

FDA FACT SHEET

THE ACCREDITATION SCHEME FOR CONFORMITY ASSESSMENT (ASCA) PILOT PROGRAM: Draft Guidance

NOTE: *The draft guidance is distributed for comment purposes only. Program will be initiated upon publication of the final guidance.*

The [ASCA draft guidance](#), published on September 23, 2019, outlines the voluntary ASCA Pilot Program's proposed expectations for medical device manufacturers, accreditation bodies and testing laboratories. This Fact Sheet provides an abbreviated overview of the draft guidance. It does not offer a comprehensive review of the guidance and readers should carefully examine the full draft guidance to gain a complete understanding of program details as currently proposed.

Introduction

The voluntary ASCA Pilot Program is intended to capitalize upon the growing prominence of consensus standards in medical device review, offering a means to make conformity assessment in medical device review more efficient. A voluntary program, in accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA), and as part of the enactment of [MDUFA IV](#), to the Federal [Food, Drug & Cosmetic Act](#), the ASCA Pilot is intended to enhance confidence in manufacturers' Declarations of Conformity (DOC) through the use of ASCA-accredited testing laboratories. In short, the FDA, relying upon international conformity assessment standards and a set of FDA-identified ASCA program specifications, proposes to recognize accreditation bodies who would accredit testing laboratories to test medical devices using ASCA-eligible standards. The next step would be *ASCA Accreditation* of the testing laboratories by the FDA, after which manufacturers may engage them for testing to ASCA-eligible standards. Since the test results would come from an ASCA-accredited testing laboratory, the FDA would not need to review the complete test reports supporting the Declaration of Conformity nor ask for additional information or internal FDA consultations regarding test methods unless warranted.

What are the qualifications for the Accreditation Bodies and Testing Laboratories to participate in the ASCA Pilot?

As currently proposed, the ASCA Pilot would utilize international conformity assessment standards as the foundation of the program. In order to be recognized by the FDA for participation in the ASCA Pilot, accreditation bodies would need to have signatory status with the International Laboratory Accreditation Cooperation (ILAC)'s Mutual Recognition Arrangement (MRA), which requires compliance with [ISO/IEC 17011: 2017 Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies](#).

Testing laboratories would be accredited by an ASCA-recognized accreditation body to [ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories](#) as well as additional ASCA program specifications that build upon the framework of ISO/IEC 17025. Note that ISO/IEC 17025 outlines requirements for testing laboratories to demonstrate competence and the ability to generate valid results; for example, resource requirements, equipment and facility needs, handling samples, different validation methods and reporting results. ISO/IEC 17025 is typically used as the foundation for conformity assessment schemes, to which additional specifications are added, based on the scope of the program. Thus, in addition to compliance with ISO/IEC 17025, testing laboratories would also need to meet ASCA program specifications, which include personnel competency expectations such as qualifications and training, handling test and calibration items, and specifics for reporting results, as well as equipment needs for the standards and test methods eligible for inclusion within the ASCA Pilot.

How would the ASCA Pilot work?

Under the ASCA Pilot program, an accreditation body would request recognition from the FDA demonstrating their qualifications and agreeing to the terms of participation. Once an accreditation body is recognized by the FDA to a particular scope, it would in turn be able to accredit testing laboratories to ISO/IEC 17025 and the ASCA program specifications.

Once a testing laboratory is accredited by an accreditation body, it would apply to the FDA in a two-step process to gain *ASCA Accreditation*. In the first step, the FDA would recognize it for the purpose of the ASCA Pilot, identifying the scope of ASCA-eligible standards and test methods. In the second step, the FDA would grant *ASCA Accreditation*, if appropriate. Once a testing laboratory is ASCA-accredited, it would be able to conduct testing for manufacturers to determine conformance of a device with a standard included in the ASCA Pilot. When an ASCA-accredited testing laboratory conducts such testing, it would provide a complete test report containing the information specified by the ASCA Pilot to the device manufacturer, who could then include a Declaration of Conformity, (along with supplemental documentation such as summary test report(s), examples of which appear in Appendices in the draft guidance), as part of a premarket submission to the FDA. The 2018 [Appropriate Use of Consensus Standards in Premarket Device Submissions](#) offers more information about Declarations of Conformity and their important role in regulatory review.

What standards and test methods are being proposed for the ASCA Pilot?

Standard	Standard Title	Test method(s)
Biological evaluation of medical devices		
ISO 10993-4	ISO 10993-4: <i>Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood</i>	Complement Activation
ISO 10993-4 and ASTM F756	ISO 10993-4: <i>Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood</i> ASTM F756: <i>Standard Practice for Assessment of Hemolytic Properties of Materials</i>	Direct and Indirect Hemolysis
ISO 10993-5	ISO 10993-5: <i>Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity</i>	MEM Elution Cytotoxicity
ISO 10993-10	ISO 10993-10: <i>Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization</i>	Dermal Irritation, Intracutaneous Reactivity Irritation, Guinea Pig Maximization Sensitization, and Closed Patch Sensitization
ISO 10993-11	ISO 10993-11: <i>Biological evaluation of medical devices – Part 11: Tests for systemic toxicity</i>	Acute Systemic Toxicity
ISO 10993-11 and USP 151	ISO 10993-11: <i>Biological evaluation of medical devices – Part 11: Tests for systemic toxicity</i> USP <151>: <i>Pyrogen Test</i>	Material-Mediated Pyrogenicity
ISO 10993-12	ISO 10993-12: <i>Biological evaluation of medical devices – Part 12: Sample preparation and reference materials</i>	Sample preparation for all test types
Basic safety and essential performance		
ANSI/AAMI 60601-1	<i>Medical electrical equipment – Part 1: General requirements for basic safety and essential performance</i> (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601/80601 family)	
IEC 61010-1	<i>Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements</i> (along with the FDA-recognized particular standards in the IEC 61010 family)	

For more information:

- [Accreditation Scheme for Conformity Assessment \(ASCA\)](#)

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U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov