



**U.S. FOOD & DRUG
ADMINISTRATION**

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

ANNUAL REPORT through 2018

Center for Devices and Radiological Health

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INTRODUCTION

The Standards and Conformity Assessment Program (S-CAP) supports the Food and Drug Administration's (FDA) mission of protecting and promoting public health through the development, recognition and use of voluntary consensus standards in regulating medical devices, radiation-emitting products and emerging technologies. The Center for Devices and Radiological Health (CDRH) is committed to making safe and effective medical devices available to patients in an efficient manner. An important element of our regulatory framework is a robust standards program.

CDRH encourages medical device sponsors to use FDA-recognized voluntary consensus standards in their product submissions, as conformity to relevant standards both streamlines regulatory review and fosters quality. Capitalizing upon the increasingly prominent role that standards play in regulatory science and practice, CDRH is expanding its standards program to include an accreditation initiative intended to improve the device review process by enhancing product reviewers' confidence in conformance documentation from manufacturers. The Center, with significant input from stakeholders in the medical device and conformity assessment communities, has begun the process of establishing this voluntary pilot program, entitled the *Accreditation Scheme for Conformity Assessment (ASCA)*.

As required by the FDA Reauthorization Act of 2017 (FDARA),¹ FDA committed to establish an ASCA Program using FDA-recognized consensus standards. One of the actions FDA committed to undertake was the development and initiation of a pilot for an ASCA program with stakeholder input by the end of FY 2020. The ASCA Pilot is anticipated to augment confidence in and reliance upon Declarations of Conformity (DOCs)² to certain FDA-recognized standards. The outcome is intended to translate into greater consistency and predictability in FDA's approach to assessing conformance to standards in medical device reviews by enhancing FDA's confidence in the testing laboratories' test methods and results. The need for internal FDA consultations, complete test report reviews, and additional information requests is anticipated to decrease, benefiting both FDA and manufacturers. Ultimately, we expect that the ASCA Pilot will help FDA ensure safe, effective, and high quality medical devices are available to patients.

This report provides further details of the progress attained toward the establishment of the voluntary ASCA Pilot during the calendar years (CY) 2017 and 2018. The report is structured as follows:

- Section I provides details on development of the ASCA Pilot to date, including the proposed design, goals, and the standards FDA is considering for inclusion in the ASCA Pilot.
- Section II presents information on FDA staffing.
- Section III summarizes outreach activities for external and internal stakeholders, including training initiatives.
- Section IV provides an overview of anticipated next steps for the ASCA Pilot.

SECTION I: ASCA PILOT DEVELOPMENT

¹ See Public Law 115-52, available at <https://www.congress.gov/115/plaws/publ52/PLAW-115publ52.pdf>.

² Refer to *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*, 'Guidance for Industry and FDA Staff' available at: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

What is the ASCA Pilot?

The ASCA Pilot is intended to allow FDA to work directly with accreditation bodies that will accredit testing laboratories to certain FDA-recognized standards. This accreditation is built upon an assessment under the international conformity assessment standard ISO/IEC 17025:2017,³ plus additional ASCA program specifications which will be outlined in a draft guidance.

The intention is for testing laboratories, which are accredited by FDA-recognized accreditation bodies to ISO/IEC 17025:2017 and the additional ASCA program specifications, to be able to apply to FDA for *ASCA Accreditation* by demonstrating their ability to perform testing for a specific set of eligible standards in the ASCA Pilot (more information on the standards FDA is considering for inclusion appears below). From the initial accreditation through subsequent years' re-accreditations, the intent is for FDA-recognized accreditation bodies to manage the processes necessary to ensure that testing laboratories conduct testing in a manner consistent with ISO/IEC 17025 and the ASCA program specifications.

FDA intends to grant *ASCA Accreditation* to testing laboratories who wish to participate and who demonstrate their ability to meet the ASCA program specifications outlined in the Pilot. Manufacturers will be able to engage with these testing laboratories to perform testing for their specific devices and use this information to support a DOC in accordance with FDA guidance *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*⁴ to the ASCA-eligible standards (see Figure 1 which schematically depicts the relationships described). Since the testing is conducted by a reliable – and accredited – source, manufacturers, the FDA and the public can be confident that their contents are complete and accurate.

To promote transparency and active participation in the ASCA Pilot, and as required per our commitments identified in Medical Device User Fee Amendments of 2017 (MDUFA IV),⁵ the FDA intends to establish and maintain a publicly-accessible Web page⁶ listing accreditation bodies, testing laboratories and the FDA-recognized consensus standard(s) for which the testing laboratories have been granted *ASCA Accreditation*.

³ More information about the ISO 17025:2017 *testing and calibration laboratories* standard is available at <https://www.iso.org/home/standards/popular-standards/isoiec-17025-testing-and-calibra.html>

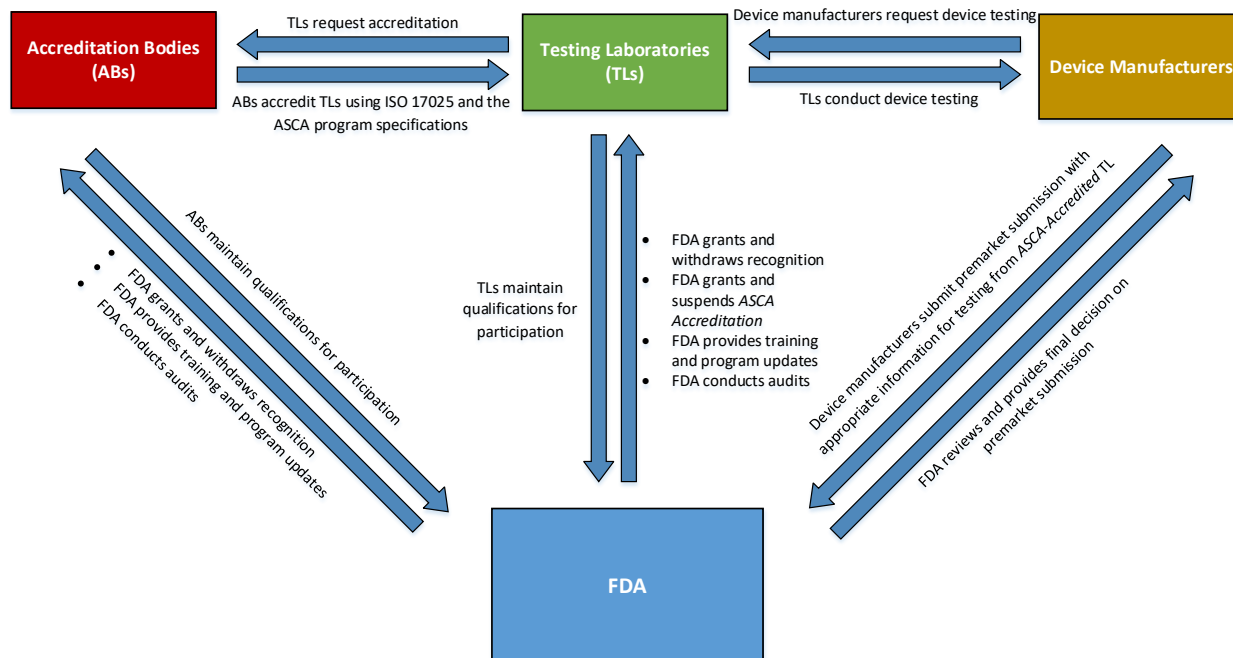
⁴ Guidance may be accessed here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices>

⁵ MDUFA IV Commitment Letter:

<https://www.fda.gov/downloads/ForIndustry/UserFees/MedicalDeviceUserFee/UCM526395.pdf>

⁶ <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm624509.htm>

Figure 1: The ASCA Pilot Scheme



ASCA Pilot Goals

The ASCA Pilot’s goals are to:

- Enhance confidence in medical device testing
- Promote consistency and predictability in the premarket review process
- Encourage effective use of FDA resources
- Enhance regulatory efficiency
- Support international harmonization

Ultimately, the ASCA Pilot is intended to improve FDA’s approach to evaluating conformance to standards in medical device review, thereby reducing the need for consultations, complete test report review and requests for additional information often needed during the premarket review process

Standards in the ASCA Pilot

Per the MDUFA IV commitment letter, the ASCA Pilot will include a minimum of five appropriate FDA-recognized standards, at least one of which will be device-specific. CDRH conducted an analysis of

potential standards and asked for input from the public in a *Federal Register* notice⁷ and from participants in a May 2018 public workshop⁸ to determine appropriate standards for inclusion in the ASCA Pilot. Standards addressing biocompatibility and basic safety and essential performance of medical electrical devices (see below for specific standards to be piloted) are being considered because they address critical safety and performance issues and are used broadly across different device types, and reviewers and manufacturers have a high degree of confidence in them and their utility. These standards are performance-based, and have at least some pass/fail criteria, or the means to establish these criteria, and we envision they will yield valuable experience for the ASCA Pilot. Please see the CDRH Standards Recognition Web page for more information about these standards.⁹

Biological Evaluation of Medical Devices

- ASTM F756: Standard Practice for Assessment of Hemolytic Properties of Materials
- ISO 10993-4: Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood
- ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- USP <151>: Pyrogen Test
- ISO 10993-12: Biological evaluation of medical devices -- Part 12: Sample preparation and reference materials

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-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)

Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical 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 60601/80601 family)

⁷ See 82 FR 22548; available at <https://www.govinfo.gov/app/details/FR-2017-05-16/2017-09850>

⁸ <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm>

⁹ Recognized Consensus Standards Database available at: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

- 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)

SECTION II: ASCA PILOT STAFFING

In 2018, the Center added four new full-time employees to the existing S-CAP staff dedicated to the ASCA Pilot. In addition to these permanent positions, a technical specialist from the National Institute for Standards Technology (NIST) Standards Coordination Office has contributed expertise to ASCA Pilot efforts. Other technical and scientific staff from across the Center, including those responsible for reviewing premarket submissions, are participating in the ASCA Pilot.

The ASCA Pilot team is responsible for the overarching project plan to ensure that we meet MDUFA IV commitments and remain on track to accomplish its goals.

SECTION III: ASCA PILOT OUTREACH

ASCA Pilot staff have conducted extensive outreach to introduce and raise awareness of the program. The first public opportunity to introduce the ASCA Pilot and elicit public input was a formal request for comments published in the *Federal Register* in May of 2017.¹⁰ Insights from these comments have been considered in the development of the ASCA Pilot. A second key element of formal outreach was the public workshop held May 22-23, 2018 on the FDA campus in Silver Spring, Maryland.¹¹ Several hundred individuals from across the medical device manufacturing and standards conformity assessment communities participated, in person or online. Designed to elicit information from attendees, the workshop agenda was heavily skewed toward group participation, in true workshop form.

In addition, the ASCA Pilot staff have conducted educational sessions about the purpose of the ASCA Pilot. Since 2017, more than fifty sessions with internal and external stakeholders have taken place. Externally, twelve meetings were held with Standards Developing Organizations and key Technical Committees and twenty-one formal presentations were shared with outside groups (fourteen with industry groups and seven with non-profits and professional societies). ASCA Pilot staff convened ten 'round-table' type discussions and participated in five site visits to testing laboratories in which information about the ASCA Pilot was introduced.

Internally, ASCA Pilot staff have provided background sessions to senior leadership across the Center and offered training to device reviewers on the program's purpose and proposed approach. This top-line information remains accessible on-line, and more formal training will be developed as the ASCA Pilot continues to evolve. Until then, communication goals in the short term are to continue raising awareness about the ASCA Pilot and to work with stakeholders on the development of the program.

Staff training will be key to the success of the ASCA Pilot and is proceeding along two tracks. The first training track is directed toward ASCA Pilot staff to provide the background necessary to launch and administer the program. During 2018, Center employees took advantage of multiple *Experiential*

¹⁰ See 82 FR 22548; available at <https://www.govinfo.gov/app/details/FR-2017-05-16/2017-09850>

¹¹ <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm>

Learning Program opportunities at testing laboratories to gain familiarity with the conformity assessment environment. In addition, the NIST technical specialist delivered numerous trainings on conformity assessment broadly and accreditation more specifically. Formal training programs targeted for ASCA Pilot staff and other interested CDRH employees were presented internally in September and October 2018 on three key international conformity assessment standards: ISO/IEC 17025:2017, ISO/IEC 17011:2017 and ISO/IEC 17065:2012.¹²

The second training track aims to introduce the elements of the ASCA Pilot to CDRH staff and raise awareness of its tenets. In addition to including ASCA Pilot references and updates during multiple ‘All Hands’ meetings, a ‘Lunch and Learn’ program directed at reviewers and management was presented on May 3, 2018, and a formal studio recording was published for those unable to attend that session. A video introduction to the ASCA Pilot narrated by Captain Scott Colburn was also recorded and presented to Center staff.

Finally, the Center has produced the following resources to help disseminate important aspects of the ASCA Pilot:

- Training and communication materials on the development aspects of the ASCA Pilot
- New public Web page¹³
- ASCA Public Workshop materials¹⁴

SECTION IV: NEXT STEPS

ASCA Pilot staff are committed to advancing the momentum achieved to date with the ASCA Pilot. In the coming year, implementing the comprehensive ASCA Pilot project plan will be an important priority, along with communicating routinely with stakeholders and anticipating needs of the evolving program. It is expected that the following activities, among others, will be summarized in the 2019 ASCA Pilot Annual Report:

- Publish the draft Guidance *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program: Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff*
 - This draft guidance will include information about participation in and operation of the ASCA Pilot. Identified on CDRH’s Fiscal Year 2019 Proposed Guidance Development

¹² These standards’ full titles are: ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories; ISO/IEC 17011 Conformity assessment - Requirements for accreditation bodies accrediting conformity assessment bodies (ISO/IEC 17011:2017); and ISO/IEC 17065 Conformity assessment - Requirements for bodies certifying products, processes and services. Go to <https://www.iso.org/home.html> for more information about these standards.

¹³ Available at:

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm624509.htm>

¹⁴ ASCA Public Workshop:

<https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm>

listing,¹⁵ the intent is for the guidance to be published by the end of FY 2019 and public comment will be sought at that time.

- Provide timely updates to the ASCA Web page, as necessary
- Explore information technology needs and capabilities to track conformity assessment activities
- Conduct additional internal and external training and outreach activities with ASCA Pilot stakeholders
- Continue to work with stakeholders for further input on programmatic improvements and/or considerations for expansion

¹⁵ Available at:

<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm529396.htm>