

The Accreditation Scheme for Conformity Assessment (ASCA): A New CDRH Program to Streamline Device Review

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Abstract

The Standards and Conformity Assessment Program (S-CAP) at FDA encourages manufacturers to rely upon consensus standards in their device submissions. Citing an FDA-recognized standard typically reduces the amount of conformity assessment documentation needed and streamlines FDA review. Device submission analysis by FDA's standards staff revealed that standards are frequently used inappropriately, resulting in extraneous documentation and delays in assessing conformity in device review.

To improve the use of standards, S-CAP devised the Accreditation Scheme for Conformity Assessment (ASCA), in which qualified testing laboratories may receive *ASCA Accreditation* to certain frequently cited standards, with the expectation that ASCA testing in submissions will require less documentation and review. Though results are preliminary, the submissions received to date highlight that review of ASCA testing was more efficient than non-ASCA testing.

Introduction

ASCA capitalizes on the increasing prominence and advantages of international voluntary consensus standards in regulatory science. Since consensus standards are essentially 'crowd-sourced' across many types of experts around the globe, their quality is enhanced. Standards also provide a least-burdensome approach to regulation because expectations across international jurisdictions can be harmonized.

FDA formally recognizes consensus standards that meet our expectations for regulatory applications. When a manufacturer cites an FDA-recognized standard, they include a declaration of conformity in their submission which typically means less documentation is needed. ASCA builds upon this use of recognized standards, providing the following advantages over using non-ASCA standards:

- Less need for Additional Information questions, and fewer expert consults are required because complete test reports are rarely needed
- Identifies the minimum documentation needed to accompany a declaration of conformity
- Templates are provided for ASCA declarations of conformity and Summary Test Reports

ASCA was designed to reduce the time needed to review conformity assessment in device submissions.

Materials and Methods

ASCA began as a pilot program, authorized by the Medical Device User Fee Amendments of 2017 (MDUFA IV). First, S-CAP identified the problems we wished to solve:

- Unnecessary delays in reviewing conformity assessment due to confusion among manufacturers about needed documentation
- Unnecessary Additional Information questions and internal consults
- Excessive review of complete test reports

Based upon this analysis, S-CAP established the main goal for ASCA: to streamline conformity assessment in premarket device submissions.

S-CAP then conducted a two-day public workshop to determine the program parameters that would drive progress toward this goal. S-CAP worked with participants from across the medical device manufacturing, standards, conformity assessment, and regulatory communities to conceptualize the foundation for the ASCA pilot. Tables 1 and 2 list the standards included in

Specifically, standards from two commonly used and important series were chosen.

Table 1: Basic Safety and Essential Performance standards

Standard	Standard Title
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 series)
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 series)

Table 2: Biocompatibility standards

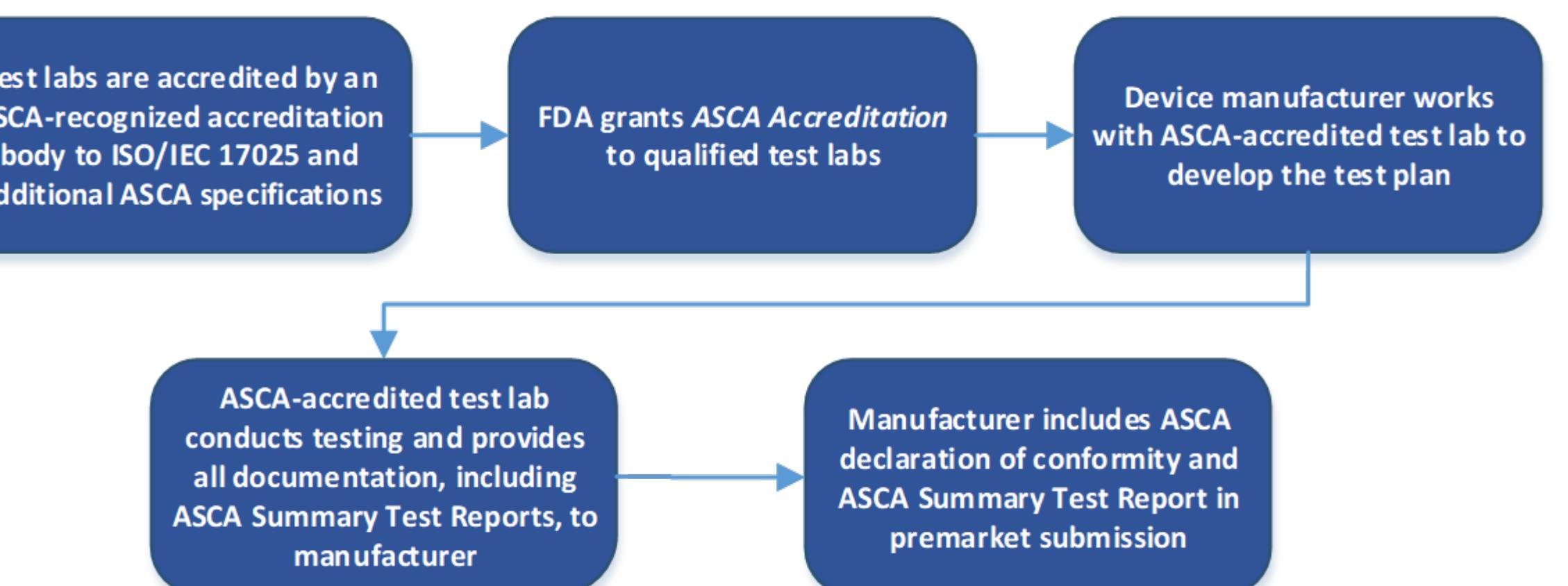
FDA Recognized Consensus Standard	Test Method(s)
ISO 10993-4	Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-23*	In Vivo Dermal Irritation, Intracutaneous Reactivity Irritation
ISO 10993-10*	Closed Patch Sensitization
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

Working with a conformity assessment expert from the National Institute for Standards Technology (NIST), the team drafted the program parameters, relying heavily upon two international conformity assessment standards to create a program that is not 'home grown' and instead follows international guidelines whenever possible.

Results and Discussion

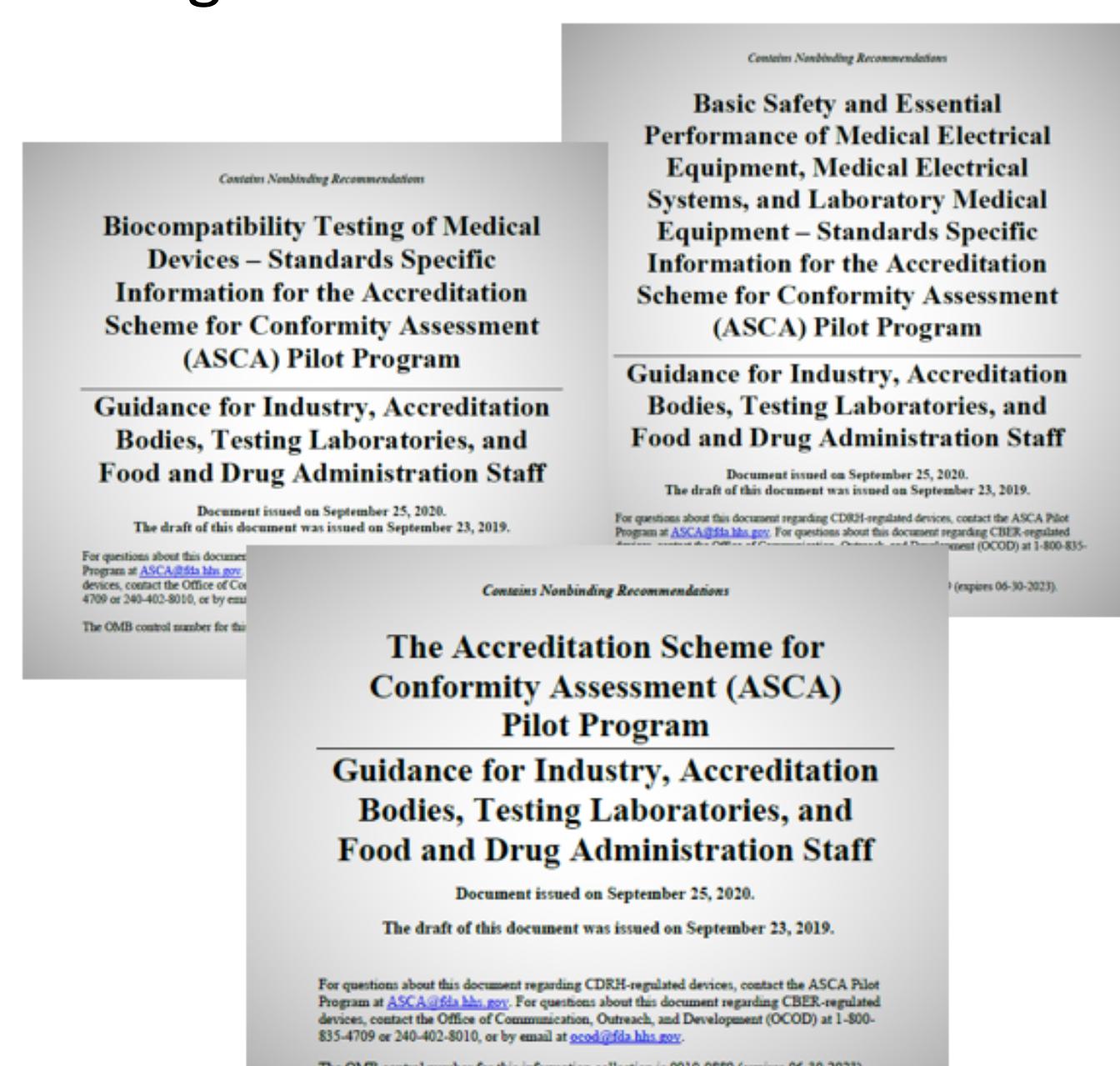
The ASCA team established the following scheme, depicted in Figure 1:

Figure 1: the ASCA Scheme



As is customary, the program was established by guidance, the draft of which received public consultation. Once comments were considered, three final guidances were published outlining how the program works, and the program specifications testing laboratories must meet to qualify.

Figure 2: the ASCA guidance documents



The standards-specific guidances include example ASCA declarations of conformity and ASCA Summary Test Reports for the test labs and manufacturers. The ASCA Summary Test Report templates are designed to provide the information that FDA staff need in a streamlined format to facilitate the review of these elements of a premarket submissions. FDA review staff use a mirrored document and checklist to conduct their reviews according to ASCA principles, further enhancing efficiencies. A sample biocompatibility Summary Test Report appears in Figure 3. It is two pages in total and may take less than 30 minutes to review.



Figure 3: a sample biocompatibility Summary Test Report

Extensive communications and program promotion followed to encourage accreditation bodies and testing laboratories to apply for participation. The team created the processes and work instructions to implement the program and a database to manage documentation and ensure adherence to ASCA policies. An internal quality management framework compliant with CDRH's Quality Management System was established and an audit was conducted; the results concluded that ASCA met all expectations and followed all internal procedures. Feedback about the ASCA program from conformity assessment bodies and industry has been uniformly positive; manufacturers directed FDA in the latest MDUFA cycle (2023-2027) to convert the program from a pilot to a permanent program and provided sufficient funds to support the transition and consider expansion.

The FDA has granted *ASCA Recognition* to five accreditation bodies and *ASCA Accreditation* to ninety-six testing laboratories, ninety-four for the basic safety and essential performance scope and two for the biocompatibility scope. The FDA has received 20 submissions with ASCA testing, across five OHTs. The results:

- 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.

Conclusion

FDA has increased confidence in the testing contracted and performed at ASCA-accredited testing laboratories. The ASCA program, while in its infancy, is so far meeting its goals of streamlining conformity assessment in device review. Additionally, through its application reviews, ASCA has also highlighted areas that test labs can improve the quality of their testing and reporting. Finally, to support long term success data from additional submissions will facilitate a deeper analysis of the ASCA program and drive future improvements.