



**FDA**

**U.S. FOOD & DRUG  
ADMINISTRATION**

**ACCREDITATION SCHEME FOR  
CONFORMITY ASSESSMENT (ASCA)**  
ANNUAL REPORT CALENDAR YEAR 2022

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Center for Devices and Radiological Health

# ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) ANNUAL REPORT CALENDAR YEAR 2022

**Center for Devices and Radiological Health  
US Food and Drug Administration**

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## SECTION I: INTRODUCTION

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

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

This 2022 ASCA Pilot annual report outlines progress achieved toward the establishment of the ASCA Pilot during the calendar year 2022.<sup>2</sup> The report proceeds as follows:

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

## SECTION II: ASCA PILOT BACKGROUND

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

### ASCA Pilot Goals

The goals of the ASCA program are:

- Enhance confidence in medical device testing
- Promote consistency and predictability in the premarket review process
- Encourage effective use of FDA resources
- Enhance regulatory efficiency
- Support international harmonization

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<sup>1</sup> 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>

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

<sup>3</sup> 21 U.S.C. 360d(d)

<sup>4</sup> See Pub. L. 115-52

<sup>5</sup> See also MDUFA IV Commitment Letter: <https://www.fda.gov/media/100848/download>

<sup>6</sup> See section 514(d)(3)(B) of the FD&C Act.

## ASCA Pilot Design

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

If a device manufacturer chooses to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to the FDA, the device manufacturer includes an ASCA declaration of conformity, an ASCA Summary Test Report and a cover letter that indicates that the submission contains ASCA testing as part of their premarket submission. For testing conducted under ASCA, the 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.

- ASCA Pilot program guidance: [\*The Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program - Final Guidance\*](#)<sup>8</sup>
- 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\*](#)<sup>9</sup>
- Biocompatibility standards-specific guidance: [\*Biocompatibility Testing of Medical Devices- Standards Specific Information for the Accreditation Scheme for Conformity Assessment \(ASCA\) Pilot Program\*](#)<sup>10</sup>

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<sup>7</sup> See <https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html>

<sup>8</sup> The ASCA program guidance can be found here: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program>

<sup>9</sup> 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>

<sup>10</sup> 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>

## Standards in the ASCA Pilot

ASCA includes FDA-recognized consensus standards and related test methods across two scopes: biocompatibility and basic safety and essential performance. These standards were selected because they address critical safety and performance issues and are used broadly across different device types. In addition, they were chosen because their use is frequently associated with FDA requests for additional information and often require additional resources in premarket review. Please see the CDRH Recognized Consensus Standards Database for more information about these standards.<sup>11</sup>

**Table 1: List of standards and test methods for the ASCA Pilot: biocompatibility**<sup>12</sup>

FDA-Recognized Standard	Test method(s)
ISO 10993-4*	SC5b-9 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 Pilot: basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment**<sup>13</sup>

Standard	Standard Title
60601/80601	<i>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)</i>
61010-1	<i>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)</i>

<sup>11</sup> See <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/search.cfm>

<sup>12</sup> 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>

<sup>13</sup> 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>

## SECTION III: ASCA PROGRESS IN 2022

### Device Submissions with ASCA Testing

In 2022, the FDA received five submissions that contain ASCA testing: four with basic safety and essential performance testing and one with biocompatibility testing. The following conclusions were drawn from these submissions:

- The ASCA Summary Test Reports used the format provided in the ASCA standards-specific guidance documents and the declarations of conformity and Summary Test Reports included all critical data and testing conditions.
- FDA reviewers had greater confidence in the ASCA testing results, and because the ASCA Summary Test Reports were complete and because the internal FDA review checklists use a similar format, reviewers were able to conduct the conformity assessment elements of the device reviews efficiently.
- In one submission, a device sponsor used ASCA testing for one test (60601-1) and non-ASCA testing for another, similar test (60601-1-2). The results showed that the ASCA test review found zero deficiencies and the length of the report was one-tenth the length of a typical complete test report. The non-ASCA testing found four deficiencies (one major) and the report was approximately five times the length of the report with ASCA testing.

### Administrative Progress

- As of November 2022, the FDA has granted *ASCA Recognition* to five accreditation bodies<sup>14</sup> and *ASCA Accreditation* to ninety-one testing laboratories, ninety for the basic safety and essential performance scope and one for the biocompatibility scope.<sup>15</sup> All five ASCA-recognized accreditation bodies renewed their applications in 2022.
- *Staff/Resources*: The ASCA Pilot met all hiring targets for the MDUFA IV time period.
- *IT progress*: During MDUFA IV, the ASCA team established a secure system to store documents and manage ASCA workflow processes. The ASCA program has now begun the process to improve this infrastructure as part of CDRH's Digital Transformation initiative.<sup>16</sup>

In response to stakeholder feedback, the ASCA team has also launched a plan to integrate the ASCA webpages with the Recognized Consensus Standards Database<sup>17</sup> to establish a direct connection between the FDA-recognized standards and the scopes of *ASCA Recognition* for accreditation bodies and *ASCA Accreditation* for testing laboratories (these scopes include the

<sup>14</sup> 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>

<sup>15</sup> 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>

<sup>16</sup> More information about CDRH's Digital Transformation may be found here: <https://www.fda.gov/news-events/fda-voices/how-cdrhs-digital-transformation-initiative-will-strengthen-premarket-review-program>

<sup>17</sup> The Recognized Consensus Standards Database may be accessed here: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

standards and test methods for which the accreditation bodies are ASCA-recognized and the testing laboratories are ASCA-accredited).

## CDRH Quality Management Program Audit Results

Working with the CDRH Quality Management Program,<sup>18</sup> the ASCA team developed an ASCA Program Quality Management framework that conforms with the Center’s overarching approach to quality management and takes advantage of the Center’s ISO 9001:2015 Certified Quality Management System (QMS) processes and tools. The ASCA Pilot’s quality framework outlines the program’s processes, services and management and incorporates the Center’s commitment to quality management and to continually improve our products and services.

In 2022, the ASCA team formally requested an audit of the ASCA Pilot’s procedures, products and services to assess: (1) whether the ASCA Pilot met its MDUFA IV commitments and (2) whether ASCA met its established policies, procedures and timelines. A summary of the audit findings follows:

1. MDUFA IV Commitments: the ASCA Pilot met all of its MDUFA IV commitments, including:
  - Public workshop
  - Educational sessions
  - Develop and initiate the Pilot
  - Internal IT system
  - Process for recognizing and accrediting accreditation bodies and testing laboratories respectively
  - Process for reaccreditation and suspension/withdrawal of accreditation bodies and testing laboratories
  - Publicly-accessible website<sup>19</sup>
  - Identify appropriate standards for inclusion in ASCA<sup>20</sup>
  - ASCA annual reports<sup>21, 22</sup>
  - Stakeholder engagement for program improvements
  
2. Policies, procedures and timelines:
  - Accreditation body *ASCA Recognition* decision work items:
    - All six accreditation body work items met their stated sixty-day decision timeline<sup>23</sup>
    - Four of six were completed within thirty days

<sup>18</sup> 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%20bring%20identified%20issues%20to%20a%20satisfactory%20resolution>

<sup>19</sup> See <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>

<sup>20</sup> ASCA standards can be found here:

[https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start\\_search=1&sortcolumn=st&ascapilotyn=on&pagenum=5](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfstandards/results.cfm?start_search=1&sortcolumn=st&ascapilotyn=on&pagenum=5)

<sup>21</sup> The ASCA annual reports may be downloaded at the ASCA web page here: <https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca>

<sup>22</sup> The FY 2019 Performance Report to Congress included a Corrective and Preventive Action (CAPA) associated with the late issuance of the FY 2019 Annual Report. This CAPA was resolved by the time of this audit. The auditor found that all annual reports are available on the ASCA web page.

<sup>23</sup> Five of the work items were for original applications for ASCA Recognition; one was for a scope expansion.



- Testing laboratory *ASCA Accreditation* decision work items:
  - 28% of testing laboratory work items met their stated sixty-day decision timeline
  - Of those over sixty days, 85% were completed within sixty-one days
  - A ‘nonconformity’ was opened for exceeding testing laboratory application review time and a resolution is under development.
- All ASCA Pilot work items followed the ASCA Quality Management framework’s process.
- The audit concluded that the following best practices were demonstrated:
  - Work items in the ASCA Pilot are well-documented.
  - ASCA Pilot items related to MDUFA are readily accessible on the ASCA program’s web page.
  - The ASCA program leverages its quality management tools to track and manage the program.

## External Outreach

### *Accreditation Bodies*

During 2022, the ASCA team led ten virtual meetings with all five 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, approximately twenty-five 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 six formal training sessions for technical assessors and managers to support the accreditation bodies in their assessments of testing laboratories.

### *Testing Laboratories*

Training for testing laboratories emphasized two 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.

Interactions with biocompatibility testing laboratories included the following:

- Two Question and Answer webinars with biocompatibility testing laboratories
- Twenty-eight one-on-one teleconferences with testing laboratories
- Over one hundred and twenty communications by email

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

- Multiple training communications to all ASCA-accredited testing laboratories
- ‘Office Hours’ meetings: three opportunities for testing laboratories to participate in question and answer sessions
- Teleconferences with individual laboratories to support their application processes and prepare them to conduct ASCA testing
- Three mandatory meetings with ASCA-accredited testing laboratories
- Extensive email outreach to provide programmatic updates via email



## Industry

The ASCA team continued to focus its efforts with industry on promoting the Pilot's benefits and how to use ASCA testing, including how submissions with ASCA testing should be compiled.

The ASCA team delivered ten presentations to industry, five to professional societies and standards development organizations, and four to testing laboratories and their customers.

### 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 Pilot. Training initiatives in 2022 included the following:

- Partnered approach to ASCA submissions, whereby an ASCA technical expert from S-CAP was paired with a premarket reviewer for hands-on training to evaluate the testing in an ASCA submission
- Basic safety and essential performance formal training sessions
  - Review staff: two
  - Review managers: two
  - Office of Science and Engineering Laboratories: two
  - CDRH Specialty Task Groups: twelve
- Biocompatibility formal training sessions: CDRH
  - Review staff: one
  - Review managers: three
- Biocompatibility formal training sessions: CBER
  - Review staff: one
  - Review managers: one
- Enhanced the internal-facing *ASCA Reviewer Resource Page* with links to training materials, work instructions, and other tools to hone reviewer skills
- Town Halls
  - CDRH: one
  - Office of Strategic Partnerships and Technology Innovation (OST): one
  - Standards and Conformity Assessment Program: two

## SECTION IV: ASCA NEXT STEPS

### Transition to Permanent Program

The MDUFA V reauthorization<sup>24</sup> converts the ASCA Pilot to a permanent program. In 2023, the ASCA team will take steps to support this transition.

To prepare for the transition to a permanent program and to accommodate program improvements consistent with MDUFA V commitments, the FDA has begun the process of updating the ASCA guidance

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<sup>24</sup> See sec. 2005 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, P.L. 117-180, available at <https://www.congress.gov/117/plaws/publ180/PLAW-117publ180.pdf>

documents. We intend to seek public comments on changes to the guidances as FDA transitions from the Pilot to the permanent program.

### **External Outreach**

The ASCA team intends to prioritize educational programs to encourage participation in ASCA, including at conferences and stand-alone events. Timely updates will be published 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 intends to hold regular meetings with stakeholders to discuss progress on ASCA programmatic details. As appropriate, the ASCA team intends to conduct site visits with accreditation bodies and testing laboratories as part of our obligations under the program specifications.

Finally, the ASCA team intends to begin discussions with stakeholders on the development of decision criteria to determine how to appropriately expand the ASCA program. This outreach may entail a public workshop or other means to solicit input on how expansion decisions should be approached.

### **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 testing.

### **ASCA Pilot Evaluation**

The ASCA team will evaluate ASCA Pilot performance and analyze submission and other data. Per the MDUFA V Commitment Letter,<sup>25</sup> the ASCA team will complete an assessment of the viability of the ASCA Pilot by March of 2024.

### **ASCA Annual Report**

The ASCA team intends to publish an annual report on ASCA's 2023 progress by the end of January 2024.

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<sup>25</sup> The MDUFA V Commitment Letter can be found here: <https://www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2022-mdufa-v>