



The Accreditation Scheme for Conformity Assessment of Medical Devices to FDA-Recognized Standards Pilot Program (ASCA)

Introduction

The Food and Drug Administration (FDA) and the medical device community are committed to making safe and effective medical devices available to patients in an efficient and least burdensome manner. An important element of FDA's regulatory framework is a robust standards program. The Center for Devices and Radiological Health (CDRH) encourages medical device sponsors to use recognized consensus standards in their submissions; conformance with relevant standards fosters quality and promotes public health.

CDRH is expanding its standards program to include an accreditation initiative that will improve the device review process by enhancing product reviewers' confidence in conformance documentation from manufacturers. This pilot program, endorsed and funded in the 2017 Medical Device User Fee Amendments (MDUFA), is entitled the *Accreditation Scheme for Conformity Assessment*, or ASCA. The ASCA pilot aims to streamline the conformity assessment of medical devices when certain FDA recognized standards are used.

ASCA capitalizes upon the increasingly prominent role that standards play in regulatory science and practice. It will authorize FDA-qualified Accreditation Bodies (ABs) to accredit testing laboratories (TLs) to ASCA program requirements that are built upon international consensus conformity assessment standards. This voluntary pilot's system of checks and balances will enhance FDA's confidence in TLs' attestations of a product's conformity to standards, which means that reviewers will be able to accept manufacturers' Declarations of Conformity based upon these attestations without further review of the test protocols and detailed test results. The expected result: increased consistency and predictability in the way FDA determines conformance to standards in product review.

This report outlines the ASCA scheme and introduces readers to the contours of the program. It then offers details about a public workshop being held May 22-23, 2018 designed to familiarize attendees with CDRH's approach and elicit their feedback. Participants' input will also be used to develop a draft guidance for manufacturers and FDA staff. The report closes with a summary of anticipated next steps as the pilot takes shape over the next four years.

How ASCA Works

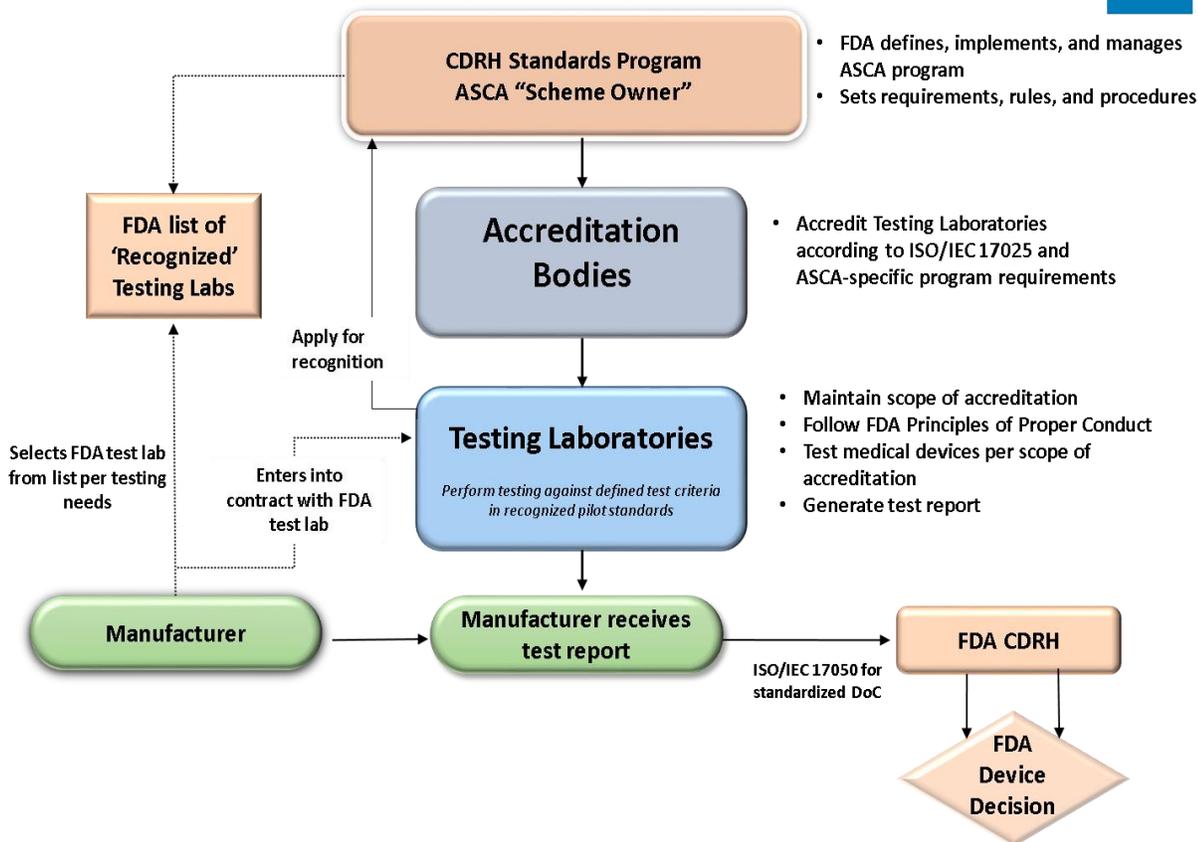
Under the ASCA pilot, the FDA will select one or more ABs who meet FDA-specified program requirements to accredit testing laboratories to assess conformance with certain standards. Testing labs may apply to these ABs for accreditation in order to qualify to perform testing for device sponsors. Testing labs accredited to ASCA-specific requirements may then apply to FDA for recognition to participate in this pilot program. From the initial accreditation through subsequent years' re-accreditations, the ABs will manage the processes and administrative requirements necessary to ensure that testing labs conduct testing in a manner that satisfies program expectations.

Manufacturers will be able to contract with the ASCA recognized testing labs to perform testing and provide test reports and summaries. Manufacturers can then use this information to support a Declaration of Conformity (per

ISO/IEC 17050 ‘Conformity assessment – Supplier’s declaration of conformity’) to standards in the ASCA pilot. Since these reports originate from a trusted – and accredited – source, manufacturers and the FDA can be confident that their contents are complete and accurate. Figure 1 below depicts the relationships between the FDA, the ABs, testing labs and manufacturers.

Figure 1: ASCA Pilot Roles and Work Flow

ASCA Conformity Assessment Model



Standards to be Piloted

The FDA conducted an analysis of potential standards to determine which would be appropriate to include in the ASCA pilot. The program will use standards from IEC 60601 and ISO 10993 (see Table 1 below for specific standards to be piloted). Standards from these two important standards families were chosen because they are used broadly across different devices, and reviewers and manufacturers have a high degree of confidence in them and their utility. They are performance based, and have at least some pass/fail criteria, or the means to establish these criteria. They feature consistent and repeatable test methods and procedures, and their application will yield valuable experience for the ASCA pilot.

Table 1 Standards Selected for the ASCA Pilot Program

| Standard | Device | Standard | Test |
|-----------|---|-------------|---|
| 60601-1 | Base standard Basic Safety and Essential Performance | ISO 10993-5 | Cytotoxicity |
| 60601-1-2 | Collateral Electromagnetic Compatibility for all devices | 10993-10 | Irritation Sensitization |
| 60601-1-8 | Collateral alarms for all devices | 10993-11 | Acute Systemic Toxicity Material-Mediated Pyrogenicity Test =+ USP 151 Pyrogenicity |
| TBD | Device-specific standard | 10993-4 | Hemolysis + Complement Activation; ASTM F756 |

Program Requirements

The ASCA scheme relies upon ISO/IEC 17025 'General requirements for the competence of testing and calibration laboratories.'¹ ASCA builds on the foundation that this important international consensus standard provides to identify program requirements for the testing laboratories who wish to become accredited. As ISO/IEC 17025 is a framework of basic expectations, it is incumbent upon the scheme developers, in this case the FDA, to build out this framework with details specific to the standards to which the testing labs will be accredited. The ASCA team is in the process of identifying expectations specific to the standards chosen for the pilot program. It is anticipated that additional ideas will emerge from the ASCA public workshop (see details below).

The Public Workshop

The ASCA public workshop² will take place at the FDA White Oak, Maryland campus on May 22 and 23, 2018. Its purpose is to share with stakeholders a draft design of the ASCA program. FDA hopes to obtain input and recommendations on the ASCA program, its framework and procedures, and requirements. Feedback gained through this meeting will also aid in the development of a draft ASCA guidance, another MDUFA IV commitment.

This workshop presents background information about the proposed ASCA pilot program, its objectives and plans, what issues it aims to resolve and how. It will consist of both plenary presentations and breakout sessions. A keynote presentation will provide high-level background information about standards use and standards conformity assessment in medical device regulatory processes, major existing conformity assessment programs, and significance of and challenges to national and international harmonization.

Following plenary presentations, breakout sessions will be convened. Each breakout session is designed to focus on a major ASCA-related topic and to elicit thoughtful improvements from session participants. The topics to be discussed include:

- Performance metrics to judge the success and impact of the ASCA program
- Technical and administrative requirements for Accreditation Bodies
- Discussion of the standards selected for the ASCA pilot
- Roles the test labs can play in the ASCA pilot

¹ <https://www.iso.org/standard/39883.html>

² Details can be found at <https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm592094.htm>

Next steps

The ASCA program is expected to promote efficiencies in regulatory submissions and streamline the review process. Its benefits will extend beyond device review processes and may indeed promote the use of standards in regulatory processes and advance regulatory science.

This pilot will benefit from participation by all stakeholders. CDRH asks that you give careful thought to how the scheme can be improved, and come to the public workshop prepared to share your insights. Your feedback will enable us to implement a framework that meets the needs of manufacturers, while maintaining our emphasis on safety and quality. We encourage you to attend and contribute your expertise to these efforts, including the publication of a formal guidance in the future. Ultimately, a sound program will help bring better devices to market sooner, and that means that the needs of the most important beneficiaries – patients – will be met.