The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Overview

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October 8, 2019
Discussion Topics

➢ FDA Standards & Conformity Assessment Program (S-CAP)
➢ Proposed ASCA Pilot Program
  • Background
  • Conformity Assessment Model
  • Scope of Accreditation – Selected Standards
  • Program Specifications
  • Participant Qualifications
➢ Questions/Discussion
FDA Standards & Conformity Assessment Program

➢ Enhances the use of consensus standards in the design, development and evaluation of medical devices across their lifespans

➢ Relies upon a collaborative approach to standards development and application

➢ Draws upon expertise from across the medical device and standards communities
  • advances regulatory science;
  • promotes patient safety; and
  • supports a least burdensome regulatory framework
S-CAP Standards Recognition Program

➢ Section 514(c) of FD&C Act
  • Clarified how FDA will process requests for recognition and how manufacturers may use a Declaration of Conformity (DoC) towards recognized standards

➢ Requires FDA to publish rationale for recognition (or non-recognition) of standards

➢ Mandates training for FDA staff

➢ Development of accreditation program (ASCA) to a subset of recognized standards
ASCA Background

➢ Medical Device User Fee Amendments of 2017 (MDUFA IV)
  • FDA & Industry agreed to establish a conformity assessment accreditation scheme for testing laboratories
  • evaluate medical devices according to certain FDA-recognized standards

➢ The FDA Reauthorization Act of 2017 (FDARA) amended section 514 of the FD&C Act by adding a new subsection (d) titled, “Pilot Accreditation Scheme for Conformity Assessment”
What is the Proposed ASCA Pilot Program?

A voluntary pilot conformity assessment program to improve the premarket regulatory process

- Uses FDA-accepted accreditation bodies to accredit test labs to certain recognized standards
- Standardized test reports from device sponsors will enhance consistency and predictability
ASCA Conformity Assessment Hierarchy

Accredits Testing Labs according to ISO/IEC 17025 and FDA program specifications

Conducts testing and produces test reports of specific product characteristics per defined test method

FDA
- Defines and oversees pilot
- Establishes additional specific program specifications to clarify ISO/IEC conformity assessment standards
- Specifies rules and procedures for approval at all levels of the program

Accreditation Body
ISO/IEC 17011 + FDA program specifications

Testing Laboratory
ISO/IEC 17025 + FDA program specifications

Medical Device Product Characteristics
Basic Safety and Essential Performance
Biocompatibility

Manufacturer contracts with testing lab for testing report to submit to FDA
## Proposed ASCA Pilot Scope

The following standards have been proposed for scope of accreditation during the ASCA Pilot Program.

### Basic Safety & Essential Performance of medical electrical equipment, medical electrical systems, & laboratory equipment

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
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<tbody>
<tr>
<td>ANSI/AAMI ES60601-1</td>
<td>Medical electrical equipment—Part 1: General requirements for basic safety and essential performance <em>(along with the FDA-recognized collateral and particular standards in the 60601 family)</em></td>
</tr>
<tr>
<td>IEC 61010-1</td>
<td>Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements <em>(along with the FDA-recognized particular standards in the 61010 family)</em></td>
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### Biological Evaluation of Medical Devices

<table>
<thead>
<tr>
<th>Standard</th>
<th>Tests</th>
</tr>
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<tbody>
<tr>
<td>ISO 10993-4*</td>
<td>Complement Activation</td>
</tr>
<tr>
<td>ISO 10993-4 and ASTM F756</td>
<td>Direct and Indirect Hemolysis</td>
</tr>
<tr>
<td>ISO 10993-5</td>
<td>MEM Elution Cytotoxicity</td>
</tr>
<tr>
<td>ISO 10993-10</td>
<td>Dermal Irritation, Intracutaneous Reactivity</td>
</tr>
<tr>
<td>ISO 10993-11</td>
<td>Acute Systemic Toxicity</td>
</tr>
<tr>
<td>ISO 10993-11 and USP 151</td>
<td>Material-Mediate Pyrogenicity</td>
</tr>
<tr>
<td>ISO 10993-12</td>
<td>Sample preparation for all test types</td>
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</tbody>
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* See also ISO/TS 10993-20 for information on when complement activation should be considered for anaphylaxis *(Table 2, Hypersensitivity Column)*
Proposed ASCA Program Specifications

Draft guidance Appendix A and B built upon framework of ISO/IEC 17025.

➢ Each Appendix identifies the program specifications for each ASCA scope of accreditation above and beyond the ISO/IEC 17025 specifications

  • Appendix A: ASCA Program Specifications for the Biological Evaluation of Medical Devices
  
  • Appendix B: ASCA Program Specifications for the Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Equipment
Proposed Roles and Responsibilities

Accreditation Bodies
- TLs request accreditation
- ABs accredit TLs using ISO 17025 and ASCA program specifications
- ABs maintain qualifications for participation

Testing Laboratories
- TLs conduct device testing and provide test reports
- TLs maintain qualifications for participation

Device Manufacturers
- Device manufacturers request device testing
- FDA grants and withdraws recognition
- FDA grants and suspends ASCA Accreditation
- FDA provides training and program updates
- FDA conducts audits

FDA
- FDA reviews and provides final decision on premarket submission
- FDA provides training and program updates
- FDA conducts audits
- FDA grants and suspends ASCA Accreditation
Proposed ASCA Application Processes – ABs & TLs

1. Device manufacturers may use summary test reports in premarket submissions from ASCA-accredited TLs
2. FDA recognizes qualified TLs for ASCA Pilot participation and grants ASCA Accreditation
3. Device manufacturers may select ASCA-accredited TLs for testing
4. TLs may apply to participate in the ASCA Pilot
5. TLs receive accreditation from recognized ABs
6. FDA recognizes qualified ABs for ASCA Pilot participation
7. ABs may apply to participate in the ASCA Pilot

START

ABs may apply to participate in the ASCA Pilot

Device manufacturers may use summary test reports in premarket submissions from ASCA-accredited TLs

END
Proposed ASCA Participant Qualifications

➢ Accreditation Body
   • ILAC MRA signatory status
   • Based in USA
   • Agreement to terms and conditions of Appendix C in draft guidance

➢ Testing Laboratories
   • Requested scope of recognition is consistent with scope of accreditation provided by accreditation body recognized as participating in the ASCA Pilot Program.
   • Agreement to terms and conditions of Appendix D in draft guidance
Teamwork:
- Accreditation Bodies
- Testing Laboratories
- Device Manufacturers
- FDA
Stakeholder Considerations

Commenting period is 90 days. Comments are due by December 23, 2019.

Resources


➢ FDA Recognized Consensus Standards Database Link: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

Questions?

Standards and Conformity Assessment Program, ASCA Pilot: ASCA@fda.hhs.gov