ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

ANNUAL REPORT CALENDAR YEAR 2021

Center for Devices and Radiological Health

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U.S. Food and Drug Administration
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SECTION I: INTRODUCTION

The Center for Devices and Radiological Health (CDRH)'s Standards and Conformity Assessment Program (S-CAP) encourages medical device sponsors to use FDA-recognized voluntary consensus standards in their product submissions, as conformity to relevant standards both reduces regulatory burden and fosters quality. To promote standards in device development and review, the FDA has implemented the Accreditation Scheme for Conformity Assessment Pilot (ASCA).

The ASCA Pilot is designed to enhance the use of declarations of conformity (DOCs)[1] and should translate into greater consistency and predictability in FDA's approach to assessing conformance to standards in medical device review by enhancing FDA's confidence in the testing laboratories' test methods and results. Ultimately, we expect that the ASCA Pilot will help FDA ensure safe, effective, and high quality medical devices are available to patients without unnecessary delay.

This 2021 ASCA Pilot annual report outlines progress achieved toward the establishment of the ASCA Pilot during the calendar year 2021.[2] The report proceeds as follows:

- Section II provides background, including the ASCA Pilot's goals, design and current standards.
- Section III outlines progress on ASCA Pilot implementation.
- Section IV provides an overview of anticipated next steps for the ASCA Pilot.

SECTION II: ASCA PILOT BACKGROUND

The ASCA Pilot is authorized under section 514(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[3] In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA),[4] and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),[5] FDA was directed to issue guidance regarding the goals and implementation of the ASCA Pilot.[6]

ASCA Pilot Goals

The goals of the ASCA program are:

- 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

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[1] 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

[2] Previous years' annual reports may be found on the ASCA Pilot web page at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

[3] 21 U.S.C. 360d(d)

[4] See Pub. L. 115-52

[5] See *also* MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download

[6] See section 514(d)(3)(B) of the FD&C Act.

ASCA Pilot Design

Under the ASCA Pilot, accreditation bodies may apply to the FDA for *ASCA Recognition*. After review of an accreditation body's application, the FDA grants *ASCA Recognition* to organizations who meet the ASCA Pilot qualifications specified in the ASCA Pilot program guidance and two standards-specific guidances. ASCA-recognized accreditation bodies accredit testing laboratories using *ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories[7]* and the ASCA program specifications outlined in the standards-specific ASCA Pilot guidance documents.

Testing laboratories may then apply to the FDA for *ASCA Accreditation*. After review of a testing laboratory's application, the FDA grants *ASCA Accreditation* to organizations who meet the ASCA Pilot qualifications specified in the ASCA Pilot program guidance.

If a device manufacturer chooses to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to the FDA, the device manufacturer includes a declaration of conformity with the appropriate supplemental documentation (e.g., ASCA Summary Test Report) as part of their premarket submission. For testing conducted under the ASCA Pilot, the FDA will have confidence in the testing laboratories' test methods and results and does not intend to request additional information regarding testing methodologies.

Standards Included in the ASCA Pilot

The ASCA Pilot includes ninety-four FDA-recognized standards and related test methods across two scopes: Biocompatibility and Basic Safety and Essential Performance. These standards were selected because they address critical safety and performance issues and are used broadly across different device types. In addition, they were chosen because their use is frequently associated with FDA requests for additional information and often require additional resources in premarket review. Please see the CDRH Recognized Consensus Standards Database for more information about these standards.[8]

Table 1: List of Standards and Test Methods for the ASCA Pilot: Biocompatibility [9]

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
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

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[7] See https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

[8] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm

[9] See the biocompatibility standards-specific guidance for a full listing of biocompatibility standards and test methods included in the ASCA Pilot: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

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

Table 2: List of Standards for the ASCA Pilot: Basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment[10]

Standard	Standard Title
60601/80601	*Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with certain FDA-recognized collateral and particular standards in the IEC/ISO 60601-80601 series)*
61010-1	*Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with certain FDA-recognized particular standards in the IEC 61010 series)*

SECTION III: ASCA PROGRESS IN 2021

Final Guidance Documents

The FDA published three final guidance documents in September 2020 that outline ASCA Pilot program specifications and expectations.

- ASCA Pilot program guidance: *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance*

- Basic Safety and Essential Performance standards-specific guidance: *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*

- Biocompatibility standards-specific guidance: *Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*

Administrative Progress

The ASCA Pilot was launched upon publication of the final ASCA guidance documents on September 25, 2020. In November 2020, the FDA granted *ASCA Recognition* to five accreditation bodies.[11] These ASCA-recognized accreditation bodies then began to evaluate their testing laboratory clients who wished to apply for *ASCA Accreditation*. By April 2021, the FDA had granted *ASCA Accreditation* to fifty-three testing laboratories and published their names in an initial list of ASCA-accredited testing laboratories.

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[10] See the basic safety and essential performance standards-specific guidance for a full listing of basic safety and essential performance standards included in the ASCA Pilot: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

[11] The list of ASCA-recognized accreditation bodies may be found here: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-recognized-accreditation-bodies

By October 2021, a total of seventy-six basic safety and essential performance and one biocompatibility testing laboratory had received *ASCA Accreditation*.[12]

- *ASCA web upgrades*: The ASCA web presence was expanded in 2021 to include dedicated web pages for accreditation bodies,[13] testing laboratories[14] and manufacturers.[15] Substantive improvements provide greater detail on how to prepare an application for *ASCA Accreditation* and how to compile a device submission that contains testing to standards included in the ASCA Pilot.

- *Work processes and standard operating procedures:* CDRH refined its workflows and standard operating procedures to drive efficient implementation and management of the ASCA Pilot program.

- *Staff/Resources:* The ASCA Pilot has met all hiring targets for the Pilot phase of the program.

- *IT progress:* The ASCA team established a formal infrastructure to manage the Pilot. The system securely stores documents and manages ASCA workflow processes. Documentation for *ASCA Recognitions* and *ASCA Accreditations* has been successfully administered.

Quality Management System (QMS)

Working with the CDRH Quality Management Program,[16] the ASCA team developed an ASCA Program Quality Management framework that conforms with the Center's overarching approach to quality management and takes advantage of the Center's ISO 9001:2015 Certified Quality Managmeent System (QMS) processes and tools. The ASCA Pilot's quality framework aligns with and exemplifies the Center's commitment to continually improve our products and services. More than forty-five QMS documents, including standard operating procedures, work instructions, and templates have been developed and implemented for the ASCA Pilot.

The ASCA team monitors and reviews performance relative to the ASCA Pilot quality objectives and makes timely adjustments as needed to fulfill the needs and expectations of our stakeholders. The team will continue to track nonconformities, risks and complaints. In addition, the identification of risks and continuous process improvements are ongoing priorities and QMS documents will be updated accordingly.

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[12] The list of ASCA-accredited testing laboratories may be found here: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-accredited-testing-laboratories
[13] See https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-bodies-how-participate-asca-pilot
[14] See https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/testing-laboratories-how-participate-asca-pilot
[15] See https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/manufacturers-how-participate-asca-pilot
[16] See https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-quality-management-program#:~:text=The%20CDRH%20Quality%20Management%20Program%20provides%20tools%20and,in%20bringing%20identified%20issues%20to%20a%20satisfactory%20resolution

Outreach

Accreditation Bodies

During 2021, the ASCA Team led monthly teleconferences with all five ASCA-recognized accreditation bodies. The purpose of these calls was to provide direction and answer questions about the *ASCA Accreditation* requirements to which the accreditation bodies evaluate testing laboratories. In addition, more than twenty teleconferences with individual accreditation bodies were held, which enabled these organizations to successfully evaluate the testing laboratories interested in *ASCA Accreditation*. Finally, multiple training sessions were conducted to train biocompatibility technical assessors and managers, and to support the accreditation bodies in their assessments of testing laboratories.

Testing Laboratories

Training for testing laboratories interested in *ASCA Accreditation* began in 2020 and continued in 2021 as these laboratories began to compile their applications to the FDA for *ASCA Accreditation*.

Outreach to Biocompatibility testing laboratories included several Question and Answer sessions and over forty teleconference calls with individual testing laboratories to introduce the program and application expectations. The ASCA team also developed tools and resources to aid them in their applications for *ASCA Accreditation*, including the *ASCA Pilot Training Companion Document for Biocompatiblity Testing*.

Interactions with Basic Safety and Essential Performance testing laboratories featured multiple training communications with all ASCA-accredited testing laboratories and numerous teleconferences with individual laboratories to support their application processes and prepare them to conduct ASCA testing.

Industry

Outreach to industry focused on two priorities: raising awareness about the program's launch and educating industry on how to use ASCA testing, including how submissions with ASCA testing should be compiled. Two public programs were presented and recorded: a public Webinar[17] and a two-part Industry Basics program.[18] These programs are also a part of CDRH Learn, the Center's portal for industry education.[19]

The ASCA team delivered thirteen training sessions to industry and professional societies, including the national RAPS Convergence and the AdvaMed MedTech conferences. Three events with standards development organizations took place, and three presentations were made to international testing laboratory groups.

Internal outreach: staff training

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[17] The webinar recording may be accessed here: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-asca-pilot-streamlining-conformity-assessment-device-submissions

[18] The Industry Basics recording may be accessed here: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/cdrh-industry-basics-workshop-consensus-standards-and-accreditation-scheme-conformity-assessment

[19] See https://www.fda.gov/training-and-continuing-education/cdrh-learn

Recognizing the importance of review staff to program success, the ASCA team has utilized multiple approaches and venues to conduct training on how to assess testing conducted under the ASCA Pilot. Training initiatives in 2021 included the following:

- Two training sessions with the Office of Product Evaluation and Quality staff: one to describe the tenets of the ASCA Pilot program and one focused on implementation aspects related to the identification and evaluation of an ASCA Pilot submission
- Created an example review model submission to guide reviewers on how to assess testing in an ASCA Pilot submission
- Developed the internal-facing *ASCA Reviewer Resource Page* with links to training materials, work instructions, and other tools to enhance reviewer skills
- Conducted formal training session on the tenets of the ASCA Pilot program for Center for Biologics Evaluation and Research staff

SECTION IV: ASCA PILOT NEXT STEPS

In 2022, the ASCA focus will be on encouraging device sponsors to participate in the ASCA program. Additional priorities include communicating and engaging routinely with stakeholders to ensure the obligations and objectives of the ASCA Pilot program are met. The following initiatives are planned for 2022:

Outreach

The ASCA team will continue to conduct educational and promotional programs to encourage participation in the ASCA Pilot, including at conferences and as stand-alone events. Timely updates will be published to the ASCA Pilot web pages, including changes to the lists of ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories as needed.

Regular meetings will be held with stakeholders to discuss progress on ASCA Pilot programmatic details. If travel restrictions are eased, the ASCA team intends to begin routine site visits with accreditation bodies and testing laboratories as part of our obligations under the program specifications.

CDRH Training

Ongoing training will be conducted for CDRH and CBER review staff and management on how to review ASCA Pilot device submissions and appropriately evaluate associated testing. Additionally, the ASCA team expects to launch a formal partnered approach to ASCA submissions, whereby an ASCA expert will be paired with a reviewer to do hands-on training to evaluate the testing in an ASCA submission.

ASCA Pilot Evaluation

The ASCA team will track ASCA submissions to evaluate ASCA Pilot performance and analyze the data. Per the MDUFA IV Commitment Letter, the ASCA team will complete an assessment of the viability of the ASCA Pilot.