Docket No. FDA–2017–N–1067

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Via Regulations.gov

IFIA Americas Committee
6718 Kenwood Forest Lane
Bethesda, MD 20815

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

Re: *Request for Comments on Food and Drug Administration Accreditation Scheme for Conformity Assessment Pilot Program; Docket No. FDA–2017–N–1067*

The International Federation of Inspection Agencies, Inc. ("IFIA") is pleased to submit comments on the "Accreditation Scheme for Conformity Assessment ("ASCA") Pilot Program".

IFIA is a global trade federation that represents over 60 of the world's leading international testing, inspection and certification companies. These have a combined turnover in excess of $24 billion and over 300,000 employees globally. IFIA members' activities encompass every aspect of inspection, certification and related testing. IFIA member companies offer a number of services, including certification and inspection, systems audits, training, technical and documentary support. Through providing these services, IFIA members aim to ensure that not only regulatory requirements are fulfilled, but also that reliability, economic value, environmental impact and social responsibility are enhanced.

IFIA fully supports the FDA's commitment to use international voluntary standards to fulfil FDA's policy goals and believes that the Accreditation Scheme for Conformity Assessment Pilot Program, if designed correctly, 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.

In order to be successful, the **program must clearly provide a large incentive in terms of shortened review times or reduced fees** otherwise manufacturers that have their own labs and conduct their own verification testing will not want to add the requirements of accreditation to join the program. Therefore, the streamlining of premarket approvals and benefits of program must be substantial and clearly communicated.

Thank you for the opportunity to offer the following comments. If you have any questions regarding our submission, please feel free to contact IFIA's U.S. representative, Roberta Telles at +1.240.507.3392.

Sincerely,

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IFIA's Response to Questions on Federal Register Notice:

1. ***For the ASCA pilot program to achieve success,***

    a. ***What FDA recognized consensus standards available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm need to be included to successfully get a sponsor/manufacturer to be willing to participate in the program?***

IFIA recommends consensus standards associated with testing that is traditionally performed by third-party laboratories such as Biocompatibility, Electrical Safety Testing including EMC, Sterility. This may include collateral and/or particular standards.

1. *IEC 60601-1*
2. *IEC 60601-1-2*
3. *UL 2900*
4. *ISO 11607-1*
5. *ISO 10993-x*
6. *IEC 60601-2-61*
7. *IEC 62304*
8. *IEC 62366*
9. *IEC/UL 61010-1, 3rd edition*

Additional standards for FDA consideration:

- *ISO 11135-1*
- *ISO 11137-2*
- *ISO 11138-1*
- *ISO 11737-1*
- *ISO 11737-2*
- *ISO 14698-1*
- *ISO 14698-2*
- *ISO 17665-1*
- *ASTM D 4169*
- *ASTM D 4332*
- *ASTM F88/F88M*
- *ASTM F1140/F1140M*
- *ASTM F1886/F1886M*
- *ASTM F 1929*
- *ASTM F 1980*
- *ASTM F 2054/F2054*
- *ASTM F 2096*
- *ASTM F2761*
- *ANSI/AAMI ST77*

Rationale: Many medical test standards are complex and require expertise and specialized knowledge for proper interpretation and application of such. Using existing standards where manufacturers and third-party organizations have already gained a lot of experience will benefit all parties with a consistent approach of evaluation, testing and documentation and will allow FDA to rely on results from recognized accredited Test Laboratories. Benefits are cost savings for manufacturers due to faster turn-around times and a more effective and faster premarket reviews.

b. What impact/efficiencies would you like to see from the pilot program?

IFIA would like to see FDA accepting the declaration of conformity with **no additional review during the 510(k) evaluations**, which would reduce the 510(k)-approval time considerably.

Rationale: significant reduction in the review cycle will reduce time to market while reducing the burden on FDA resources, providing incentive for manufacturers / sponsors to join the pilot program and allowing FDA to best focus its resources.

c. What does success of the pilot program look like?

For IFIA, a successful ASCA pilot program means that FDA would accept the reports without the need to make substantial reviews, with improved turnaround times and uniformity of results that will provide the incentives for industry to participate.

In addition, IFIA recommends the following Acceptance Criteria for a successful ASCA:

- No major findings by the FDA for reports issued by the certifying bodies and the FDA agrees with the decision by the certifying bodies. Some minor FDA findings such as clerical errors would be acceptable
- For any standard, the sample size of reports should be at least 300 and not more than 4 laboratories for a given standard
- Findings would be classified per the risk to the public if the error had been allowed to pass. Findings would be counted and a score developed for that standard and participating labs

The Acceptance Criteria recommended above would empower the testing laboratories operating under the ASCA-program to submit their compliance judgement without the need to address further questions related to standards conformance.

IFIA also recommends that FDA clearly communicate the process for participating in the program and continue engaging all relevant stakeholders during all stages of the development, implementation and evaluation of the pilot program in order to incorporate feedback and lessons learned in a timely manner.

d. Outline any challenges in the use of recognized voluntary consensus standards (e.g., acceptance of test results from accredited test labs, standardized test reports, consistent test methods, well-defined standards) that FDA should focus on while developing the ASCA pilot?

One challenge is that product standards regularly include requirements for which laboratory testing is not the appropriate evaluation technique. For example, some product standards have extensive requirements that pertain to the design process (i.e. the risk management system) of a product. FDA should not assume either ISO/IEC 17025 or ISO 15189 are the appropriate competency requirements for the body performing the evaluation. Rather, a body meeting the requirements of ISO 17021-1 and ISO 17021-3 should be considered.

FDA should consider adopting only one of the ISO laboratory standards, either 17025 or 15189 which is the most applicable to pre-clinical testing (non-clinical) testing, with the appropriate deviations for ASCA.

With respect to other challenges, in many cases, voluntary consensus standards for end products reference other standards as requirements, especially for components and materials used in end products. The FDA would need to be explicit about evaluations needed for the requirements in referenced (e.g., component or material) standards. Under ASCA, would a component manufacturer obtain evaluation of its component(s) from an accredited lab and then allow end-product manufacturers to submit that evaluation as part of the end-product evaluation?

Regarding standardized test reports, consistent test methods, and well-defined standards, IFIA does not foresee any challenges with voluntary consensus standards that are not also present in regulatory agency standards.

Report formats should be standardized -- the IECEE-scheme is using a good overview of their harmonized test report formats every participating test laboratory has access to, good instructions on how to issue new report formats and how to change existing report formats are given. FDA should develop a standard test report format for use by all participating accredited test labs or alternatively, for each adopted standard, FDA could assign a participating accredited lab to develop a template to be validated among other participating accredited labs.

Additionally, participating Labs should review and compare their test procedures and equipment for any standard test. Labs should perform test method validation where products with known defects are sent to each lab and tested. All labs should find same defects or noncompliance and document this in the report.

It is important to note that product standards are published after a technology is in use. FDA should provide clarity in the cases when new technologies or uses are allowed to be evaluated by the test lab.

2. ***To help reduce duplicative efforts, overlap, or conflict with other conformity assessment schemes, what benefits/concerns of the ASCA work to align with other existing schemes that utilize the same consensus standards?***

Where an adequately rigorous certification scheme exists, this should be the first criteria for participating bodies. If the FDA believes the accreditation scheme is robust, this can be the basis for acceptance. If the FDA believes that the accreditation scheme is not adequate, the accreditation can be one of the qualification requirements. One example to consider would be the IEC CB scheme. This is applicable to IEC 60601 series of tests where IEC has standards and labs are accredited to ISO 17025.

Another example is the OSHA Nationally Recognized Testing Laboratory (NRTL) program, which utilizes some of the voluntary consensus standards that could be included in the FDA ASCA model. While the two models are considerably different, duplication, overlap and conflict between OSHA NRTL and ASCA can be minimized should FDA use the ISO/IEC 17000 (and/or ISO 15189 where applicable) series standards as the basis for ASCA.

3. ***What are the benefits, weaknesses, incentives/disincentives associated with a model that uses one or more private sector accreditation bodies to accredit testing laboratories to the appropriate scope of accreditation for ISO/IEC 17025 (General requirements for the competence of testing and calibration laboratories) or ISO 15189:2012—Medical laboratories—Requirements for quality and competence plus FDA ASCA program specific requirements? FDA would still retain the authority to recognize, deny, amend, or revoke recognition of testing laboratories and maintain the official list of recognized testing laboratories.***

A model that uses private sector accrediting bodies would allow FDA to leverage private sector resources and keep overhead down. Another benefit is that it uses existing accreditation requirements, so labs

understand what is required for compliance. Nonetheless, FDA confidence needs must be satisfied and important oversight responsibilities must remain with FDA even though FDA is not the direct accreditor. That mean that FDA will need to review competence of any accreditation body it approves since not all accreditation bodies are not created equal.

Below additional points for FDA's consideration:

- ISO/IEC 17025 sets requirements for the competence, consistency and impartiality of calibration and testing laboratories. However, it does not address "quality" except for the contribution of competence, consistency and impartiality to quality

- The primary benefit that fulfilment of ISO/IEC 17025 is intended to deliver is consistently reliable test and calibration results. Whether the testing/calibration laboratory meets any of the other expectations of its customers and stakeholders is outside the scope of ISO/IEC 17025

- ISO 15189 states that it is a combination of ISO/IEC 17025 and ISO 9001 and is targeted specifically to "Medical laboratory services . . . essential to patient care" which include "the examination of patients in consultation cases, and that those services actively participate in the prevention of disease in addition to diagnosis and patient management"

- Reconsideration of some requirements in ISO 15189 may be needed when the document is applied to a laboratory performing testing of medical devices

- The assurance of fulfilment of accreditation requirements is generally highest from laboratory accreditation to ISO/IEC 17025 compared to other forms of accreditation

- Laboratory testing and calibration are much more dependent on procedures, equipment and facilities and less reliant on subjective human assessment and decision making than other forms of conformity assessment. As a result, it is easier to achieve consistent accreditation assessments among different accreditation bodies that provide comparable assurances that laboratories meet accreditation requirements

- Laboratory accreditation to ISO 15189, while broader in scope (includes requirements for "quality" that are not included in ISO/IEC 17025), is less consistent as both laboratories and individual accreditation assessors must make more subjective decisions and assessment related to the "quality" requirements in ISO 15189

- Private sector laboratory accreditation has the added benefit of shifting costs and resource challenges from FDA to the private sector. Competition among multiple private sector accreditation bodies utilizes market forces to minimize costs and burdens faced by accredited laboratories

- However, those same competitive forces between accreditation bodies can trigger a downward spiral in the effectiveness of accreditation activities. For example, labs can use competitive forces between accreditation bodies to drive down the frequency and extent of surveillance assessments of accredited labs. Accreditation bodies must react to demands for less costly surveillance to retain customers

- FDA should consider setting certain accreditation parameters that all participating accreditors must follow to prevent a downward spiral resulting from competition between accreditation bodies. With this approach, both FDA and industry stakeholder can realize the benefits from using multiple private sector accreditation bodies without the related risks. This approach is far preferable to the "single accreditation body per country" model practiced in other regions

- In the terminology of the ISO/IEC 17000 series of standards, these parameters for accreditation are part of the accreditation "scheme" – the rules and procedures for carrying out laboratory accreditation. The "scheme" for accreditation is a subset of the overall ASCA scheme – and FDA is the owner of the ASCA scheme including those elements that pertain to laboratory accreditation

- As a scheme owner, FDA will also need to consider what level of decision making it will provide to arbitrate differences in perspective that may arise among participating accreditation bodies, as laboratory accreditation is not free from subjectivity in assessments. For example, the extent of impartiality protections in accredited laboratories within a manufacturer of medical devices, or the need for estimations of measurement uncertainties in reported test results could easily be topics accreditation bodies in ASCA ask FDA as the scheme owner to resolve

4. Where no appropriate accreditation bodies step forward to serve the needs for the specific areas within the ASCA program, FDA is considering a model under which it will serve as the accreditation body. What are the benefits, weaknesses, incentives/ disincentives associated with this approach, and how do you compare this approach to the private sector approach?

IFIA believes that models in which a federal agency serves as alternative to private sector accrediting bodies provides the following benefits/weakness:

- Benefits:
    - Provides common requirements where none may currently exist
    - Labs already inspected by FDA will be comfortable with an accreditation

- Weakness:
    - Adds to FDA burden. Labor to perform and maintain accreditation could offset labor savings realized with acceptance of accredited lab reports
    - Increased time to add a new standard to an accredited scope

Additional considerations:

- Models in which a federal agency serves as a "backstop" or alternative to private sector conformity assessment (including accreditation) can introduce unintended consequences, potentially leading to underperformance of the program

- When a federal agency serves as the accreditor, there are fewer incentives to help drive private sector investment. Private sector conformity assessment (including accreditation) bodies face the additional risk that significant portions of the market will continue to seek out the agency for accreditation, making the investment needed to establish accreditation less attractive for private sector bodies

- As the ASCA pilot takes shape, FDA should clearly signal its intent to enter the market if no private sector accreditation bodies step forward to participate

- Should the FDA elect to serve as an ASCA accreditation body, the Agency should consider working with existing accreditation groups within the Federal Government to eliminate duplicative efforts. Additionally, the FDA should leverage the recommendations set forth in the HHS Health Care Industry Cybersecurity Task Force (HCIC TF) report (https://www.phe.gov/Preparedness/planning/CyberTF/Documents/report2017.pdf) to Congress to solicit additional funding that would be needed to adequately resource FDA to serve as an accreditation body

5. ***Describe your familiarity with accreditation to ISO/IEC 17025 (General requirements for testing and calibration laboratories) or ISO 15189:2012—Medical laboratories—Requirements for quality and competence? If accredited, what is the scope of accreditation?***

IFIA member labs are ISO 17025 accredited. This may include all IEC 60601-1 collateral and particular standards as well as EMC tests associated with IEC 60601-1-2. Related standards may include battery safety, lighting safety, and non-medical electrical that are applicable to IVD products (IEC 61010 family).

6. ***Do you utilize another management system other than ISO/IEC 17025 or ISO 15189:2012—Medical laboratories—Requirements for quality and competence? If so, what management system has been implemented?***

The management system requirements in ISO/IEC 17025 (and all other ISO CASCO standards) are intended to assure that the body is effective in self-governance for ongoing fulfilment of the requirements in the standard. ISO/IEC 17000 series standards are not requirements for systems to achieve management objectives in a general area, (e.g., quality, environmental impact, occupational safety and health, etc.) and are rather requirements for the competence, consistency and impartiality of conformity assessment bodies.

As a multifaceted conformity assessment bodies, IFIA members have direct experience with fulfilment of ISO/IEC 17020 (inspection bodies), ISO/IEC 17065 (product process, service certification bodies), ISO/IEC 17024 (personnel certification bodies), ISO/IEC 17021-1 (management system certification bodies) and other ISO CASCO standards.

7. ***Are there specific FDA recognized consensus standards available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm or testing capabilities related to the medical devices sector that you perform?***

Several standards listed on referenced website are covered by IFIA members' accreditations. IFIA members provide medical electrical safety testing to IEC 60601-1 and related standards. Also included would be IEC 61010, IEC 60950, and other series of standards that may be applicable to all or part of medical electrical systems

8. ***For more complex standards, such as those that have normative references or include references to management systems (e.g., Risk Management, Quality Management, Cybersecurity, Infection Control), are there specific assessment techniques that should be included?***

Standards which are complex and do not allow specific assessment techniques which could be covered under a 17025 accreditation (e.g. Risk Management, Quality Management, Cyber Security) should be covered based on specific qualification of the organization and a qualification matrix of corresponding staff dealing with such specific assessment techniques (e.g. personnel with proper records for -x-number of projects, training records, etc.).

As referenced in 1.d., a comparison between participating labs using test cases could be performed. In the case of IEC 60601-1, the associated and prerequisite standards include ISO 14971, IEC 62304, IEC 60601-1-6 and IEC 62366. Test cases would include false positives and false negatives. ASCA pilot participating labs would be required to evaluate the same test cases and demonstrate a harmonized approach and interpretation of the standards. Once a lab demonstrates compliance and uniform interpretation, then actual test reports can be submitted to the FDA for review. The FDA would sample the test reports from each lab for a period of time and score the lab for alignment with FDA's position. Labs could be scored for compliance

and FDA can determine what is an acceptable threshold for continued accreditation at the end of the pilot study.

Finally, ISO/IEC 17021-1 includes requirements for auditing fulfilment of management system requirements. Additionally, UL 2900-1 includes specific test methods and metrics for cybersecurity testing.

9. Would you consider participating in the ASCA Pilot Program? If so, what scope of testing would you consider?

Yes, IFIA members would participate in the ASCA program. Participation would include testing and certification to relevant Electrical, Mechanical, Biological, Chemical, and Software standards listed above.

10. Generally, are there any other comments that you would like to provide regarding the development of the ASCA pilot program? Do you have recommendations for other alternatives to consider?

Below is a summary of IFIA's key recommendations to FDA:

- Focus the Pilot on standards such as Biocompatibility, Electrical Safety Testing including EMC, Sterility
- Develop Acceptance Criteria as recommended above to empower the testing laboratories to submit their compliance judgement without the need to address further questions related to standards conformance
- Clearly communicate the process for participating in the program and continue engaging all relevant stakeholders during all stages
- Accept the reports without the need to make substantial reviews in order to improve turnaround time and provide further incentive for joining the Pilot
- Be explicit about evaluations needed for the requirements in referenced (e.g., component or material) standards
- Develop standardized report formats
- Require that labs review and compare their test procedures and equipment for any standard test
- Provide clarity in the cases when new technologies or uses are allowed to be evaluated by the test lab
- Leverage existing schemes such as IEC CB Scheme and OSHA NRTL and use the ISO/IEC 17000 (and/or ISO 15189 where applicable) series standards as the basis for ASCA to minimize conflict with existing schemes
- Whenever possible, rely on private sector accrediting bodies with FDA retaining an oversight role
- Set certain accreditation parameters that participating accreditors must follow to prevent a decrease in quality that could result from competition between accreditation bodies.