U.S. FOOD & DRUG ADMINISTRATION

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)

2019 Annual Report

Center for Devices and Radiological Health

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ANNUAL REPORT CALENDAR YEAR 2019

Center for Devices and Radiological Health
US Food and Drug Administration

SECTION 1: 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 review by enhancing FDA's confidence in the testing laboratories' test methods and results. The need for internal FDA consultations, complete test report review, 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 2019 ASCA Annual Report provides details of the progress achieved toward the establishment of the ASCA Pilot during the calendar year 2019.[3] The report is organized as follows:

- Section II provides background on the ASCA Pilot, including the proposed design, goals, and the standards FDA is considering for inclusion in the ASCA Pilot.
- Section III outlines progress on ASCA Pilot implementation.
- Section IV provides an overview of anticipated next steps for the ASCA Pilot.

[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

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

SECTION II: ASCA PILOT BACKGROUND

The concept of ASCA emerged from discussions with the medical device industry. A conformity assessment program designed with a 'least burdensome' philosophy could provide a way for the FDA's dynamic standards program 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 those 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 this pilot. Early public feedback also came from comments to a 2017 public docket that solicited input into the future ASCA Pilot,[4] and from a two-day public workshop held in 2018.[5]

ASCA Pilot Goals

The goals of the ASCA program, as identified in the draft guidance,[6] are straightforward:

- Enhance confidence in medical device testing

  The accreditation bodies and the testing laboratories participating in the ASCA Pilot are expected to meet and maintain the proposed ASCA Pilot expectations. The proposed processes and audits are intended to increase the FDA's confidence in testing by an ASCA-accredited testing laboratory to an ASCA-eligible standard.

- Promote consistency and predictability in the premarket review process

  The ASCA Pilot would not introduce new requirements for medical device manufacturers. Rather, by clearly communicating expectations for when results from ASCA-accredited testing laboratories are included in premarket submissions, the proposed ASCA Pilot is intended to promote consistency and predictability across the FDA's premarket submission programs.

- Encourage effective use of FDA resources

  Under the ASCA Pilot, the FDA does not intend to question the validity of test methods and outcomes from ASCA-accredited testing laboratories except as part of periodic audits, if the summary 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. Increased acceptance of determinations of conformity to standards allows the FDA to direct scientific and regulatory resources to other priorities.

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

[5] https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm

[6] Refer to *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program, Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories and FDA Staff*, available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program. When final, this guidance will represent FDA's current thinking on this topic.

- Enhance regulatory efficiency

  The FDA intends for the application process, periodic audits, and clear communication among participants in the ASCA Pilot to decrease the number of potential regulatory issues identified by the FDA during premarket submission review.

- Support international harmonization

  The standards within the ISO/IEC 17000 series are utilized worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers.[7] In addition, most of the FDA-recognized consensus standards proposed for the ASCA Pilot are international consensus standards. The FDA believes the experience gained in the ASCA Pilot could broadly inform international regulatory harmonization efforts.

If the ASCA Pilot goals are met, we would expect to see significant benefits.The ASCA Pilot is intended to improve FDA's approach to evaluating conformance to standards in medical device review, thereby reducing the need for internal FDA consultations, complete test report review and requests for additional information often needed during the premarket review process, hence benefiting both the FDA and manufacturers. Ultimately and most importantly, ASCA is intended to help the FDA meet its goal of ensuring safe, effective, and high-quality medical devices are available to patients without unnecessary delay.

Standards Proposed for Inclusion 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* notice[8] and from participants in a May 2018 public workshop[9] 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.[10]

Table 1: Proposed List of Standards and Test Methods to Be Used During the ASCA Pilot

Biological evaluation of medical devices

[7] See NIST SP 2000-01 ABCs of Conformity Assessment (2018) available at: https://www.nist.gov/publications/abcs-conformity-assessment
[8] See footnote 4
[9] See footnote 5
[10] Recognized Consensus Standards Database available at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Standard	Standard Title	Test method(s)
ISO 10993-4[11]	ISO 10993-4: *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood*	Complement Activation
ISO 10993-4 and ASTM F756	ISO 10993-4: *Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood* ASTM F756: *Standard Practice for Assessment of Hemolytic Properties of Materials*	Direct and Indirect Hemolysis
ISO 10993-5	ISO 10993-5: *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*	MEM Elution Cytotoxicity
ISO 10993-10	ISO 10993-10: *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*	Dermal Irritation, Intracutaneous Reactivity Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization
ISO 10993-11	ISO 10993-11: *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*	Acute Systemic Toxicity
ISO 10993-11 and USP 151	ISO 10993-11: *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity* USP <151>: *Pyrogen Test*	Material-Mediated Pyrogenicity
ISO 10993-12	ISO 10993-12: *Biological evaluation of medical devices – Part 12: Sample preparation and reference materials*	Sample preparation for all test types

Basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment

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)

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

SECTION III: ASCA PILOT IMPLEMENTATION PROGRESS

ASCA Pilot Draft Guidance[12]

In accordance with FDARA, and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),[13] the FDA was directed to publish a draft guidance regarding the goals and implementation of the ASCA Pilot program no later than September 30, 2019.[14] On September 23, 2019, the *Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff* and its associated notice of availability were published and FDA sought comments and suggestions from stakeholders.

ASCA Pilot Staffing

The ASCA Pilot has met its hiring targets for the years 2017-2019: 3 hires in FY 2018 and 1 in FY 2019. S-CAP intends to hire one additional employee in FY 2020.

An additional detailee was also selected to help with internal training initiatives and we continue to draw upon the expertise of our NIST consultant. Lastly, a team lead within S-CAP for the ASCA Pilot program was named.

Augmenting the ASCA team are FDA consultants from across the Center who are proficient in the proposed standards' families and their associated testing. These 'ASCA Advisors,' comprised of scientists, engineers and reviewers, meet with the ASCA team at least monthly to share their experience with the standards themselves and assist with implementation considerations.

ASCA Pilot Outreach

Internal Outreach

The ASCA Pilot internal outreach continued this year and focused on two key areas: (1) enhancing conformity assessment skills and knowledge among the ASCA team; and (2) raising general awareness among non-ASCA Center staff in preparation for initiation of the ASCA Pilot upon finalization of the guidance.

As part of the first focus area, key ASCA staff took part in 'CDRH's Experiential Learning Program'[15] opportunities with site visits to testing laboratories that do testing in the areas of Biological Evaluation and Basic Safety and Essential Performance. The ASCA team lead also participated in the *NIST Standards Boot Camp*[16] which had a strong emphasis on conformity assessment.

As part of the second focus area, internal outreach for non-ASCA Center staff was conducted to increase awareness of the pending ASCA Pilot program. Focused educational sessions for staff from the Office of

[12] See footnote 6
[13] See also MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download
[14] See Section 514(d)(3)(B) of the Federal Food Drug and Cosmetic Act (FD&C Act)
[15] See CDRH's Experiential Learning Program website, available at: https://www.fda.gov/science-research/fda-science-jobs-and-scientific-professional-development/cdrhs-experiential-learning-program
[16] See Standards and Conformity Assessment Training for Government Agencies Web site, available at: https://www.nist.gov/federal-agency-training

Product Evaluation and Quality (OPEQ) and the Office of Science and Engineering Laboratories (OSEL) were held to introduce and reinforce the concepts included within the ASCA draft guidance[17] and solicit feedback internally. Additional meetings were also held with the S-CAP's Specialty Task Groups and Liaisons who are the FDA technical staff participating in consensus standards development and recognition activities.[18]

Although the final details of the ASCA Pilot will not be available until the final ASCA Pilot Program guidance is published, the ASCA team is currently developing strategies and the framework for formal training plans for review staff to facilitate implementation of the guidance upon its publication.

External Outreach

Outreach to external stakeholders is an integral part of the ASCA team's preparations for eventual implementation of the ASCA Pilot. Throughout 2019, the ASCA team has been engaged in a robust communications effort to raise awareness of the publication of the draft guidance.[19] Further, the ASCA team has been participating in stakeholder events such as conferences, symposia and meetings during which FDA has had the opportunity to introduce the ASCA Pilot and the draft guidance.

As part of the communication stategy for the publication of the Draft ASCA guidance, FDA communications included an FDA In Brief, directed toward trade organizations[20] and social media, as well as a public Webinar[21] to promote visibility and encourage comments.

External outreach has included speaking with manufacturers, trade associations, accreditation bodies, testing laboratories and standards developing organizations to further enhance their familiarity with the draft guidance and encourage effective commenting on the draft guidance. See Table 2 below for a summary of the totality of these outreach events for the ASCA Pilot.

Table 2: Summary of Public Outreach

Type of Engagement	Audience Type	Number of Events
Roundtables	Accreditation Bodies	10
Presentations	Testing Laboratories	3
Presentations	Industry	15
Presentations	Standards Developing Organizations	12
Communications and webinar surrounding the publication of the draft guidance	All stakeholders	

[17] See footnote 6
[18] For more information on CDRH's standards recognition program, see http://fda.yorkcast.com/webcast/Play/8866483d519d4e4f9d94d5ee20b8e9ae1d
[19] See footnote 6
[20] Available at: https://www.fda.gov/news-events/fda-brief/fda-brief-fda-announces-pilot-program-increase-consistency-and-predictability-premarket-reviews
[21] Available at: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-accreditation-scheme-conformity-assessment-asca-pilot-program-draft-guidance-10282019

Current Resources

The Center has produced the following publicly available resources to help disseminate important aspects of the ASCA Pilot and draft guidance:

- New public Web page[22] including a Frequently Asked Questions page[23]
- FDA Fact Sheet[24]
- ASCA Draft Guidance Webinar materials, including slides and a transcript[25]

ASCA Pilot Administrative Progress

Working ahead to lay the groundwork (where practicable) for an 'out of the gate start' upon publication of the final ASCA Pilot guidance, the ASCA team has investigated the steps necessary to ensure that premarket submissions that include testing from an ASCA-accredited testing lab 'fit' with other programs in CDRH and that a quality management system (QMS) can be incorporated into the ASCA Pilot. Below are priorities that are being addressed in partnership with Center and Agency staff:

- Paperwork Reduction Act (PRA): The ASCA Pilot involves the collection of new information from the public. As such, a *Federal Register*[26] notice and request for comments are necessary. The initial *Federal Register* notice published on September 5, 2019 and subsequent steps to complete this process in advance of the completion of the finalization of the ASCA Pilot guidance are currently underway.
- ASCA Web page upgrades: Processes are under development that would track and report accreditation status for accreditation bodies and testing laboratories participating in the ASCA Pilot, and export status reports to the ASCA Web page on a periodic basis.
- Work processes and standard operating procedures (SOPs): As with all programs, we intend to establish the necessary workflows and SOPs to drive efficient implementation and management of the ASCA Pilot program. For example, work processes have been developed for properly responding to external queries that arrive through the ASCA@fda.hhs.gov mailbox. Another example within this category is focused on the design by Center information technology staff to ensure accurate record-keeping and recording of accreditation bodies' and testing laboratories' participation in the ASCA Pilot when active.
- Document management: Premarket submissions that include Declarations of Conformity from ASCA-accredited testing labs need to be compatible with all of the electronic systems utilized in

[22] Available at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm624509.htm
[23] See https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/frequently-asked-questions-faqs-about-accreditation-scheme-conformity-assessment-asca-pilot
[24] See https://www.fda.gov/media/132042/download
[25] See footnote 21
[26] https://www.federalregister.gov/documents/2019/09/05/2019-19102/agency-information-collection-activities-proposed-collection-comment-request-accreditation-scheme

routine device review. Ensuring that these submissions are correctly routed and flagged for their ASCA status is necessary for the program's success.

- Quality Management System: The ASCA team is working collaboratively with the CDRH Quality Management Program to incorporate the tenets of a QMS framework into the ASCA Pilot.

SECTION IV: ASCA PILOT NEXT STEPS

ASCA Pilot staff are committed to advancing the momentum achieved to date with the ASCA Pilot. In the coming year, our focus will be on publishing the final ASCA Pilot guidance and implementing its many elements. Additional priorities include communicating routinely with stakeholders and anticipating the needs of the evolving ASCA Pilot program.

The ASCA team expects to complete the drafting and publication of the final ASCA Pilot guidance, which is identified on CDRH's Fiscal Year (FY) 2020 Proposed Guidance Development listing with the intent for the guidance to be published by the end of FY2020 (September 30, 2020[27]).

Once the final ASCA Pilot guidance is published, the following initiatives will be implemented considering any changes captured in the final ASCA Pilot guidance:

- Launch educational programs to encourage participation in the ASCA Pilot
- Develop and commence formal training for accreditation bodies and testing laboratories
- Evaluate applications from accreditation bodies and testing laboratories
- Publish timely updates to the ASCA Pilot Web page, including refreshing the Frequently Asked Questions section and providing additional resources as they become available
- Make progress on information technology requirements for implementation of the ASCA Pilot
- Train CDRH review staff on how to review ASCA Pilot device submissions and appropriately evaluate associated testing
- Finalize tools to evaluate performance and other ASCA Pilot metrics
- Establish regular meetings with stakeholders, including accreditation bodies, testing laboratories, device manufacturers, standards developing organizations and FDA staff, to discuss progress and obtain further input into ASCA Pilot programmatic details
- Recruit one additional full time ASCA staff member

[27] See https://www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/cdrh-proposed-guidances-fiscal-year-2020-fy-2020