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

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Accreditation Scheme for Conformity Assessment (ASCA)
Division of All Hazards Response, Science, and Strategic Partnerships
Office of Strategic Partnership and Technology Innovation
Center for Devices and Radiological Health

October 22, 2020

Agenda

- Objectives
- Background
- ASCA Pilot
 - Scheme design
 - Selected FDA-recognized consensus standards and test methods
 - Roles and responsibilities
 - Accreditation bodies
 - Testing laboratories
 - Device manufacturers
 - FDA review staff
- Key Implementation Dates

Objectives

- Understand **why** the ASCA Pilot was developed
- Understand **how** the ASCA Pilot was developed
- Understand **what** the ASCA Pilot is, including:
 - Roles and responsibilities of relevant stakeholders
 - Process and policies specific to each stakeholder
 - Implementation timeline

The ASCA Pilot is established by statute.

- 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 consensus standards and test methods
- 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”

Why Was the ASCA Pilot Developed?

- Evidence of conformity to FDA-recognized standards is 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 must¹ 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](#))
- Even with a DOC, FDA may need to request additional information and review supplemental documentation given the **variability** in how testing was conducted.
- Additional FDA review and questions may lead to **repeated or revised testing, delays, and/or additional costs.**

1. See 514(c)(1)(B) of the FD&C Act

How Was the ASCA Pilot Developed?

- Concept of ASCA Pilot Program emerged from discussions between device manufacturers and the FDA during MDUFA IV.
- FDA published a *Federal Register* notice in May 2017 requesting comments on a set of questions regarding development and overall design of the ASCA Pilot Program.
- 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 technical expert from the National Institute of Standards and Technology is working with CDRH to develop and implement ASCA Pilot Program.
- FDA received public comment on the draft guidance published September 23, 2019.
- FDA published final guidance on September 25, 2020.

What Is the ASCA Pilot?

The ASCA Pilot is a **conformity assessment scheme** in which:

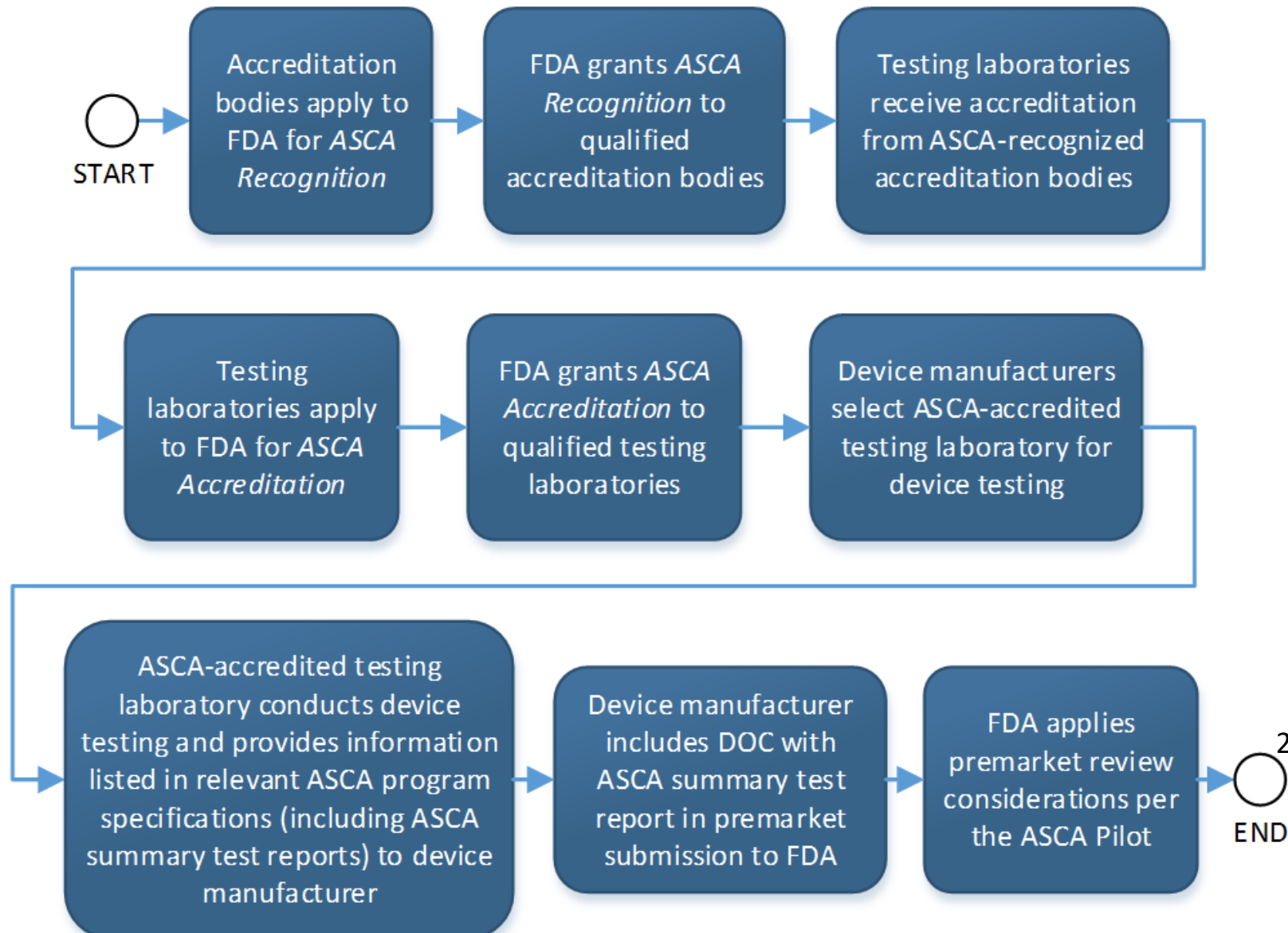
- **ASCA-recognized accreditation bodies** accredit testing laboratories using ISO/IEC 17025 and the ASCA program specifications.
- **ASCA-accredited testing laboratories** conduct medical device testing in accordance with ISO/IEC 17025 and the ASCA program specifications.
- **FDA ASCA staff** administer the ASCA program including managing participation of accreditation bodies and testing laboratories, including suspensions and withdrawals.

What is the ASCA Pilot?

The ASCA Pilot 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 aims to **improve efficiency** of the premarket review process by **building confidence** in the Declaration of Conformity through the utilization of accredited testing laboratories.



ASCA Pilot Process Flow



Where Is the ASCA Pilot Described?

The draft ASCA Pilot guidance document was split into three final guidance documents published on September 25, 2020.

ASCA Pilot Program Guidance:

1. “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program”

Standards-Specific Guidance:

2. “Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program”
3. “Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program”
 - A list of the standards and test methods selected for the ASCA Pilot
 - ASCA program specifications for those standards and test methods
 - Recommended contents for premarket submissions containing testing from an ASCA-accredited testing laboratory
 - Example Declarations of Conformity for those standards and test methods
 - Example ASCA summary test reports for those standards and test methods

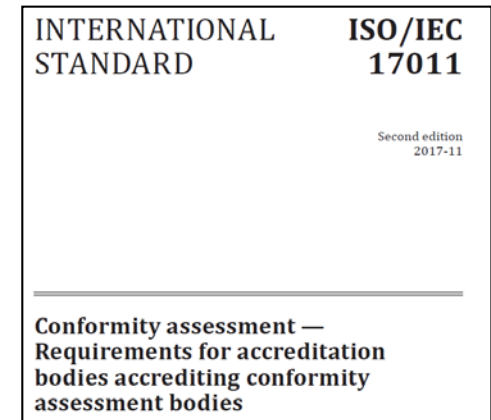
How Does the ASCA Pilot Leverage Existing Conformity Assessment Resources?



The ASCA Pilot is designed to maximize the use of existing frameworks and arrangements.

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.



How Does the ASCA Pilot Leverage Existing Conformity Assessment Resources?



In the ASCA Pilot:

- ILAC MRA signatory status is a qualification for accreditation body participation.
- The ASCA Pilot leverages the ILAC MRA policies and processes by reviewing accreditation body peer evaluation reports and/or participating as an observer during these activities.
- The ASCA Pilot leverages ISO/IEC 17011 policies and procedures by reviewing testing laboratory assessment reports and/or participating as an observer during these activities.

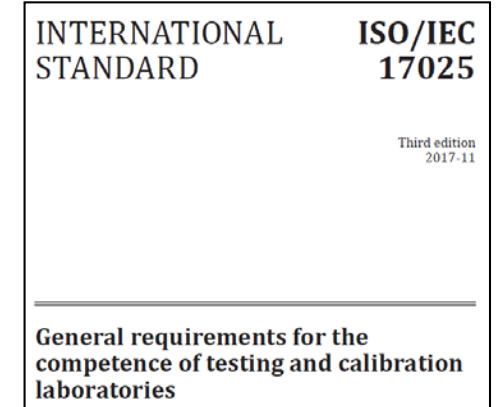
How Does the ASCA Pilot Leverage Existing Conformity Assessment Resources?



The ASCA Pilot is designed to maximize the use of existing frameworks and arrangements.

Existing Framework:

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



How Does the ASCA Pilot Leverage Existing Conformity Assessment Resources?



In the ASCA Pilot³:

- ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025 and ASCA program specifications.
- ASCA-accredited testing laboratories conduct testing in accordance with ISO/IEC 17025 and the ASCA program specifications.

3. See Section VIII.B. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Which FDA-Recognized Consensus Standards and Test Methods Are In the ASCA Pilot?



In accordance with the MDUFA IV commitment letter, the standards and test methods in the ASCA Pilot:

- Include both cross-cutting (horizontal) and device-specific (vertical) standards.
- Are of public health significance.
- 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 Medical Equipment



IEC 60601/80601 series of standards recognized by FDA at the time of final guidance publication:

- ANSI/AAMI ES 60601-1
- IEC and US adopted collaterals [60601-xx]
- IEC 60601-2-xx and the IEC or ISO 80601-2-xx particulars

Biocompatibility Testing of Medical Devices

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 ⁶	Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization
ISO 10993-10 and ASTM F720 ⁷	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

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

ASCA Program Specifications

ISO/IEC 17025 served as foundation for ASCA program specifications found in the standards-specific ASCA Pilot guidance documents. The working group that developed these specifications consisted of technical experts and personnel from 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).

ASCA Program Specifications for the Biological Evaluation of Medical Devices

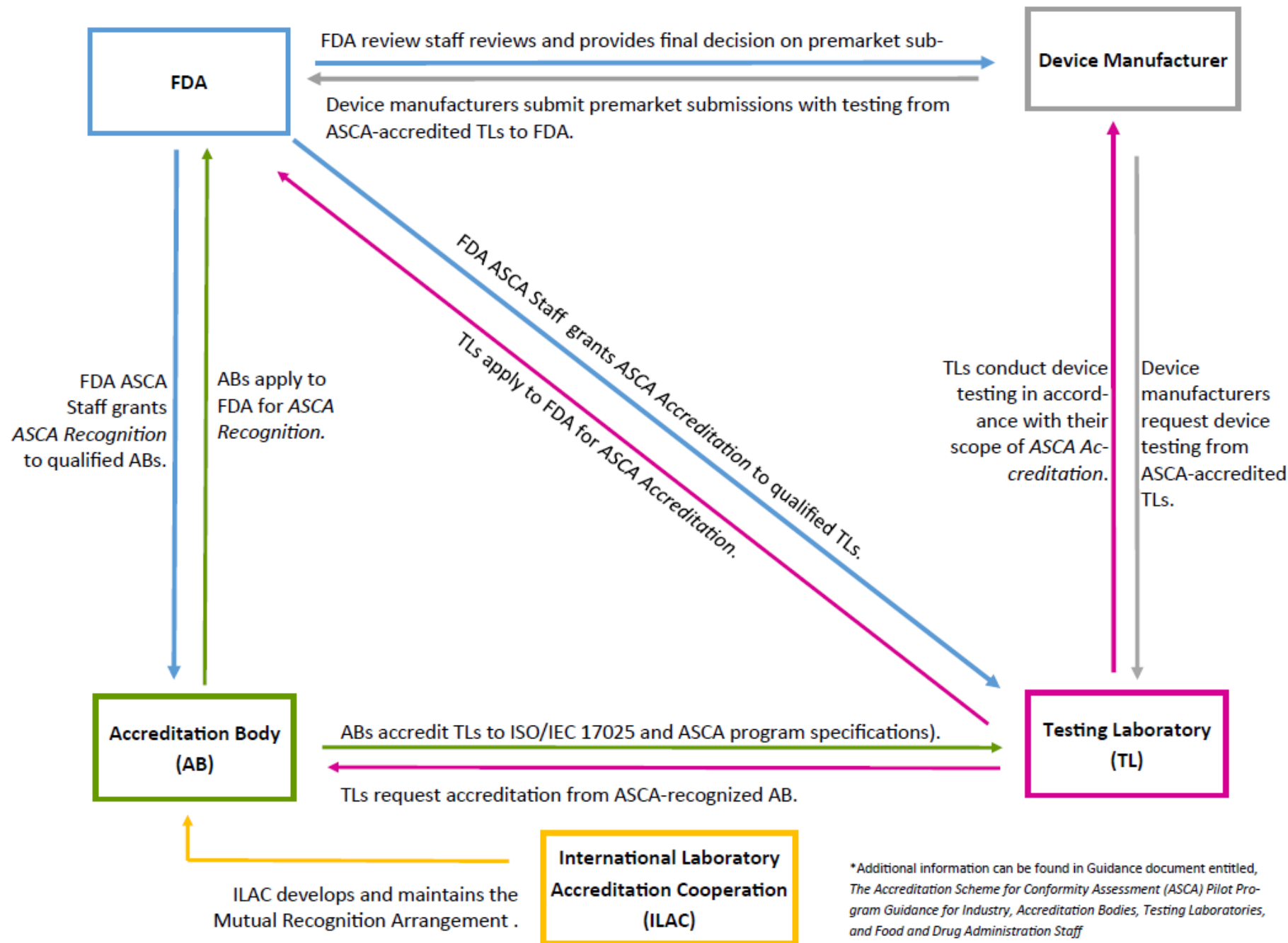
7.2 Selection, verification and validation of methods

- a) The testing laboratory 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)

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 testing laboratory 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 testing laboratory 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



Policies and Processes for Accreditation Bodies

Role

- ASCA-recognized accreditation bodies accredit testing laboratories using the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each FDA-recognized consensus standard and test method in their scope of *ASCA Recognition*⁴

Qualifications

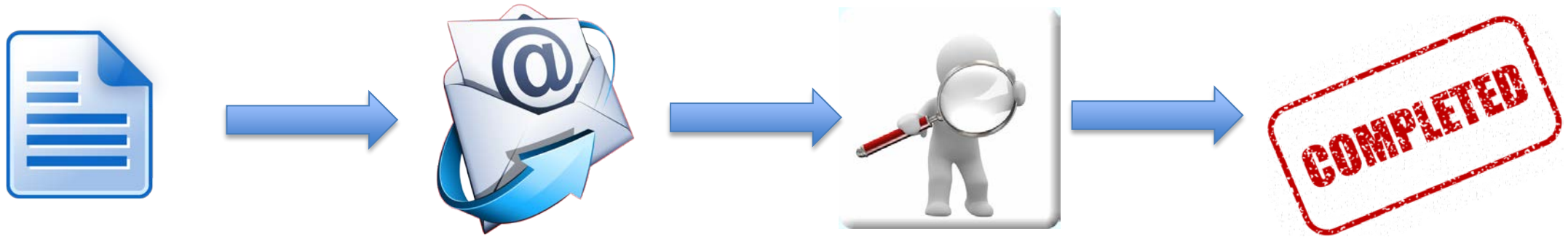
- Signatory status of Testing: ISO/IEC 17025 to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)
- Based in the United States
- Agreed to terms of participation

4. See Section X. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Policies and Processes for Accreditation Bodies



Application Process



- Accreditation Body drafts application for *ASCA Recognition* consistent with Appendix A of ASCA Pilot program guidance
- Accreditation body submits application via email to ASCA@fda.hhs.gov
- FDA reviews application within 60 days
- FDA notifies accreditation body of final decision via e-mail and if applicable, of any issues precluding *ASCA Recognition*

Policies and Processes for Accreditation Bodies



FDA intends to periodically **audit** accreditation bodies to ensure that they are adequately fulfilling program expectations.

Level 1 Audit

- **What:** FDA reviews a copy of the most recent ILAC peer re-evaluation report
- **Why:** periodic assessment to ensure adherence to program expectations

Level 2 Audit

- **What:** FDA reviews a copy of the most recent ILAC peer re-evaluation report and participates as an observer during next scheduled ILAC peer re-evaluation.
- **Why:** Level 1 audit insufficient (e.g., persistent issues with testing laboratories accredited by an accreditation body)

Level 3 Audit

- **What:** FDA initiates on-site or remote audit of accreditation body outside of ILAC MRA peer evaluation schedule
- **Why:** Level 1 and Level 2 audits insufficient (e.g., public health concern regarding safety or a device)



Policies and Processes for Accreditation Bodies

Withdrawal of *ASCA Recognition* cancels the accreditation body's full scope of *ASCA Recognition* and removes them from the ASCA Pilot entirely⁵.

Why?

FDA no longer has confidence in the accreditation body's ability to adequately fulfill its role in the ASCA Pilot; for example:

- Violation of law or violation of policies outlined in this guidance or other standards-specific ASCA Pilot guidances
- Failure to correct nonconformity
- Failure to adhere to signed agreement
- Information materially bearing on safety or effectiveness of a device that reasonably relates to the accreditation body
- Withdrawal or suspension of *ASCA Accreditation* for a testing laboratory that was accredited by the accreditation body

5. See Section X.F. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Policies and Processes for Accreditation Bodies



How?

- FDA sends a withdrawal letter via email to the contact on record for the accreditation body
- Accreditation body voluntarily requests withdrawal by submitting email to ASCA@fda.hhs.gov

In either case

- FDA notifies ASCA-accredited testing laboratories accredited for the ASCA Pilot by the now-withdrawn accreditation body
- Accreditation body submits new application for *ASCA Recognition* to participate again

Policies and Processes for Testing Laboratories

Role

- ASCA-accredited testing laboratories perform testing in accordance with the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each FDA-recognized consensus standard and test method in their scope of *ASCA Accreditation*⁶
- After testing is complete, ASCA-accredited testing laboratories provide the information listed in the relevant ASCA program specifications (including an ASCA summary test report) to the device manufacturer

Qualifications

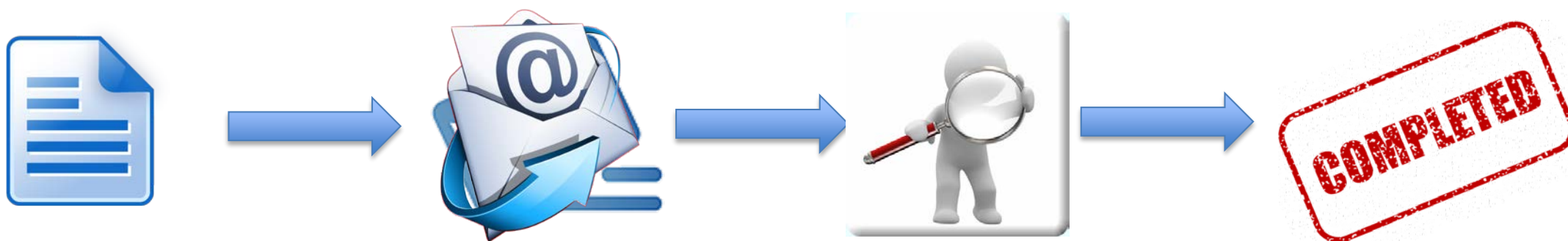
- Requested scope of *ASCA Accreditation* consistent with scope of accreditation provided by an ASCA-recognized accreditation body
- Agreed to terms of participation

6. See Section XI. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Policies and Processes for Testing Laboratories



Application Process



- Testing laboratory drafts application for *ASCA Accreditation* consistent with Appendix B of ASCA Pilot program guidance
- Testing laboratory submits application via email to ASCA@fda.hhs.gov
- FDA reviews application within 60 days
- FDA notifies testing laboratory of final decision via email and if applicable, of any issues precluding *ASCA Accreditation*

Policies and Processes for Testing Laboratories



FDA intends to periodically **audit** testing laboratories to ensure that they are adequately fulfilling program expectations.

Level 1 Audit

- **What:** FDA reviews a copy of the most recent assessment report
- **Why:** periodic assessment to ensure program expectations

Level 2 Audit

- **What:** FDA reviews a copy of the most recent assessment report and participates as an observer during next scheduled assessment of the testing laboratory by the accreditation body
- **Why:** Level 1 audit insufficient (e.g., concerning trend in testing laboratory's complaint logs)

Level 3 Audit

- **What:** FDA initiates on-site or remote audit of the testing laboratory outside of the assessment schedule established by the accreditation body
- **Why:** Level 1 and Level 2 audits insufficient (e.g., public health concern regarding safety or a device)

Policies and Processes for Testing Laboratories



Suspension of *ASCA Accreditation* puts temporary constraints on one or more FDA-recognized consensus standards or test methods in the testing laboratory's scope of *ASCA Accreditation* while issues are addressed⁷.

Why?

FDA identifies potential concerns regarding the testing laboratory's ability to adequately fulfill its role in the ASCA Pilot; for example:

- Existence of a nonconformity
- Inadequate completion of training or communication with FDA
- Information materially bearing on safety or effectiveness of a device that reasonably relates to the testing laboratory
- Withdrawal of *ASCA Recognition* from the accreditation body that accredited the testing laboratory for the ASCA Pilot

7. See Section XI.F. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Policies and Processes for Testing Laboratories



How?

- FDA initiates suspension by sending a letter via email to the contact on record for the testing laboratory
- Testing laboratory voluntarily requests suspension by submitting email to ASCA@fda.hhs.gov

In either case

- FDA notifies the accreditation body that accredited the lab for the ASCA Pilot
- A testing laboratory requests suspension be lifted by sending a response to ASCA@fda.hhs.gov

Policies and Processes for Testing Laboratories

Withdrawal of *ASCA Accreditation* cancels the testing laboratory's full scope of *ASCA Accreditation* and removes them from the ASCA Pilot entirely⁸.

Why?

FDA no longer has confidence in the testing laboratory's ability to adequately fulfill its role in the ASCA Pilot; for example:

- Violation of law or violation of policies outlined in this guidance and other standards-specific ASCA Pilot guidances
- Failure to correct nonconformity
- Failure to adhere to signed agreement
- Information materially bearing on safety or effectiveness of a device that reasonably relates to the testing laboratory
- Withdrawal of *ASCA Recognition* from the accreditation body that accredited the testing laboratory for the ASCA Pilot

8. See Section XI.F. of [The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance](#)

Policies and Processes for Testing Laboratories

How?

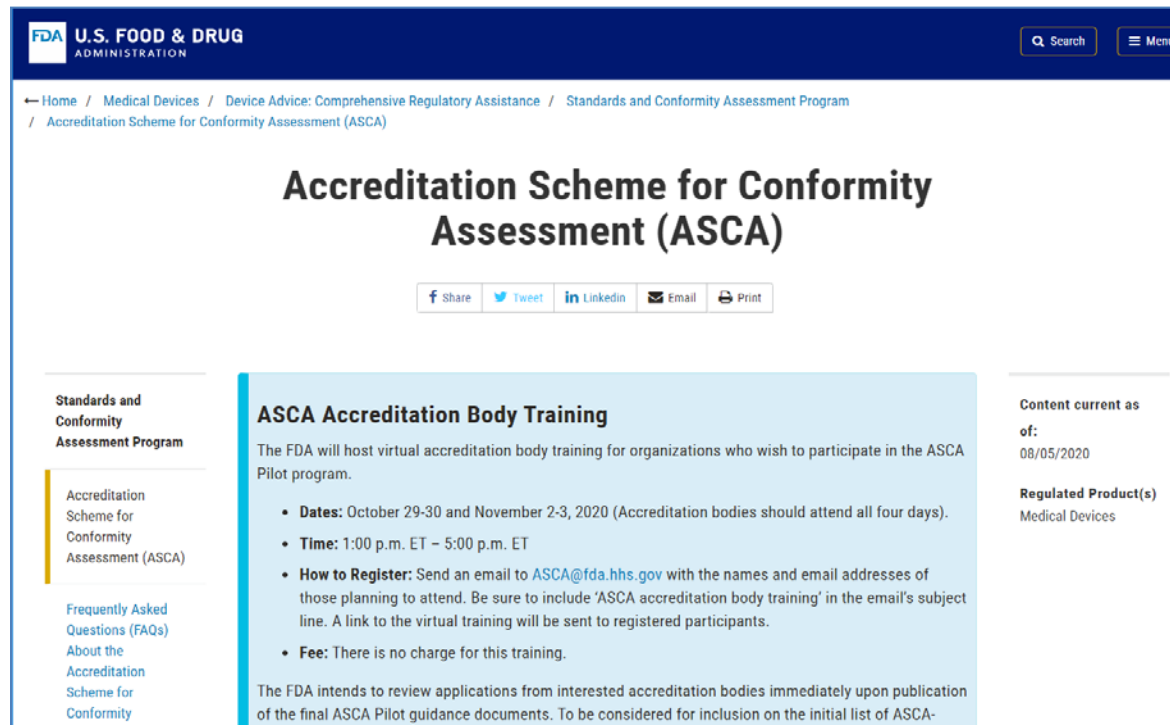
- FDA initiates withdrawal by sending withdrawal letter via email to contact on record
- Testing laboratory voluntarily requests withdrawal by submitting email to ASCA@fda.hhs.gov

In either case

- FDA notifies the accreditation body that accredited the lab for the ASCA Pilot
- Testing laboratory submits new application for *ASCA Accreditation* to participate again

Policies and Processes for Device Manufacturers

- Device manufacturers may voluntarily choose to use an ASCA-accredited testing laboratory to conduct testing included in a premarket submission⁹
- List of ASCA-accredited testing laboratories will be on the ASCA FDA website.



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Accreditation Scheme for Conformity Assessment (ASCA)

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ASCA Accreditation Body Training

The FDA will host virtual accreditation body training for organizations who wish to participate in the ASCA Pilot program.

- **Dates:** October 29-30 and November 2-3, 2020 (Accreditation bodies should attend all four days).
- **Time:** 1:00 p.m. ET – 5:00 p.m. ET
- **How to Register:** Send an email to ASCA@fda.hhs.gov with the names and email addresses of those planning to attend. Be sure to include 'ASCA accreditation body training' in the email's subject line. A link to the virtual training will be sent to registered participants.
- **Fee:** There is no charge for this training.

The FDA intends to review applications from interested accreditation bodies immediately upon publication of the final ASCA Pilot guidance documents. To be considered for inclusion on the initial list of ASCA-

Standards and Conformity Assessment Program

Accreditation Scheme for Conformity Assessment (ASCA)

Frequently Asked Questions (FAQs)

About the Accreditation Scheme for Conformity

Content current as of: 08/05/2020

Regulated Product(s)
Medical Devices

Policies and Processes for Device Manufacturers

- Device manufacturers are responsible for ensuring FDA-recognized consensus standards are selected and used appropriately¹⁰
- Considerations for development of a test plan for testing at an ASCA-accredited testing laboratory include:
 - Other relevant FDA guidance documents (e.g., device type guidance, scientific area guidance, submission type guidance)
 - Other FDA-recognized consensus standards (e.g., collateral and particular standards for basic safety and essential performance)
 - Impact of deviations from FDA-recognized consensus standards
 - Testing outside a testing laboratory's scope of *ASCA Accreditation*

Policies and Processes for Device Manufacturers

Device manufacturers are responsible for documenting how testing supports premarket authorization, even when testing is performed at an ASCA-accredited testing laboratory.

Cover Letter

- “ASCA”
- Name(s) and location(s) of the testing laboratory(ies)
ASCA Identification Number(s)
- FDA-recognized consensus standard(s) and test methods

Declaration of Conformity

- DOC plus ASCA *Accreditation* status for the testing laboratory
- See example DOCs

* See the FDA guidance: [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)

Supplemental Documentation

- See standards-specific ASCA Pilot guidance documents for example ASCA summary test reports

Policies and Processes for FDA Review Staff



- The ASCA Pilot's conformity assessment scheme provides FDA increased confidence in the methods used and results reported by ASCA-accredited testing laboratories when testing is performed within the testing laboratory's scope of *ASCA Accreditation*¹¹

- FDA intends to rely on the results from ASCA-accredited testing laboratories for the purposes of premarket review without the need for additional information related to conformance with a standard
- FDA does not intend to question the validity of test methods within a testing laboratory's scope of *ASCA Accreditation*

Policies and Processes for FDA Review Staff

Example of Exceptions

(not exhaustive)

- As part of periodic audits
- If FDA becomes aware of information that would result in suspension or withdrawal of a testing laboratory's *ASCA Accreditation*
- If FDA becomes aware of information that would result in withdrawal of the associated accreditation body's *ASCA Recognition*
- If FDA becomes aware of information materially bearing on the study conduct or quality
- If the ASCA summary test report indicates an issue with the testing or device

Policies and Processes for FDA Review Staff



What if *ASCA Accreditation* was suspended at the time of testing?

- FDA may need to review additional information and/or ask questions to determine whether the test results can be used to support a decision on a premarket submission.¹²
- FDA intends to carefully consider the issues resulting in suspension as well as which FDA-recognized consensus standards and test methods were subject to the temporary labeling constraints of the suspension.



12. See the FDA guidance: [Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices](#)

Policies and Processes for FDA Review Staff



What if *ASCA Accreditation* was withdrawn at the time of testing?

- FDA applies the policies applicable to testing from labs that never received *ASCA Accreditation*.
- FDA intends to carefully consider the nature and severity of the reasons for withdrawal of *ASCA Accreditation* when determining what, if any, postmarket action is needed for closed premarket submissions that included testing results from testing laboratories whose *ASCA Accreditation* has been withdrawn.





TEAMWORK

- Accreditation Bodies
- Testing Laboratories
- Device Manufacturers
- FDA



Key Application Dates

- FDA intends to publish a list of ASCA-recognized accreditation bodies on November 25, 2020
 - Applications received on or before November 4, 2020 will be considered for publication on this initial list
 - Applications received after November 4, 2020 will be reviewed in the order received and the list of ASCA-recognized accreditation bodies will be updated as appropriate

- FDA intends to publish an initial list of ASCA-accredited testing laboratories that will be updated throughout the Pilot.
 - FDA will update their web page to include the anticipated publication date for the initial list of ASCA-accredited testing laboratories and a date by which FDA should receive a testing laboratory's application in order for the organization to be considered for the initial list.

Appendix: Additional FDA Engagement

Accreditation Bodies

Accreditation Body Training Sessions

- **What** Overview of ASCA Pilot policies and processes for accreditation bodies
 - When** Oct 29, 2020; 1-5 pm
 - Who** Accreditation body program managers
-
- **What** Detailed instruction on how to use the ASCA program specifications during accreditation of testing laboratories for the ASCA Pilot
 - When** Oct 30, 2020 – Nov 3, 2020; 1-5 pm
 - Who** Technical assessors who will provide subject matter expertise during accreditation of testing laboratories for the ASCA Pilot



Appendix: Additional FDA Engagement

Testing Laboratories



➤ Basic Safety and Essential Performance Testing Laboratory Q&A Session

What Brief introduction to basic safety and essential performance standards-specific ASCA Pilot guidance document followed by audience Q&A

When November 16, 2020

➤ Biocompatibility Testing Laboratory Q&A Session

What Brief introduction to biocompatibility standards-specific ASCA Pilot guidance document followed by audience Q&A

When November 23, 2020

Resources

➤ Final Guidance Document Links:

- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program>
- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and>
- <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme>

➤ 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:
Heading: How to Study and Market Your Device; Subheading: Standards

<http://www.fda.gov/training/cdrhlearn>

Please complete a short survey about your FDA CDRH
webinar experience. The survey can be found [here](#)
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