration date.

4) **Recognized participants will be listed on the FDA public website**
   - Testing laboratories will be able to choose which Accreditation Body they would like to receive accreditation from.
   - Manufacturers will be able to choose which Testing Laboratory they would like to receive testing from.

Possibility of Changes to Scope of Recognition

There are three possible changes to scope of recognition:

1) Expansion of accreditation body or testing laboratory's scope of recognition to include new standards and/or test methods.

2) Withdrawal of all or part of an accreditation body or testing laboratory's scope of recognition.

3) Suspension of a testing laboratory's *ASCA Accreditation.*

Withdrawal: A permanent or broad change of status with respect to the ASCA Pilot Program

- Withdrawal of recognition means that an organization is no longer a participant in the ASCA Pilot Program.
- A new application would be needed to participate in the Pilot Program again.

Suspension: A temporary or narrow change of status with respect to the ASCA Pilot Program

- Suspension of *ASCA Accreditation* means that an organization can continue to participate in the ASCA Pilot Program (i.e. participate in FDA training), but the FDA has temporarily invalidated its *ASCA Accreditation* pending the resolution of identified issues.
- Suspension can only occur with testing laboratories.

Requests for Clarification

- A request submitted to the FDA for *clarification* of one or more *specific ASCA program specifications* from a *recognized accreditation body or testing laboratory*.
- A request presents a question relative to *implementation* of ASCA program specifications.
- This does **not** include suggestions or requests for modifications.

Send requests to: **ASCA@fda.hhs.gov**

Audits

The FDA intends to:

- periodically audit accreditation bodies and testing laboratories to ensure that they are adequately fulfilling program expectations.
- leverage existing audits by participating as an observer during audits or reviewing audit reports wherever possible.
- initiate audits if the FDA becomes aware of information that raises potential concerns with ASCA Pilot Program participation.

Existing Audits:

- Accreditation Body
  - ILAC MRA signatories are subject to peer re-evaluation every 4 years.
  - The FDA may participate as observer during peer evaluations and/or obtain copy of report.
- Testing Laboratory
  - Assessed at least every 2 years by the recognized accreditation body (ISO/IEC 17011).
  - Conduct their own internal audits every year (ISO/IEC 17025).
  - The FDA may participate as observer during these assessments & audits and/or obtain copy of report.

Device Manufacturers

This will be a **voluntary** program. It will not alter the manufacturer's responsibility to address relevant information in the premarket submission, which includes documenting how the testing supports marketing authorization, even if the testing was conducted by a testing laboratory participating in the ASCA Pilot Program.

Cover Letter

As proposed, should clearly indicate:

- "ASCA"
- Name of Testing Laboratory
- Testing Laboratory ASCA Identifying Number
- Standards used for testing device
  - Must be part of ASCA Pilot Program standards

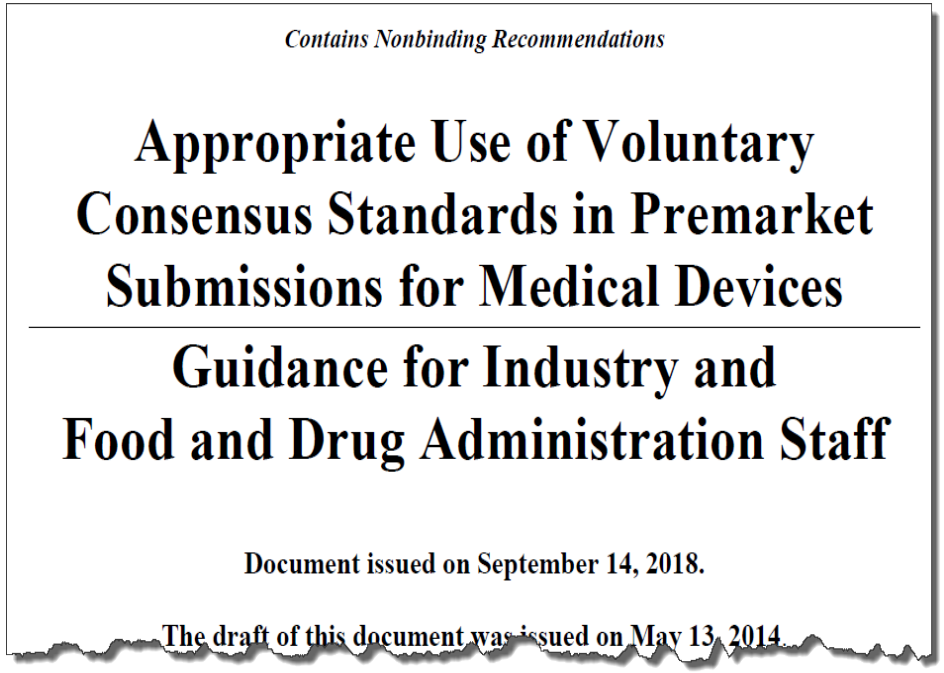
Declaration of Conformity

As proposed, should clearly indicate:

- Date testing was conducted
- Status of *ASCA Accreditation* for testing conducted
  - Ensures that *ASCA Accreditation* was not suspended during time of testing
- ASCA Summary Test Report
  - See Appendix E and F for examples

The ASCA Pilot Program and the *Appropriate Use* Guidance Document

This will be a **voluntary** program. It will not alter the manufacturer's responsibility to address relevant information in the premarket submission as outlined in the "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" guidance document. This includes documenting how the testing supports marketing authorization, even if the testing was included by a testing laboratory participating in the Pilot Program.



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[19]

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 Staff Premarket Considerations

The FDA intends to:

- Rely on the results from an ASCA-accredited testing laboratory for the purposes of premarket review provided:
  - The FDA is not aware of any information that would result in suspension of *ASCA Accreditation* or withdrawal of recognition
  - Summary test report does not indicate an issue with testing or device
- This means the FDA would generally accept a determination that a device conforms with a standard without the need for additional information related to conformance with the standard or review of a complete test report

The FDA does not intend to:

- Review methodologies for testing conducted by an ASCA-accredited testing laboratory within its recognized scope.
- Review complete test reports or request additional information:
  - Tests have concerning findings
  - Basic administrative information is missing
- Question the validity of test methods from an ASCA-accredited testing laboratory except as part of periodic audits or if the FDA becomes aware of information materially relevant to safety or effectiveness for the device.

Teamwork:

- Accreditation Bodies
- Testing Laboratories
- Device Manufacturers
- FDA

Stakeholder Considerations

Comments on the Draft Guidance are due by December 23, 2019:
https://www.regulations.gov/docket?D=FDA-2019-D-3805

Resources

- Draft Guidance Link:

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program

- ASCA Webpage Link:

  https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

- The FDA Recognized Consensus Standards Database Link:

  https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- Appropriate Use Guidance Document:

  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices

Questions?

Standards and Conformity Assessment Program, ASCA Pilot:
ASCA@fda.hhs.gov

Division of Industry and Consumer Education: DICE@fda.hhs.gov

Slide Presentation, Transcript and Webinar
Recording will be available at:
http://www.fda.gov/training/cdrhlearn
Under Heading: How to Study and Market Your Device;
Sub-Heading: Standards

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