December 23, 2019

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852


The Advanced Medical Technology Association (“AdvaMed”) is pleased to provide these comments in response to the Food and Drug Administration (“FDA” or “Agency”) Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff: “Accreditation Scheme for Conformity Assessment (“ASCA”) Pilot Program” (September 2019).

AdvaMed is the world’s largest association representing manufacturers of medical devices, diagnostic products, and health information systems. AdvaMed member companies produce technologies that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. Our members produce nearly 90 percent of the health care technology purchased annually in the United States and more than 50 percent of such technology purchased annually around the world. AdvaMed members range from the smallest to the largest medical technology innovators.

GENERAL COMMENTS

We support the Agency’s use of international voluntary consensus standards to meet regulatory requirements, which will further efforts to harmonize global medical technology regulations. Using international voluntary consensus standards to meet regulatory requirements has many benefits, including introducing efficiencies for both the regulators and the medical device industry. Such standards help minimize unnecessary costs and delays in patient access to innovative new devices. The open process encourages participation by a broad group of stakeholders in development of standards, resulting in consensus among users, practitioners, manufacturers, and government regulators on safety and effective use of devices.

We appreciate the substantial effort that FDA has put into developing this draft guidance, including extensive outreach to multiple stakeholders. We also appreciate the leveraging of ISO 17025. We provide general and specific edits that we hope will help ensure the success of the pilot. We also provide a draft proposal for the test report referred to in Annex F of the ASCA Draft Guidance.
FDA should establish metrics to objectively measure the value and effectiveness of the ASCA Pilot program.

FDA describes in the ASCA Draft Guidance goals of the program, including enhancing regulatory efficiency and international harmonization. We support these goals and request that FDA establish objective metrics to measure these goals. We also would add to the list a goal to foster partnerships among all stakeholders.

In our view, a successful pilot program would result in acceptance by FDA of the accredited report/certification without substantive review by FDA except as part of a periodic quality audit or if FDA becomes aware of new information materially relevant to safety and/or effectiveness. In measuring success, we will look for reduced review times from FDA. We would like to see FDA accept the referenced standards that are part of the program entirely on the presentation of a Declaration of Conformity (“DoC”), with no additional data or review during a 510(k) evaluation. We seek very few, if any, additional information requests related to accredited reports/certifications and/or conformance to the cited standard.

As an objective measure of this goal, FDA should plan to collect and publish data on the percentage of ASCA Pilot accredited tests submitted for which additional information is requested or questions are asked, and the reasons, as well as the percentage of ASCA Pilot accredited tests submitted for which this does not occur.

FDA should provide additional clarity regarding the scope and performance of audits of the testing laboratories and should clarify that it will not review internal audit reports. We request additional clarity regarding topics including how often audits will occur, whether the audits will be announced in advance, whether the audit will be in concert with already scheduled audits by the accrediting body, the rationale for the audit, how non-conformities will be handled, and how FDA will handle removal from the pilot program. FDA should clarify that manufacturers using ASCA will not experience an increased possibility of an audit targeting design controls and supplier management.

FDA has long recognized that, to facilitate effective internal auditing and management review, as well as the associated continuous improvement, records from internal auditing and management review generally should not be subjected to FDA review. “FDA will not review or copy reports and records that result from audits and inspections of the written quality assurance program, including audits conducted under 21 C.F.R. Part 820. . . . The intent of the policy is to encourage firms to conduct quality assurance program audits and inspections that are candid and meaningful.” FDA Compliance Policy Guide. In addition, 21 C.F.R. Part 58 states, “The records inspection and copying requirements shall not apply to quality assurance unit records of findings and problems, or to actions recommended and taken.” Moreover, FDA explained in Federal Register / Vol. 61 No. 195 / 52637 that, “FDA disagrees with the comment that quality audit reports should be subject to FDA review...and believes that the disclosure of the reports themselves would be counterproductive to the intent of the quality system... FDA, as a matter of policy, will not request to review or copy during a routine inspection...quality audit reports. FDA may request an employee in management with executive responsibility to certify in writing that the management reviews (and) quality audits... have been performed.”

Furthermore, a Testing Laboratory (“TL”) accredited to ISO 17025 already undergoes an onsite audit by the Accrediting Body (“AB”) every two years. Additionally, although not specifically required by
ISO 17205 (which only states adequate intervals), several credible ABs have all stated that they perform a paper review in the alternate years when the onsite audits are not performed. A management review report from the TL regarding ISO 17025 serves as an input to each of these annual audits by the AB, and each of these annual audits by the AB results in a report to the TL and a renewal decision regarding the TL’s ISO 17025 accreditation. FDA’s ability to review these reports and accreditations, and to observe the AB’s onsite audits of the TL, should be sufficient to satisfy the needs of ASCA.

The guidance should be revised to clarify that, for ASCA, FDA may review the following: the written processes and procedures for internal auditing and management review by ABs and TLs; the planned and executed schedules for internal auditing and management review by ABs and TLs; and the conclusions from internal auditing and management review by ABs and TLs.

However, to avoid discouraging candid and meaningful internal auditing and management review, as well as the associated continuous improvement, the guidance should be revised to clarify that FDA does not plan to participate as an observer during internal auditing and management review by ABs and TLs, and FDA does not plan to review the records from or reports from internal auditing and management review by ABs and TLs.

FDA should provide additional detail regarding how to ensure clear and transparent communication among all ASCA pilot participants regarding changes to an organization’s participation in the ASCA Pilot. While the draft guidance discusses the importance of clear and transparent communication between all participants in the ASCA Pilot, we seek additional detail of how FDA intends to accomplish this goal. For instance, in addition to maintaining an updated list of ABs/TLs on the ASCA website, including their scopes of recognition, we would suggest FDA also indicate on the website changes to the status of recognition (withdrawal or suspension) as applicable. As an alternative, we would request that FDA outline other ways the Agency will communicate with manufacturers regarding withdrawal or suspension status of ABs or TLs. We also would recommend that the guidance state that a TL should inform manufacturers with whom they have conducted business in relation to the ASCA program about any changes to their ASCA recognition within a certain timeframe, particularly when it concerns suspension activities or when the TL becomes aware of withdrawal or suspension of the AB that provided the accreditation.

FDA should address how revisions/updates to the standards will affect the pilot. We seek additional information about how revisions to standards and subsequent updates to the recognized FDA consensus standards included in the ASCA program pilot will affect the accreditation/recognition of test laboratories. For instance, it is unclear whether revision/updates to the standards would be cause for suspension and how relevant information (e.g., suspension/withdrawal) would be communicated. We would appreciate clarification as to how FDA will handle updates/revisions to the standards in the program.

FDA should consider adding examples of DoCs for TLs participating in the program. Given that the goals of the ASCA program include promoting consistency and predictability in the premarket review process, we request that FDA consider including examples of what the Declaration of Conformity (“DoC”) issued by testing laboratories participating in the ASCA Pilot program may look like. For example, it would be helpful to have an example of what the DoC would look like from a test laboratory that has been recognized to conduct conformity assessment for an entire standard versus those testing laboratories that have been recognized to only conduct conformity assessment per specific test methods.
AdvaMed thanks FDA for its consideration of these general comments, the specific comments that follow and the draft proposal for the test report referred to in Annex F of the ASCA Draft Guidance. Please do not hesitate to contact me at 202-434-7230 or jwolszon@advamed.org if you have any questions.

Respectfully submitted,

/s/

Jamie Wolszon
Associate Vice President
Technology and Regulatory Affairs

Attachment
"Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff: The Accreditation Scheme for Conformity Assessment"

Additions are indicated in underline.
Deletions are indicated in strikethrough.

<table>
<thead>
<tr>
<th>Line(s) No</th>
<th>Proposed Change</th>
<th>Comment/Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>139-41</td>
<td>When an ASCA-accredited testing laboratory conducts such testing, it may <em>should</em> provide a complete test report to the device manufacturer containing the elements listed in Appendices A and B of this guidance.</td>
<td>We would strengthen the language from &quot;may&quot; to &quot;should&quot; as the draft guidance includes complete test reports as part of premarket submissions during the pilot.</td>
</tr>
<tr>
<td>148</td>
<td>Testing performed using a previous version of the standard that has been revised can be submitted in the premarket submission if the testing was in progress or completed prior to the revision of the standard.</td>
<td>Testing could be in progress or completed at the time of the revision of the standard. Please include a statement clarifying that testing performed using a previous version of the standard that has been revised can be submitted in the premarket submission if the testing was in progress or completed prior to the revision of the standard. This approach is consistent with the Appropriate Use Guidance. This specific comment elucidates the need for more general clarity, as discussed in the cover letter, regarding how revisions/updates to standards will implicate the pilot.</td>
</tr>
<tr>
<td>191-193</td>
<td>As part of the enactment of MDUFA IV, FDA committed to publish a list of accreditation bodies and testing laboratories participating in the ASCA Pilot, including the standards within their scopes of recognition, on the FDA’s ASCA website. The ASCA website will include information on the specific test methods for a particular standard for which an accreditation body or testing laboratory is recognized.</td>
<td>Since test laboratories can be ASCA recognized even for specific test methods, it would be valuable for the FDA to also include information on the specific test methods for a particular standard for which an accreditation body or testing laboratory is recognized.</td>
</tr>
<tr>
<td>197-200</td>
<td>It is the manufacturer’s responsibility to ensure standards are selected and used appropriately</td>
<td>We request that FDA consider indicating in the guidance that it is the ASCA accredited testing laboratory’s responsibility to ensure that any</td>
</tr>
</tbody>
</table>
and that the declarations of conformity provided in a premarket submission is consistent with the guidance “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.” ASCA accredited testing laboratories should ensure that ASCA related testing is conducted based on standards and test methods in the ASCA pilot for which the test laboratory has been specifically accredited. ASCA accredited testing laboratories should also follow the provisions of the Appropriate Use Guidance, for instance, preparing and issuing DoCs consistent with the conformity assessment standards ISO/IEC 17050-1 / 17050-2, as applicable.

ASCA related testing is only conducted based on standards and test methods in the ASCA pilot for which the test laboratory has been specifically accredited. Manufacturers and testing laboratories should follow the provisions of the guidance on “Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices,” for instance, preparing and issuing DoCs consistent with the conformity assessment standards ISO/IEC 17050-1 / 17050-2, as applicable.

<table>
<thead>
<tr>
<th>Figure 1, Box 4</th>
<th>FDA recognizes qualified TLs for ASCA Pilot participation ASCA Accreditation (TL accepted into ASCA program) and grants ASCA accreditation.</th>
<th>It is our understanding that FDA recognition of a TL into the ASCA program is synonymous with ASCA accreditation. Updating the text will provide helpful clarity.</th>
</tr>
</thead>
<tbody>
<tr>
<td>271-274 and 286-290</td>
<td>We would request additional clarity regarding additional testing and determination of conforming to the standard.</td>
<td>We would request additional language regarding repeat testing and determinations of conforming to the standard to clarify that test laboratory alone is not making the determination as they may not necessarily test to the complete standard.</td>
</tr>
<tr>
<td>376</td>
<td>FDA may wish to reconsider inclusion of the reference given that the standard is 15-years old.</td>
<td>The referenced standard is fifteen-years old. FDA may wish to reconsider inclusion of the reference in light of the date.</td>
</tr>
<tr>
<td>429</td>
<td>We would propose clarifying any envisioned time limit for accreditation.</td>
<td>The draft guidance does not state whether the accreditation will have a time limit, e.g., the end of the pilot. We would propose clarifying any envisioned time limit for accreditation.</td>
</tr>
<tr>
<td>519-520</td>
<td>After recognition of a testing laboratory, FDA will generally grant testing laboratories ASCA Accreditation After FDA recognizes a testing laboratory in the ASCA pilot.</td>
<td>We recommend the proposed wording change because the use of the word “generally” could imply that some additional review is needed after a TL is recognized by the FDA, before ASCA Accreditation can be granted. It is</td>
</tr>
</tbody>
</table>

2
"Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff: The Accreditation Scheme for Conformity Assessment"

<table>
<thead>
<tr>
<th>529</th>
<th><strong>Assuming that it meets established criteria as outlined in this draft guidance, a device company’s internal TL will be eligible to participate in the ASCA pilot program.</strong></th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>We recommend including this quotation from the MDUFA IV commitment letter. FDA has reaffirmed several times, including elsewhere in the draft guidance, the intention to allow device manufacturers to apply for ASCA accreditation for their own, in-house TL. We think the language would also be helpful in this section of the draft guidance.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>608-609</th>
<th><strong>The ANSI/AAMI ES60601-1 series of standards (along with the FDA-recognized collateral and particular standards in the 60601/80601 family) apply to devices used in patient care settings, while the IEC 61010-1 series applies to devices used in laboratory settings (along with the FDA-recognized particular standards in the 61010 family).</strong></th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>Proposed to clarify that the collateral/particular standards are included as specified in other lines of the document.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>721-763</th>
<th><strong>Please provide additional detail regarding how FDA will handle laboratory scope of accreditation expansions.</strong></th>
</tr>
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<tbody>
<tr>
<td></td>
<td><strong>It is unclear how FDA will handle laboratory scope of accreditation expansions. For instance, we request clarity as to whether the test laboratory must wait until the accreditation organization has added that standard into their accreditation scope before the TL can submit this as premarket submission standard through the manufacturer to the FDA.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>991-98</th>
<th><strong>Please clarify how FDA intends to handle submissions for which some of the standards tested to are part of the pilot, but others are outside of the pilot.</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Understanding how FDA will handle mixed standards, some of which are inside the pilot and others are outside the pilot, will provide helpful clarify.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>1006</th>
<th><strong>ASCA Summary Test Report (see Appendix E and F for examples that articulate the elements FDA recommends including for</strong></th>
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</thead>
<tbody>
<tr>
<td></td>
<td><strong>We do not believe the summary test report can be included in the DoC.</strong></td>
</tr>
<tr>
<td>Page</td>
<td>Text</td>
</tr>
<tr>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>1039-1050</td>
<td>It was stated that FDA generally intends to rely on test results and does not generally intend to question the validity of the test method from ASCA-accredited testing laboratories. We strongly encourage FDA to adhere to these principles. It certainly requires training for reviewers and supervision on how the reviewers handle test reports and submissions, but any deviation from the principles would make the pilot program less effective.</td>
</tr>
<tr>
<td>1056</td>
<td>The draft guidance explicitly states that the specifications for biological evaluation are in addition to ISO 17025: 2017. These additional</td>
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<tr>
<td>1282</td>
<td>Specification above and beyond the standard include very specific competency aspects. The rationale for these specifications is unclear since we do not believe there is anything this elaborate defined or required for a manufacturer. The original ISO 17025:2017 standard requires competencies, procedures and records. We understand the value of the details to support but are concerned that these are outlined in a guidance instead of included in a standard.</td>
</tr>
<tr>
<td>1296-1300</td>
<td>It is unclear why FDA specifies calibration to three decimal places for spectrophotometer assessments as it is our understanding that number of decimal places is based on the product's design and the standards requirements.</td>
</tr>
<tr>
<td>1315</td>
<td>We are not clear why FDA has added this section on externally provided products and services as supplier management is already addressed in ISO 17025.</td>
</tr>
<tr>
<td>Clarify whether FDA means the testing laboratory or the device manufacturer when it refers to the “applicant organization.”</td>
<td>It is unclear whether FDA means the testing laboratory or the device manufacturer when it refers to the “applicant organization.” Clarification would be helpful.</td>
</tr>
<tr>
<td>We would propose either clarifying the reason for the reference or omitting the reference.</td>
<td>We are uncertain why ASTM F720 is referenced here as it is not included on pages 16-17 as one of the standards in scope for the ASCA pilot.</td>
</tr>
<tr>
<td>Clarify that it will be acceptable for the job descriptions to be located in the Human Resources files for purposes of the ASCA pilot.</td>
<td>It is unclear whether the job descriptions are expected to be in the Quality Management System or just the Human Resources files.</td>
</tr>
<tr>
<td>Clarify to address how FDA would handle scenarios where manufacturer and testing laboratory share responsibility for Verification and Validation of different parts of the standard.</td>
<td>For parts of the standard, Verification and Validation may be performed by the manufacturer not the testing laboratory, which conflicts with this expectation. We would propose clarifying how FDA would address this scenario.</td>
</tr>
<tr>
<td>Establish and maintain appropriate communication with FDA and the manufacturer. A testing laboratory should not hesitate to contact FDA regarding the ASCA Pilot.</td>
<td>Communication from the testing laboratory to FDA that is specific to a device/product should be in concert with the manufacturer. We also would appreciate clarity on purpose for the “regularly scheduled teleconferences” between FDA and the testing laboratory.</td>
</tr>
</tbody>
</table>
“Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff: The Accreditation Scheme for Conformity Assessment”

| 1804 | Please provide additional detail about the testing laboratory training expectations, including scope, length and method. | We request that FDA provide detail about the expected training, including the scope, length and method. We believe it would be helpful for a testing laboratory to understand this training expectation to determine whether to participate in the pilot program. |
| Page 54: Footnotes 72 and 73 | Revise to ensure consistency among these two Footnotes. | Footnotes 72 and 73 are inconsistent. Footnote 72 requires the inclusion of a complete test report along with the ASCA Summary Test Report in pre-market submissions to the FDA during the course of the ASCA Pilot without any caveats. By contrast, Footnote 73 requires the complete test report only if certain conditions are met. This creates ambiguity. |
| 1927-1928 | We would reorganize the box that currently includes all three scenarios: not applicable, not tested and failing results. We would break each scenario out into its own box. Thus, there would be one box for “not applicable,” a separate box for “not tested” and then a separate box for “failing result.” Each of these boxes | We believe that separate boxes for “not applicable,” “not tested,” and “failing result” will provide helpful clarity. |
"Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff: The Accreditation Scheme for Conformity Assessment"

<table>
<thead>
<tr>
<th>Annex E and Annex F</th>
<th>We propose clarifying that test laboratories are responsible for the Summary Test Report as reflected in draft of proposed Medical Device Manufacturer’s Summary Test Report.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test laboratories should be responsible for the summary test report.</td>
</tr>
</tbody>
</table>
Medical Device Manufacturer – ASCA Summary Test Report

MEDICAL ELECTRICAL EQUIPMENT OR MEDICAL ELECTRICAL SYSTEM evaluated

Describe the MEE/MES in its entirety as tested, including the equipment, accessories, applied parts and supporting peripheral equipment. Include a system diagram where clarity is needed.

MEDICAL ELECTRICAL EQUIPMENT EXPECTED SERVICE LIFE

Indicate the EXPECTED SERVICE LIFE documented in the RISK MANAGEMENT FILE and describe any required service or maintenance expected during that lifetime.

MEDICAL ELECTRICAL EQUIPMENT ESSENTIAL PERFORMANCE characteristics

Description of the ME EQUIPMENT ESSENTIAL PERFORMANCE characteristics supplied by the MANUFACTURER to the testing laboratory and which were used as acceptance criteria in the testing.

Identify MEDICAL ELECTRICAL EQUIPMENT classifications

Types of APPLIED PARTS (check all that apply)
- TYPE A APPLIED PART
- TYPE BF APPLIED PART
- TYPE CF APPLIED PART
- DEFIBRILLATION-PROOF APPLIED PART

Types of power sources (check all that apply)
- INTERNALLY POWERED
- SUPPLY MAINS
  - CLASS I
  - CLASS II

Protection against ingress of water or particulate matter (IPNN rating)

__________ for ME EQUIPMENT
__________ for ACCESSORIES
__________ for APPLIED PARTS

Type of OPERATOR (check all that apply)
- LAY
- professional
- specialized professional

________________________ (indicate specialization)
USE ENVIRONMENT (check all that apply)
☐ HOME HEALTHCARE ENVIRONMENT
☐ EMERGENCY MEDICAL SERVICES ENVIRONMENT
☐ professional healthcare facility

Types ME EQUIPMENT (check all that apply)
☐ STATIONARY
  ☐ FIXED
  ☐ HAND-HELD
☐ TRANSPORTABLE
  ☐ MOBILE
  ☐ PORTABLE
  ☐ BODY-WORN
  ☐ HAND-HELD
☐ TRANSIT-OPERABLE

Suitable for use in an OXYGEN RICH ENVIRONMENT?
☐ yes
☐ no

Mode of operation
☐ CONTINUOUS OPERATION
☐ non-CONTINUOUS OPERATION

Is the ME EQUIPMENT or are its ACCESSORIES intended to be sterile or sterilized?
☐ no
☐ yes, if yes the method: (check all that apply)
  ☐ aseptic processing
  ☐ ethylene oxide
  ☐ irradiation
  ☐ steam or dry heat
  ☐ vaporized hydrogen peroxide
  ☐ other: ________________ (indicate method)

Evaluation of the Results of Conformity Assessment
☐ The articles that were tested are identical in all material respects to the subject ME EQUIPMENT
☐ The test results demonstrate that the ME EQUIPMENT is in conformity with the standard

Standards included that are included in the ASCA program

List each standard

Standards included that are not part of the ASCA program

List each standard
1. Clauses Tested
*Rationale for any clause identified as not applicable, not tested, or had failing test results.*

☐ All clauses and subclauses were deemed applicable and tested.
   ACSA test lab used: ____________________________

☐ The following clauses and subclauses were deemed not applicable. (list and indicate why they were deemed not applicable)

☐ The following clauses and subclauses are included in this evaluation, but completed by another entity
   *Describe how other entity was utilized*

☐ No applicable clauses or subclauses had failing test results.

☐ The following clauses and subclauses were not tested.

☐ The following clauses and subclauses failed in the test results; rationale for each is provided below.

2. Anomalous Results
*Description of resolution of anomalous test results.*

☐ Anomalous results were NOT identified by the testing laboratory as a concern

☐ Anomalous results were identified by the testing laboratory as a concern; resolution of results described below.

3. Concerns Communicated by Testing Laboratory

☐ Concerns regarding BASIC SAFETY or ESSENTIAL PERFORMANCE were NOT communicated by the testing laboratory.

☐ Concerns regarding BASIC SAFETY or ESSENTIAL PERFORMANCE that were communicated by the testing laboratory; resolution described below.