U.S. FOOD & DRUG ADMINISTRATION

ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) ANNUAL REPORT CALENDAR YEAR 2025

Center for Devices and Radiological Health

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SECTION I: INTRODUCTION

The FDA's 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 the FDA's approach to assessing conformance to standards in medical device review by enhancing the FDA's confidence in the testing laboratories' (TLs) test methods and results.

This annual report outlines progress achieved toward the establishment of the ASCA Program during the calendar year 2025.[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] the FDA was directed to issue guidance regarding program goals and implementation of the ASCA Program in a pilot phase.[6] The 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]

As of this report's publication, ASCA is implemented according to the three (3) 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 initially developed for the ASCA Pilot. These guidance documents are being revised to integrate knowledge gained 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 (ABs) may apply to the FDA for *ASCA Recognition*. ASCA-recognized ABs accredit TLs 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. TLs may then apply to the FDA for *ASCA Accreditation*. Once a TL is accredited by/represented by an FDA approved ASCA-recognized AB, the TL may apply to FDA for *ASCA Accreditation*. After review of an ASCA application, the FDA grants *ASCA Accreditation* to TLs that meet the ASCA criteria established in the program and standards-specific guidance documents. Device manufacturers who select ASCA-accredited TLs to conduct testing intended to support premarket submission(s) to the FDA should submit:

1. A declaration of conformity (DOC), through either a separate document or via the built-in DOC options in the electronic submission template and resource (eSTAR) template;
2. ASCA Summary Test Report(s); and
3. A cover letter that states the submission contains an ASCA Summary Test Report(s) from an ASCA-accredited TL.

For testing conducted under ASCA, the FDA will have confidence in the TLs' 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]

[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] 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

- 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]
- 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

[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
[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

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)*
61010*	*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 and related standards, e.g., 61326-2-6)*

* These two families of standards include approximately 97 individual standards.

SECTION III: ASCA PROGRESS IN 2025

Device Submissions with ASCA Testing

From January 1, 2025 to December 31, 2025, FDA received 136 submissions that contain ASCA Summary Test Reports, compared to a total of 51 received in the first two years of the program (2022-2023) and 82 in 2024.[18] The 136 submissions in 2025 comprise:

- 510(k)s: 123
- De Novos: 7
- IDEs: 3
- PMAs: 3

All 136 submissions contained ASCA Summary Test Reports. The submissions in 2025 include:

- Number of submissions with biocompatibility testing: 24
- Number of submissions with basic safety and essential performance testing: 108
- Number of submissions with both biocompatibility and basic safety and essential performance testing: 4
- Number of FDA requests for complete test reports: 1
- Number of submissions with deficiencies: 7

[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.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/Search.cfm

[18] As of December 31, 2025, 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.

Administrative Progress

- As of December 2025, the ASCA program has the following participation: five ASCA-recognized ABs[19] and 102 ASCA-accredited TLs, 98 basic safety and essential performance TLs and 4 biocompatibility TLs.[20]

- *IT progress:* In 2025, the ASCA team launched enhancements to public databases for ASCA-accredited TLs.[21] The improved databases include the addition of the withdrawal date of withdrawn TLs, if applicable. In addition, users see a default view of ASCA test labs sorted by ASCA status to highlight TLs with active *ASCA Accreditation*.

- *ASCA quality framework metrics:* The ASCA Program Quality Management Framework, which conforms with the Center's overarching approach to quality management,[22] outlines ASCA's processes, services and management and incorporates the Center's commitment to quality management. In 2025, the ASCA team continued to track its performance:

    - An internal audit of the ASCA program was completed by the CDRH Quality Management and Organizational Excellence (QMOE) Program with no nonconformities.
    - New *ASCA Accreditation* applications: 4 new TLs received *ASCA Accreditation*. The average number of calendar days to decision or a request for additional information was 33 (goal: 60 calendar days).
    - Withdrawals from the ASCA program: 2 TLs were FDA-initiated withdrawals. 3 TLs requested to voluntarily withdraw from ASCA. The average number of calendar days to finalize voluntary withdrawal from the ASCA program was 4 (goal: 15 calendar days).
    - *ASCA Accreditation* scope expansion applications: 15 ASCA-accredited TLs applied for expansions to their ASCA scopes. The average number of calendar days to complete or a request for additional information for these actions was 55 (goal: 60 calendar days).
    - *ASCA Recognition* scope expansion applications: 1 ASCA-recognized AB requested a scope expansion which was processed in 1 calendar day (goal: 60 calendar days).
    - *Accreditation body audits:* The ASCA team concluded (1) audit of an ASCA-recognized AB. 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 TLs to determine how the accreditation body assessed and documented TL performance.

[19] The list of ASCA-recognized ABs may be found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-recognized-accreditation-bodies.cfm
[20] The list of ASCA-accredited TLs may be found here: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm
[21] See https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/asca-accredited-testing-laboratories.cfm
[22] See https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-quality-management-program

- *TL audits:* The ASCA team is conducting audits of ASCA-accredited TLs. Four (4) ASCA-accredited TL audits have been conducted, resulting in two (2) FDA-initiated. withdrawals with the remaining two (2) pending conclusion. The FDA's intent is for audits of ASCA-accredited TLs to continue in 2026.

External Outreach

Accreditation Bodies

During 2025, the ASCA team led 8 virtual meetings with all 5 ASCA-recognized ABs. The purpose of these meetings was to provide direction and answer questions about the *ASCA Accreditation* requirements to which the ABs evaluate TLs. In addition to these meetings and multiple email communications, more than a dozen virtual one-on-one teleconferences with individual ABs were held to support their efforts to successfully evaluate the TLs interested in *ASCA Accreditation*. Finally, the FDA conducted formal training sessions for 17 new technical assessors and managers to support the ASCA-recognized ABs in their assessments of TLs.

Testing Laboratories

Communications with TLs in 2025 continued to emphasize 2 priorities: instruction for how to submit and complete *ASCA Accreditation* applications and collaboration with industry to conduct and report testing in accordance with the ASCA Program specifications and other relevant FDA guidance documents.

Interactions with biocompatibility TLs included the following:

- Mandatory biocompatibility TL meetings: 1
- Technical Assessor training sessions: 12
- One-on-one teleconferences with TLs: 13
- Email communications: more than 200

Interactions with basic safety and essential performance TLs included the following:

- Provided multiple training communications to all ASCA-accredited TLs
- Held ten (10) optional 'Office Hours' meetings
- Provided support to multiple interested TLs inquiring about the ASCA application process
- Facilitated mandatory meeting with ASCA-accredited TLs
- Distributed extensive email outreach to provide programmatic updates

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.

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 2025 included the following:

- Partnered approach to submissions with ASCA Summary Test Report(s) 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 training sessions: 108
    - Biocompatibility training sessions: 24

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, the FDA has begun the process of updating the ASCA guidance documents. On September 23, 2024, the FDA issued the following draft guidances:

- The Accreditation Scheme for Conformity Assessment (ASCA) Program[23]
- Biocompatibility Testing of Medical Devices – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program[24]
- 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[25]

These draft 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 as well as the addition of 5 new biocompatibility test methods. The ASCA team is currently considering the comments received to further streamline and optimize ASCA Program operations including considering future expansion of the Program. When final, these guidances will replace the three ASCA Pilot guidances issued September 25, 2020.

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

[23] See FDA draft guidance available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-program

[24] 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

[25] 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

these events, representatives from TLs, ABs, industry, and standards development organizations shared insights for possible program enhancements and expansion approaches.

- The *Virtual Public Workshop – Accreditation Scheme for Conformity Assessment Expansion*[26] 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 Device*[27] 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.

In 2025, the input provided from interested parties at the workshops, in addition to feedback received from promotional efforts, the ASCA Program Draft Guidances for Industry, Accreditation Bodies, Testing Laboratories, and FDA Staff docket (Docket FDA-2019-D-3805) and the Public Workshop - ASCA and Use of Chemical Analysis to Support Biocompatibility of Medical Devices docket (Docket FDA-2024-N-3336), email, and interested party meetings, is being assessed for possible program enhancements and expansion approaches. The comprehensive feedback gathered from these sources provides the FDA with a substantial foundation of perspectives. The systematic review of this input received is intended to inform FDA's strategic decisions regarding the future enhancement and sustainability of the ASCA Program through modifications to the published draft ASCA guidance documents (as discussed above).

External Outreach

The ASCA team intends to continue to prioritize the development and implementation of educational programs to promote participation in ASCA, including at conferences and stand-alone events. The ASCA team intends to update ASCA web pages, including changes to the lists of ASCA-recognized ABs and ASCA-accredited TLs, in a timely manner. Additionally, the ASCA team intends to continue collaborative promotional initiatives with ASCA-accredited TLs.

Internal Outreach: Staff Training

Continuous training is intended to be provided to CDRH and CBER review staff and management regarding the ASCA Program and the review of ASCA Summary Test Reports. The ASCA team intends to continue the partnered approach to premarket submissions containing ASCA STRs and intends to use lessons learned to further develop future training materials for premarket review staff.

[26] 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

[27] 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

ASCA Annual Report

The ASCA team intends to publish an annual report on ASCA's 2026 progress by the end of January 2027.