ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

ANNUAL REPORT CALENDAR YEAR 2020

Center for Devices and Radiological Health

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U.S. Food and Drug Administration
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SECTION 1: 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. Capitalizing upon the increasingly prominent role that standards play in regulatory science and practice, S-CAP has published three final guidance documents implementing the voluntary pilot program entitled the *Accreditation Scheme for Conformity Assessment (ASCA).*[1]

- **Program guidance:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance* [2]
- **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* [3]
- **Biocompatibility standards-specific guidance:** *Biocompatibility Testing of Medical Devices-Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program* [4]

The ASCA Pilot is anticipated to augment confidence in and reliance upon declarations of conformity (DOCs)[5] to the FDA-recognized standards included in the ASCA Pilot. The outcome is intended to translate into greater consistency and predictability in the FDA's approach to assessing conformance to standards in medical device review by enhancing the FDA's confidence in the testing laboratories' test methods and results. Ultimately, we expect that the ASCA Pilot will help the FDA ensure safe, effective, and high quality medical devices are available to patients without unnecessary delay.

This 2020 ASCA Pilot annual report outlines progress achieved toward the establishment of the ASCA Pilot during the calendar year 2020.[6] The report is organized as follows:

- Section II provides background, including the ASCA Pilot's goals, design and current standards.
- Section III outlines progress on ASCA Pilot implementation.

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[1] The ASCA web page may be accessed at https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

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

[3] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

[4] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

[5] 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

[6] For additional information, see the 'Accreditation Scheme for Conformity Assessment (ASCA) Annual Report Through 2018': https://www.fda.gov/media/131266/download and the 'Accreditation Scheme for Conformity Assessment 2019 Annual Report' at https://www.fda.gov/media/134852/download

- 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). [7] In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA), [8] and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV), [9] the FDA was directed to issue guidance regarding the goals and implementation of the ASCA Pilot. [10]

The ASCA Pilot was designed with a 'least burdensome' philosophy to make conformity assessment in medical device review more efficient. When drafting the proposed ASCA framework, the FDA received feedback from many stakeholders: the medical device industry; policy, science and engineering staff from across CDRH; and professionals in the accreditation and conformity assessment professions, including accreditation bodies and testing laboratories. We have also received technical support from a conformity assessment expert from the National Institute of Standards and Technology (NIST), who helped us conceptualize and implement this pilot. Early public feedback also came from comments to a 2017 public docket that solicited input into the future ASCA Pilot[11] and from a two-day public workshop held in 2018. [12] In addition, the FDA considered all comments submitted to the 2019 draft guidance docket. [13]

ASCA Pilot Goals

The goals of the ASCA program are:

- Enhance confidence in medical device testing

  The ASCA Pilot includes application processes and periodic audits of accreditation bodies and testing laboratories as well as the processes that will be followed for suspension or withdrawal. These processes and audits are intended to increase confidence in the testing performed by ASCA-accredited testing laboratories by ensuring that ASCA-recognized accreditation bodies meet the criteria specified by the FDA in this guidance and any relevant standards-specific ASCA Pilot guidance documents throughout their participation in the program. The increased confidence in testing may be particularly helpful for premarket submissions that rely on DOCs to FDA-recognized consensus standards using test results from ASCA-accredited testing laboratories.

- Promote consistency and predictability in the premarket review process

  The ASCA Pilot does not introduce new requirements for medical device manufacturers. Rather, by clearly communicating expectations for how results from ASCA-accredited testing

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[7] 21 U.S.C. 360d(d)

[8] *See* Pub. L. 115-52

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

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

[11] *See* 82 FR 22548; available at https://www.govinfo.gov/app/details/FR-2017-05-16/2017-09850

[12] *See* https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm

[13] The ASCA Pilot draft guidance and comments may be found here: https://www.regulations.gov/docket?D=FDA-2019-D-3805

laboratories are included and reviewed in premarket submissions, the ASCA Pilot intends to promote consistency and predictability in all of the FDA's premarket submission programs.

- Encourage effective use of FDA resources

    The increased acceptance of DOCs under the ASCA Pilot allows the FDA to direct scientific and regulatory resources to other priorities.

- Enhance regulatory efficiency

    By virtue of a testing laboratory's *ASCA Accreditation*, device manufacturers can be more confident early in the product development lifecycle that testing to the FDA-recognized consensus standards and test methods within the laboratory's scope *of ASCA Accreditation* is likely to meet the FDA's regulatory requirements. The FDA expects that the application process, periodic audits, and clear communication among participants in the ASCA Pilot will decrease the need for the FDA to request additional information regarding testing methodologies when a premarket submission includes DOCs to a FDA-recognized consensus standard eligible for inclusion in the ASCA Pilot.

- Support international harmonization

    The FDA used elements from international conformity assessment standards in the ISO/IEC 17000 series to establish the ASCA Pilot. The standards within the ISO/IEC 17000 series are used worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers. [14] In addition, the FDA-recognized consensus standards and test methods selected for the ASCA Pilot are international consensus standards. The FDA believes the experience gained in the ASCA Pilot could broadly inform international harmonization efforts such as standards' use across jurisdictions.

ASCA Pilot Design

The ASCA Pilot is designed as follows: 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[15]* 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.
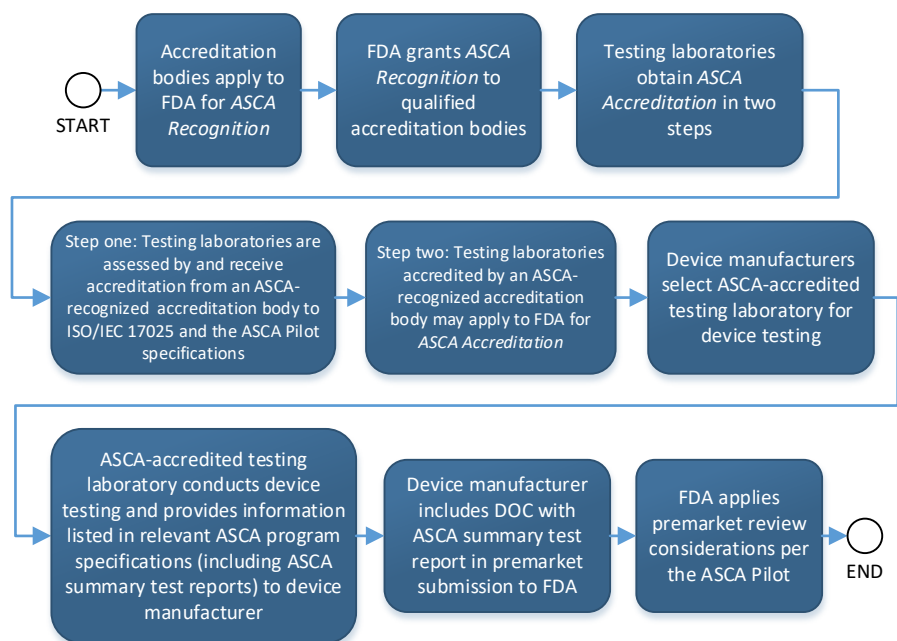
A device manufacturer may choose to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to the FDA. For such testing, ASCA-accredited testing laboratories provide the

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[14] See NIST SP 2000-01 ABCs of Conformity Assessment (2018) available at: https://www.nist.gov/publications/abcs-conformity-assessment
[15] *See* https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html

device manufacturer with all the information listed in the relevant ASCA program specifications. When 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, the FDA will have confidence in the testing laboratories' test methods and results and does not intend to request additional information regarding testing methodologies. Figure 1 below outlines the process flow for the ASCA Pilot.

Figure 1 Process Flow for the ASCA Pilot

Standards Included in the ASCA Pilot

Per the MDUFA IV commitment letter, the ASCA Pilot includes a minimum of five appropriate FDA-recognized standards, at least one of which is device-specific. In making its decision about the standards to include in the Pilot, CDRH relied upon input from the public in the 2017 *Federal Register* notice[16] and the May 2018 public workshop[17] to determine appropriate standards for inclusion in the ASCA Pilot.

Ultimately, the ASCA Pilot includes seventy-eight FDA-recognized standards (eight standards with ten test methods in biocompatibility and seventy standards from the basic safety and essential performance (ANSI/AAMI 60601-1 and IEC 61010-1) series. These standards were selected because they address critical safety and performance issues and are used broadly across different device types. They 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. In addition, they were chosen because their use is frequently associated with FDA requests for additional information and often require excessive resources in premarket review.

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[16] See footnote 11
[17] See footnote 12

Finally, this selection of standards will prove valuable to help the FDA evaluate how the ASCA Pilot program specifications can enhance the FDA's confidence in these test results and their declarations of conformity.

Tables 1 and 2 list the standards included in the ASCA Pilot. Please see the CDRH Recognized Consensus Standards database for more information about these standards. [18]

Table 1: List of Standards and Test Methods for the ASCA Pilot: Biocompatibility [19]

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

* 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[20]

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

SECTION III: ASCA PILOT IMPLEMENTATION

Final Guidance Documents

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

[19] 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

[20] 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

In accordance with FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV), [21] the FDA was directed to publish a draft guidance outlining the ASCA Pilot's goals and implementation no later than September 30, 2019 and final guidance no later than September 30, 2020. [22] On September 25, 2020, the FDA published three final guidance documents, which replaced the single draft guidance document.

- 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*

Program Launch

The ASCA Pilot implementation plan was launched upon publication of the ASCA guidance documents on September 25, 2020. At that time, ASCA staff immediately began to engage with accreditation bodies and testing laboratories to describe the ASCA Pilot and roles and responsibilities. The first step was to encourage accreditation bodies to submit applications for *ASCA Recognition* in a timely fashion by reemphasizing the initiation of the ASCA Pilot to our stakeholder distribution list.

Mandatory training for accreditation body staff was conducted over four days (October 29-30 and November 2-3, 2020). Ninety-nine technical assessors and program managers from five accreditation bodies participated in this training.

Accreditation bodies were offered the opportunity to appear on an 'initial list' of ASCA-recognized accreditation bodies if their applications were received by the FDA no later than November 4, 2020 and met FDA specifications. On November 25, 2020, six weeks after the Pilot launch, five accreditation bodies met that deadline and the initial list of ASCA-recognized accreditation bodies along with their scopes of recognition was posted on the ASCA web page. [23]

Expediting the publication of this initial list of ASCA-recognized accreditation bodies meant that testing laboratories who wished to participate in the ASCA Pilot could begin their application process. Testing laboratories have a similar opportunity to appear on an initial list of ASCA-accredited testing laboratories, and applications need to be received by the FDA no later than February 9, 2021. An initial list of ASCA-accredited testing laboratories is expected to be posted on the ASCA web page by April 12, 2021.

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

[22] *See* Section 514(d)(3)(B) of the Federal Food Drug and Cosmetic Act (FD&C Act)

[23] *See* https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/asca-recognized-accreditation-bodies

Quality Management System

Working collaboratively with the CDRH Quality Management Program, [24] the ASCA team developed a 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 Managmment System (QMS) processes and tools. The ASCA Pilot's quality framework aligns with and exemplifies the Center's commitment to continually improve the quality of our products and services.

In order to incorporate quality into the ASCA Pilot, the team:

- Developed a quality management framework that leverages core values and concepts in ISO 9001:2015 by adopting CDRH Quality Management Program processes and tools.
- Developed ASCA Pilot-specific standard operating procedures, work instructions, forms and templates to deliver consistently high quality products and services.

Outreach

Outreach to external stakeholders remains an integral part of the ASCA team's preparations for launch and implementation of the ASCA Pilot. During 2020, communications with external stakeholders appropriately consisted of program updates and preparation for the publication of the final guidance. Once the final guidances were posted on September 25, 2020, the ASCA team launched a strategic outreach program that included:

- A public webinar to discuss the final guidances and initiation of the ASCA Pilot (October 16, 2020)[25]
- Introductions to the ASCA Pilot and question and answer opportunities for manufacturers in October and November 2020
- Program updates to other stakeholders, including testing laboratories and standards development organizations in October 2020
- Two Question and Answer sessions for testing laboratories interested in participating in the ASCA Pilot in November 2020
  - Basic safety and essential performance
  - Biocompatibility

Administrative Progress

The ASCA team worked proactively to establish the framework for the initiation of the ASCA Pilot upon publication of the final ASCA Pilot guidance documents, taking the steps necessary to support accreditation bodies seeking *ASCA Recognition*. The ASCA team has prepared and tested internal CDRH systems and processes to be able to receive, identify and review premarket submissions that include testing from ASCA-accredited testing laboratories, once laboratories have obtained *ASCA Accreditation*

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[24] *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

[25] Webinar materials may be found at https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-accreditation-scheme-conformity-assessment-asca-pilot-program-final-guidances-10222020

and appear on the ASCA web page, anticipated to occur in spring or summer 2021. Below are additional activities completed in partnership with Center and Agency staff:

- *ASCA web page upgrades*: The ASCA web page has been updated accordingly to reflect the publication of the final guidances and to include a link to the list of ASCA-recognized accreditation bodies. [26]

- *Work processes and standard operating procedures (SOPs):* CDRH has established the necessary workflows and SOPs to drive efficient implementation and management of the ASCA Pilot program.

- *Staff/Resources:* The ASCA Pilot has met its hiring targets for the years 2017-2020: three hires in FY 2018, one in FY 2019 and one in 2020.

    o The ASCA team has conducted outreach with the FDA review staff and management to raise awareness of the Pilot Program's launch.
    o S-CAP Senior Standards Advisors have conducted a comprehensive five-part training series for Center staff on the appropriate use of consensus standards in device submissions, including declarations of conformity. These sessions provide a grounding to prepare for ASCA Pilot submissions and are available on-line for future use.
    o The ASCA team has drafted formal training goals and objectives and comprehensive training for technical review staff has been initially completed. Shortly after the initial list of ASCA-accredited testing laboratories is published (anticipated April 12, 2021), additional training of technical review staff and management will be conducted to assure operationalization of the ASCA Pilot.

SECTION IV: ASCA PILOT NEXT STEPS

The 2019 ASCA Pilot annual report reflected commitments for 2020 that effectively provided the foundation for a 2020 ASCA Pilot launch. The ASCA team has met these expectations by conducting training for accreditation bodies and testing laboratories, evaluating (and providing *ASCA Recognition* to) five accreditation bodies, establishing the CDRH information technology systems necessary to process ASCA Pilot device submissions once able to receive, and developing tools to evaluate ASCA Pilot metrics.

In 2021, the ASCA Pilot staff are committed to advancing the full operationalization of the ASCA Pilot. Our focus will be on bringing qualified accreditation bodies and ASCA-accredited testing laboratories into the ASCA Pilot and encouraging sponsors to submit marketing authorizations as ASCA device submissions. Additional priorities include communicating and engaging routinely with stakeholders to ensure we meet the objectives of the ASCA Pilot program.

The following initiatives are intended to be implemented in 2021.

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[26] *See* https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

CDRH Systems

- *Document management:* Premarket submissions that include declarations of conformity from ASCA-accredited testing laboratories need to be compatible with all of the electronic systems utilized in routine device review. For example, SMART templates for premarket submissions have been updated to include checks for ASCA Pilot files and will be rolled out as soon as we have evaluated and identified ASCA-accredited testing laboratories on our web page.

Outreach

- Educational programs to encourage participation in the ASCA Pilot will be conducted. For example, the FDA's *Industry Basics* series will offer a two-part program in 2021 emphasizing the practical aspects of using standards and participating in the ASCA Pilot.
- The FDA's annual REdi Conference (May 2021) will discuss the ASCA Pilot.
- Timely updates will be published to the ASCA Pilot web page, including:
  - Changes to the lists of ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories as those entities join the ASCA Pilot and/or their scopes and status change
- Regular meetings will be held with stakeholders, including accreditation bodies, testing laboratories, device manufacturers, standards developing organizations and FDA staff to discuss progress on ASCA Pilot programmatic details.

CDRH Training

- Training will be conducted for CDRH review staff and management on how to review ASCA Pilot device submissions and appropriately evaluate associated testing.

ASCA Pilot Evaluation

- The ASCA team will finalize tools and metrics to evaluate ASCA Pilot performance and begin tracking program results.

Quality Management

- The FDA will monitor and review performance relative to the ASCA Pilot quality objectives and make timely adjustments as required to better fulfill the needs and expectations of our stakeholders.
- The identification of risks and continuous process improvements will be ongoing priorities and as necessary SOPs, work instructions and templates will be updated accordingly.