U.S. FOOD & DRUG ADMINISTRATION

Center for Devices and Radiological Health Accreditation Scheme for Conformity Assessment (ASCA)

Annual Report Calendar Year 2024

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA)
ANNUAL REPORT CALENDAR YEAR 2024

Center for Devices and Radiological Health
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SECTION I: INTRODUCTION

The Center for Devices and Radiological Health's (CDRH) Division of Standards and Conformity Assessment (DSCA) 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 (ASCA) Program.

ASCA's objective is to enhance the use of declarations of conformity (DOCs)[1] and promote 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.

This annual report outlines progress achieved toward the establishment of the ASCA Program during the calendar year 2024.[2] The report proceeds as follows:

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

SECTION II: ASCA BACKGROUND

ASCA 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 program goals and implementation of the ASCA Program in a pilot phase.[6] FDA has concluded the ASCA pilot phase[7] and is establishing an ongoing ASCA Program, in accordance with amendments made to section 514 by section 2005 of the FDA User Fee Reauthorization Act of 2022, part of the Medical Device User Fee Amendments of 2022 (MDUFA V).[8]

Note that at the time of this report, ASCA is still being implemented under the three guidance

[1] For a description of DOCs and their appropriate utilization, please refer to FDA guidance entitled *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,* 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 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.

[7] See FDA's webpage entitled Accreditation Scheme for Conformity Assessment (ASCA) available at: https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/accreditation-scheme-conformity-assessment-asca

[8] See Pub. L. 117-180, Division F: "FDA User Fee Reauthorization Act of 2022" (FUFRA)

documents published to establish the ASCA Pilot. These guidance documents are being updated to reflect lessons learned during the Pilot phase.[9]

ASCA Goals

The goals of the ASCA program are the following:

- 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

ASCA Design

Under the ASCA program, qualified accreditation bodies may apply to FDA for *ASCA Recognition*. ASCA-recognized accreditation bodies accredit testing laboratories using *ISO/IEC 17025:2017: General requirements for the competence of testing and calibration laboratories*[10] and the ASCA program specifications outlined in the standards-specific ASCA Pilot guidance documents.

Testing laboratories may then apply to FDA for *ASCA Accreditation*. After review of a testing laboratory's application, FDA grants *ASCA Accreditation* to organizations who meet the ASCA qualifications outlined in the program and standards-specific guidance documents. If a device manufacturer chooses to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to FDA, the device manufacturer includes an ASCA declaration of conformity, an ASCA Summary Test Report and a cover letter that notes the submission contains ASCA testing. For testing conducted under ASCA, FDA will have confidence in the testing laboratories' test methods and results and does not intend to request additional information regarding testing methodologies.

Three ASCA guidance documents provide direction and program specifications: one program guidance and two standards-specific guidances.[11]

- ASCA Pilot program guidance**:** *The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program - Final Guidance* [12]
- 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* [13]

[9] The three draft guidances can be found here: https://www.regulations.gov/docket/FDA-2019-D-3805/document
[10] See https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html
[11] FDA acknowledges that draft ASCA Program and standards-specific guidances were issued September 23, 2024. When finalized, these draft guidances are intended to supersede the ASCA guidances referenced in footnotes 12-14 which were issued September 25, 2020.
[12] The ASCA Pilot guidance can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program
[13] The basic safety and essential performance standards-specific guidance can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and

- Biocompatibility standards-specific guidance: *Biocompatibility Testing of Medical Devices-Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*[14]

Standards in the ASCA Program

ASCA includes FDA-recognized consensus standards and related test methods across two scopes: biocompatibility scope (Table 1) and the basic safety and essential performance scope (Table 2). These standards were selected because they address critical safety and performance issues and are used broadly across different device types. In addition, 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.[15]

Table 1: List of standards and test methods for the ASCA program: biocompatibility [16]

FDA-Recognized 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**	Closed Patch Sensitization
ISO 10993-23**	Dermal Irritation, Intracutaneous Reactivity Irritation
ISO 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).

** ISO 10993-10:2010 split into ISO 10993-10:2021 and ISO 10993-23:2021

Table 2: List of standards for the ASCA program: basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment[17]

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)*

[14] The biocompatibility standards-specific guidance can be found here: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme

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

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

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

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 2024

Device Submissions with ASCA Testing

From January 1, 2024 to December 31, 2024, FDA received 82 submissions that contain or refer to ASCA testing, compared to a total of 51 received in the first two years of the program (2022-2023).[18] The 82 submissions in 2024 comprise:

- Q-submissions: 11
- 510(k)s: 64
- De Novos: 2
- IDEs: 4
- PMAs: 1

When the 11 Q-submissions are separated from the other submission types listed (because they are not an authorizing submission but rather a feedback request mechanism and thus did not contain an ASCA Summary Test Report), 71 submissions contained ASCA Summary Test Reports.

- Number of submissions with biocompatibility testing: 15
- Number of submissions with basic safety and essential performance testing: 51
- Number of submissions with both biocompatibility and basic safety and essential performance testing: 3
- Number of FDA requests for complete test reports: 1
- Number of submissions with deficiencies: 1

Administrative Progress

- As of December 2024, FDA has granted *ASCA Recognition* to five accreditation bodies[19] and *ASCA Accreditation* to 107 testing laboratories, 102 for the basic safety and essential performance scope and 5 for the biocompatibility scope.[20]

- *IT progress:* In 2024, the ASCA team launched enhanced public websites for the ASCA-recognized accreditation bodies[21] and ASCA-accredited testing laboratories.[22] The new websites

[18] As of December 31, 2024, all of the data provided in this report are for ASCA submissions to the Center for Devices and Radiological Health. No ASCA submissions have been received by the Center for Biologics Evaluation and Research.
[19] 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
[20] 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
[21] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-recognized-accreditation-bodies.cfm
[22] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm

contain easily accessible information about these entities. For example, the listing of ASCA-accredited testing laboratories reflects each laboratory's ASCA status, the standards in their scope, including title, recognition number and the laboratory's scope history. In addition, each listing now contains the full text for exclusions, replacing the previous asterisk notation. Finally, each standard included in ASCA links to its Supplementary Information Sheet (SIS) in the FDA's Recognized Consensus Standards database.

- *ASCA quality framework metrics:* The ASCA Program Quality Management Framework, which conforms with the Center's overarching approach to quality management,[23] outlines ASCA's processes, services and management and incorporates the Center's commitment to quality management. In 2024, the ASCA team continued to track its performance:

    - New *ASCA Accreditation* applications: 5 new testing laboratories received *ASCA Accreditation*. The average number of calendar days to decision was 54 (goal: 60 calendar days)
    - Voluntary withdrawals from the ASCA program: 6 testing laboratories requested to withdraw from ASCA. The average number of calendar days to finalize voluntary withdrawal from the ASCA program was 13 (goal: 15 calendar days)
    - *ASCA Accreditation* scope expansion applications: 22 ASCA-accredited testing laboratories applied for expansions to their ASCA scopes. The average number of calendar days to complete these actions was 11 (goal: 60 calendar days)
    - *ASCA Recognition* scope expansion applications: 1 ASCA-recognized accreditation body requested a scope expansion which was processed in 24 calendar days (goal: 60 calendar days)
    - *Accreditation body audits:* The ASCA team is conducting audits of all 5 ASCA-recognized accreditation bodies. These audits entail a review of ASCA documents, an evaluation of training and quality systems programs and an assessment of ASCA-specific standard operating procedures. The audits also include records review for a sample of their ASCA-accredited testing laboratories to determine how the accreditation body assessed and documented testing laboratory performance.
    - *Testing laboratory audits:* The ASCA team has begun performing audits of ASCA-accredited testing laboratories. To date, 3 testing laboratory audits are in process and more are planned for 2025.

External Outreach

Accreditation Bodies

During 2024, the ASCA team led 6 virtual meetings with all 5 ASCA-recognized accreditation bodies. The purpose of these meetings was to provide direction and answer questions about the *ASCA Accreditation* requirements to which the accreditation bodies evaluate testing laboratories. In addition to these meetings and multiple email communications, more than 20 virtual one-on-one teleconferences with individual accreditation bodies were held to support their efforts to successfully evaluate the testing laboratories interested in *ASCA Accreditation*. Finally, the FDA conducted formal training sessions for 12

[23] See https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-quality-management-program

new technical assessors and managers to support the ASCA-recognized accreditation bodies in their assessments of testing laboratories.

In 2024, 2 ASCA staff members attended 3 accreditation body conferences to advance FDA and accreditation body knowledge and expertise and to promote the ASCA Program.

Testing Laboratories

Communications with testing laboratories in 2024 continued to emphasize 2 priorities: how to compile complete *ASCA Accreditation* applications and how to work with industry to conduct and report testing according to the ASCA Program specifications and other relevant FDA guidance documents.

Interactions with biocompatibility testing laboratories included the following:

- Question and Answer webinars with biocompatibility testing laboratories: 2
- Mandatory biocompatibility testing laboratory meetings: 3
- Technical Assessor training sessions: 2
- One-on-one teleconferences with testing laboratories: 9
- Email communications: more than 150

Interactions with basic safety and essential performance testing laboratories included the following:

- Multiple training communications to all ASCA-accredited testing laboratories
- 'Office Hours' meetings: 3
- Multiple teleconferences with individual testing laboratories to support their application processes and prepare them to conduct ASCA testing
- Mandatory meetings with ASCA-accredited testing laboratories: 2
- Extensive email outreach to provide programmatic updates via email
- Events co-promoting the ASCA program with ASCA-accredited testing laboratories: 3

Industry and other interested parties

The ASCA team continued to focus its efforts with external parties to promote the program's benefits and how to use ASCA testing, including how submissions with ASCA testing should be compiled.

The ASCA team's outreach in 2024 totaled 39 events for external audiences:

- Presentations to industry, standards development organizations and professional societies: 23
- Regulatory Affairs Professionals Society (RAPS) local and regional chapter events: 13 (six in-person and seven virtual presentations)
- Co-promotional events with ASCA-accredited testing laboratories: 3

Internal Outreach: Staff Training

Recognizing the importance of review staff knowledge and training for program success, the ASCA team has utilized multiple approaches and venues to conduct training on how to assess testing conducted under the ASCA Program. Training initiatives for reviewers and managers in 2024 included the following:

- CDRH training, including internal rounds, town halls and focused training:
    - Partnered approach to ASCA submissions, whereby an ASCA technical expert from DSCA was paired with a premarket reviewer for hands-on training to evaluate the testing in each ASCA submission
    - Basic safety and essential performance formal training sessions: 1
    - Biocompatibility formal training sessions: 1
- Center for Biologics Evaluation and Research (CBER) training:
    - Basic safety and essential performance formal training sessions: 1
    - Biocompatibility formal training sessions: 1

SECTION IV: ASCA NEXT STEPS

ASCA programmatic improvements

To accommodate the transition from pilot to permanent program and program improvements consistent with MDUFA V commitments, FDA has begun the process of updating the ASCA guidance documents. On September 23, 2024, FDA issued the following draft guidances:

- The Accreditation Scheme for Conformity Assessment (ASCA) Program[24]
- Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program[25]
- 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) Program[26]

These guidances include updates to the ASCA Program based on feedback from public meetings, webinars, interested party meetings, and lessons learned internally during the pilot phase. When final, these guidances will replace the three ASCA Pilot guidances issued September 25, 2020.

In 2025, the ASCA team will continue auditing ASCA-accredited testing laboratories.

ASCA Expansion

The ASCA team plans to give careful consideration to how and when to expand the ASCA Program. To solicit input from interested parties, 2 public workshops were conducted in 2024. At these events, representatives from testing laboratories, accreditation bodies, industry and standards development organizations shared insights for possible program enhancements and expansion approaches.

[24] See FDA draft guidance available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program
[25] See FDA draft guidance available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme-0
[26] See FDA draft guidance available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and-0

- The *Virtual Public Workshop – Accreditation Scheme for Conformity Assessment Expansion*[27] was held virtually on April 17, 2024. In this workshop, the FDA requested that interested parties share their perspectives and priorities regarding potential expansion of the program. It drew approximately 275 participants.

- The *Public Workshop - Accreditation Scheme for Conformity Assessment and Use of Chemical Analysis to Support Biocompatibility of Medical Devices*[28] was conducted on November 6, 2024. More than 100 biocompatibility testing experts attended in person and more than 1000 streamed the workshop virtually in this discussion about how ASCA might be expanded to include chemical characterization testing.

External Outreach

The ASCA team intends to prioritize educational programs to encourage participation in ASCA, including at conferences and stand-alone events. Timely updates are intended to be made to the ASCA web pages, including changes to the lists of ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories as needed. The ASCA team also plans to continue co-promotional programs with ASCA-accredited testing laboratories.

Internal Outreach: Staff Training

Ongoing training will continue for CDRH and CBER review staff and management on how to review ASCA device submissions and appropriately evaluate associated ASCA testing.

ASCA Annual Report

The ASCA team intends to publish an annual report on ASCA's 2025 progress by the end of January 2026.

[27] See the workshop web page for more information: https://www.fda.gov/medical-devices/medical-devices-news-and-events/virtual-public-workshop-accreditation-scheme-conformity-assessment-expansion-april-17-2024-04172024

[28] See the workshop web page for more information: https://www.fda.gov/medical-devices/medical-devices-news-and-events/public-workshop-accreditation-scheme-conformity-assessment-and-use-chemical-analysis-support