



17 December 2019

TIC Council Americas, formerly known as IFIA
Americas Committee)

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

Re: "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff."
Docket No. FDA-2019-D-3805

The TIC Council Americas is pleased to provide comments on the "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff."

TIC Council is the global trade federation representing the independent third-party Testing, Inspection and Certification (TIC) industry which brings together more than 90-member companies and organizations from around the world to speak with one voice. Its members provide services across a wide range of sectors: consumer products, medical devices, petroleum, mining and metals, food, and agriculture among others. Through provision of these services, TIC Council members assure that not only regulatory requirements are met, but also that reliability, economic value, and sustainability are enhanced. TIC Council's members are present in more than 160 countries and employ more than 300,000 people across the globe.

TIC Council fully supports the FDA's commitment to use of international voluntary standards to fulfil FDA's policy goals and believes that the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program, can bring substantial benefits to all stakeholders by minimizing costs and reducing time to market, ensuring that patients can more rapidly benefit from innovative medical technology.

We appreciate the opportunity to provide the attached comments on the FDA's "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff." Should you have any questions, please don't hesitate to contact Karin Athanas at +1 240 762 8069 / kathanas@tic-council.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Hanane Taidi".

Hanane Taidi
Director General
TIC Council

A handwritten signature in black ink, appearing to read "Roberta Telles".

Roberta Telles
Executive Director
TIC Council Americas
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Re: “The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program; Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff.”

General Comments:

TIC Council continues to support and recommend the use of third-party conformity assessment bodies (CABs) including testing laboratories in determining conformance with voluntary consensus standards such as those used in the ASCA pilot. The use of independent third-party CABs has been shown to reduce instances of non-conformance¹ and therefore, are the preferred method for determining conformance and we recommend that the FDA consider a revision to mandate use of accredited third-party testing laboratories, where applicable, to ensure consistency in the device approval process and a level playing field between testing laboratories.

Due to the time and resource commitments that laboratories will need to deploy to ensure the successful development of compliance management system documents (e.g. policies and procedures), training and re-training of staff, redesign of metrological traceability and reporting processes, and obtaining separate accreditation as part of the ASCA Pilot, laboratories take on the highest burden and yet, manufacturers could determine the additional cost does not out weight the small reduction in time to market and will continue to use unaccredited, ASCA Pilot non-compliant laboratories. By ensuring all laboratories performing testing as part of the FDA ASCA program are compliant with Appendix A and B, it will ensure a level playing field between laboratories and increase confidence that FDA staff have in the declarations of conformance received from device manufacturers.

In consideration of the strong dependency of safety/essential performance on cybersecurity and the current activities of the FDA to strengthen the awareness on manufacturer side renewing the Guidance document for “Premarket Submission for Management of Cybersecurity in Medical Devices” (Draft October 2018), we recommend adding cybersecurity competence as a requirement to the criteria catalogue of accreditation bodies offering ISO/IEC 17025 accreditation to testing laboratories and also to the testing laboratories.

In its current form, the program is not designed to be inclusive of CB Schemes; however, future iterations of the program which incorporate use of CB Schemes could help support the program. Two suggestions for incorporating the IEC CB Schemes are included below for your consideration.

- 1) Modify the ASCA program to accept the IECEE CB Scheme by signing a MOU with a commitment to IECEE to include a specific part dealing with the requirements of ASCA program which will be applied to CBTL candidates for being recognized under ASCA program (specific part to be included in the peer-assessment of IECEE). This solution is equivalent to treating the IECEE CB scheme in the same way as an accreditor.
- 2) Labs which have been recognized under the ASCA program (according the process as it is written in the document) may recognize a CB scheme Test report and test certificates for issuing their own reports (the ASCA document in appendix B, 6.6 p 37, line 1296 to line 1300), accepts the use of subcontractors/externals results, provided it has been issued under ISO 17025 + ASCA program requirements).

¹ TIC Federations Consumer Product Market Survey, 2018, https://www.tic-council.org/application/files/1415/5903/8639/IFIA_CIPC_239_2014-2016_Market_survey_report.pdf

In reviewing the document, many sections require written records or documents, but does not clearly state whether these written documents must be physical or if non-paper-based systems will be permitted. We recommend revision to explicitly permit the use of electronic or non-paper-based systems. This will alleviate confusion and allow for those labs which use non-paper-based systems to participate.

Specific Comments - The following table includes the full list of TIC Council Questions and Comments:

Section	Comments
Section VIII	The guidance currently does not reference a mechanism for appealing a decision made by the FDA. We recommend that language be included both in the accreditation body and laboratory sections addressing the process to be followed to appeal a decision.
Technical requirements (§ VII –B)	For medical Electrical equipment, the standards mentioned (IEC 60601 series and IEC 61010 series) are appropriate and are covered by the standards of the IECEE CB Scheme, including national deviations, so no issue on it.
Quality system and requirement for Labs (Appendix B)	The requirements are based on the compliance with ISO 17025:2017, plus some specific requirements of ASCA program which are covered or may be covered without specific problem by rules of IECEE CB Scheme for CBTLs.
Qualification criteria for participation (§ VIII – A)	The qualification criteria are very restrictive: to be recognized, the test lab shall be accredited by an accreditation body which has been recognized under ASCA program and which is located in US. This doesn't allow (for time being) possibility of foreign testing laboratory to use their national accreditation body (once recognized in ASCA program) for recognition under ASCA program and this doesn't allow use of CB scheme.

Line	Comments
183-186; and 805-815	<p>The FDA identifies its authority to suspend a testing laboratory's ASCA Accreditation if the FDA identifies an issue or when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which the premarket submissions included testing from an ASCA-accredited testing laboratory.</p> <p>It is noted that reports are issued from accredited testing laboratories to manufacturers and manufacturers, when ready, compile those reports into formal submissions which are provided to the FDA as part of an approval request. Because testing laboratories do not provide formal reports directly to the FDA, it is recommended that the FDA take into account the traceability of the report issued by the testing laboratory, the device it is applicable to – if a precursor to the device submitted for approval – and whether testing was performed accurately and in accordance with procedure at the time of testing. To ensure a fair evaluation of changes that may have occurred between the time of testing and submission that would have had a materially relevant effect on the testing performed and appropriateness of that device for submission to the FDA for approval.</p>
513-528	The document does not appear to identify the frequency upon which ASCA Accreditation will be renewed. However, lines 718-720 refer to the accreditation body or testing laboratory applying for continuation of their participation 6 months prior to the expiration

	of its recognition. We recommend the addition of language that would specify the cycle of renewal.
513-528	As FDA undertakes the ASCA pilot, the TIC Council believes that there is a shared responsibility between government, industry, and conformity assessment providers to achieve a balance between robust safety outcomes with financial and time to market efficiency. The adoption of strategies and activities that incentivize participation by manufacturers is essential for the program to be sustainable. Similarly, participating conformity assessment organizations must effectively partner with manufacturers and FDA in order to make this program economically viable and sustainable in the market. Barring foreknowledge of regulatory process improvements, which could theoretically be characterized through ex post facto analysis of the pilots, could FDA identify their minimum set of technical regulatory expectations for each of the pilot domains that would provide the maximum level of confidence in expedited clearance / approval, which could then be reflected in ASCA program artifacts such as standardized conformity assessment report templates?
642-652 and Appendix C, section C	<p>It is noted that A. Qualifications 1. Accreditation Body Qualifications subsection a. does not specifically require that an accreditation body's MRA certificate include evidence that the accreditation body has been recognized to offer accreditation to ISO/IEC 17025 for testing.</p> <p>Also, Appendix C, Section C requires that the ILAC MRA scope include ISO/IEC 17025, but does not specify that the recognition must be for testing. ILAC offers recognition to ISO/IEC 17025 for testing and/or calibration.</p> <p>It is recommended that this be added to ensure any accreditation body approved as part of the ASCA Pilot has been recognized by ILAC as having the necessary competence to offer ISO/IEC 17025 accreditation to testing laboratories. Such evidence could come in the form of review of the ILAC MRA Signatory listing on the ILAC website or requesting a copy of an accreditation body's MRA signatory agreement certificate.</p>
665-678	Testing laboratories work in a wide range of industries and their Scopes of Accreditation may include methods in addition to and outside the ASCA Pilot scope. Recommend revision to clarify that only those methods applicable to the ASCA Pilot would be reviewed, but that the FDA recognizes that a testing laboratory's Scopes of Accreditation from one or many accreditation bodies may have other methods not applicable to the ASCA Pilot.
694-700	<p>It is noted that in lines 701-702, the FDA will document the testing laboratory's accreditation from an accreditation body recognized as participating in the ASCA Pilot."</p> <p>And also, that accreditation body applications will be reviewed over the course of 60 days and that this may result in the request for additional information to address potential issues with an applicant's information. While this sounds reasonable, it is noted that for the initial launch of the program this may cause significant delays between the time of Pilot launch to when the first set of testing laboratories will be receiving the ASCA Accreditation.</p> <p>If accreditation bodies must first be recognized, this means testing laboratories cannot reasonably apply until accreditation bodies have been recognized and listed on the FDA website. Testing laboratories would need to seek supplemental assessment and accreditation to the ASCA Pilot specific requirements found in Appendix A and B. A step that very likely will require on-site assessment by a recognized accreditation body and the</p>

	<p>time and fees generally associated with such scope expansions. Additionally, a delay is expected while accreditation body assessors and/or staff attend ASCA training and program materials are developed to support this new program.</p> <p>Following FDA approval/recognition of accreditation bodies, training of accreditation body staff and/or assessors, development of accreditation program materials, performance of on-site assessments and completion of a post-assessment corrective action process (if applicable), the testing laboratory could then apply for recognition by the FDA. A series of steps that could take months if not a full year to complete. It's noted that line 1804 requires that staff at the testing laboratory also attend training under the ASCA Pilot prior to performing testing, this will serve to further delay of offering services to device manufacturers.</p> <p>To ensure all participants and device manufacturers who may wish to make use of laboratories approved in the ASCA Pilot have reasonable expectations, it is recommended that estimates of the time needed to complete each step be included in the guidance or communicated on the FDA website. It is also recommended that methods for streamlining this introductory onboarding process be considered. This could include temporary approval of applicant laboratories to offer services pending final confirmation by a recognized accreditation body with 12 months of application.</p>
950-951	<p>This section refers to recognition of testing laboratories, but erroneously references ISO/IEC 17011 which applies to accrediting bodies. Propose revision to correct as follows:</p> <p>“A testing laboratory must be assessed at least every 2 years by the recognized accreditation body in order to maintain conformance to ISO/IEC 17011-17025.”</p>
Appendix A and B	<p>Appendix A and B include additional requirements that ASCA Pilot participant laboratory are expected to comply with. Upon review, the sections include specific requirements for training, policies and procedures, calibration ranges and specifications, and other areas that could be interpreted as applying the laboratory in whole and not just in cases where the laboratory has been requested to perform testing by a device manufacturer as part of the ASCA Pilot.</p> <p>Clarification that such requirements only apply in cases where the laboratory is performing work at the request of a device manufacturer as part of the ASCA Pilot will ensure that requirements placed on laboratory do not conflict with other accreditation schemes and that the program does not inadvertently disadvantage laboratories that work in multiple industries by requiring the application of additional requirements above and beyond ISO/IEC 17025 that would create burden for the laboratory when providing work to other industries not related to the ASCA Pilot.</p> <p>Examples: Lines 1279-1295 for metrological traceability: Many programs exist where a lower threshold of calibration is needed. Applying this requirement to any method a testing laboratory may consider would have significant negative affect on the laboratory's ability to service other programs and customers.</p>
1296-1300	The requirement found in section 6.6, line 1296 appears to suggest an ASCA recognized accreditation body could be used, but the work requested subcontracted to a laboratory

	<p>that is not recognized by the FDA as part of the ASCA program, but rather found by the subcontracting laboratory to be in compliance with ISO/IEC 17025 and the ASCA requirements.</p> <p>Recommend clarification as whether an ASCA accredited testing laboratory may subcontract work meant to fall within the scope of the ASCA pilot to a laboratory that is not equally accredited by the FDA to perform testing as part of the ASCA Pilot.</p>
Appendix C section C	<p>Bullet point 3 states that accreditation body applicants shall provide “a current list and description of any conformity assessment services offered for which the scope includes any of the standards and/or test methods in the ASCA Pilot.”</p> <p>In accordance with ISO/IEC 17011, accreditation bodies are prohibiting from offering conformity assessment services and so would not have a “Scope” which includes any of the standards and/or test methods in the ASCA Pilot.</p> <p>An accreditation body may offer programs which require program participant laboratories be accredited to standards and/or test methods in the ASCA Pilot.</p> <p>It is recommended that this bullet point be revised to offer clarification as to what records are being requested.</p>
1127, 1166, 1223, 1232, 1239	<p>These sections of the guidance require participation in proficiency testing; however, reference to specific programs that would be acceptable are not included. It is recommended that clarification be provided as to the types of proficiency check that would be considered acceptable. In the absence of further clarification, compliance with this requirement might vary dependence on the assessor or accreditation body performing the evaluation.</p>