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Office of the Center Director

Center for Devices and Radiological Health

Food and Drug Administration

Via email: [scott.colburn@fda.hhs.gov](mailto:scott.colburn@fda.hhs.gov)

Re: FDA-2017-N-1067, *Accreditation Scheme for Conformity Assessment Pilot Program*

Dear Scott,

As the leading trade association representing the manufacturers of medical imaging equipment and radiopharmaceuticals, the Medical Imaging & Technology Alliance (MITA) is responding to the public docket on *Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program*. We encourage the FDA to continue to seek input on the pilot and implementation of the program.

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**General Comments**

MITA and its Members support ongoing efforts by the Agency to rely on established, harmonized, consensus-based standards to support applications that show products to be safe and effective.

**Areas for clarification**

MITA and its Members appreciate the information included in the FR notice, but request additional clarification on several aspects of the program. Specifically:

1. What in detail will be “ASCA specific program requirements” that have to be fulfilled by the lab?
2. Will there be only one Accreditation Body? Will it be limited to operation within the United States?
3. What is the process to become a pilot partner?
4. FDA should provide additional clarification on how the ASCA program is different from the third party review program. Our understanding is that the ASCA program would be useful for a subset of requirements that could be included in a 510(k) application. If this is the case, additional information about the value and benefits of the program would be appreciated.
5. Are there distinctions between first, second and third party test houses being considered for the ASCA program? If so, what are these distinctions?

**Questions & Answers**

Below are the questions posed by the FDA in its FR notice and the MITA answers to these questions.

*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*](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?*

In general, MITA recommends that the Agency focus the ASCA program on standards that include defined pass/fail criteria and avoid standards that require risk management as a way to define pass/fail. Specifically, MITA recommends consideration of the following standards:

* IEC 60601 series standards for medical electrical equipment (especially EMC, alarm standards)
* Digital Imaging and Communication in Medicine (DICOM)
* Biocompatibility standards (ISO 10993 series of standards)
* Usability standards (e.g., IEC 62366-1:2015, *Medical devices -- Part 1: Application of usability engineering to medical devices*)
* Sterility
* IEC 62494-1: 2008, *Medical electrical equipment - Exposure index of digital X-ray imaging systems - Part 1: Definitions and requirements for general radiography*
* Alarm standards (alerts and alarms, visual and audible)
* NEMA XR 25-2010, *Computed Tomography Dose Check*

MITA urges the Agency to carefully consider which standards to include in the program in order to avoid adding unnecessary burden to the manufacturers or the Agency. For instance, there are a number of industry standards that are currently tested by manufacturers (e.g., NEMA Image Quality) that should not be included in the ASCA program.

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

MITA encourages the Agency to implement the ASCA program such that the FDA accept a Declaration of Conformity from an accredited standards laboratory completely with no additional data or review during a 510(k) evaluation. We believe that such acceptance is the only way to fully realize the potential efficiencies from the program. MITA believes that such implementation will lead to a reduction in review time. MITA also encourages the FDA to avoid additional information requests related to accredited reports or certifications of conformance to standards included in the ASCA program.

MITA is concerned that the process may become too burdensome for manufacturers or testing laboratories. It is necessary to carefully consider the implementation of the program to ensure that the ASCA program does not lead to more time being spent on testing or declarations of conformity. Additionally, MITA encourages the Agency to consider ensuring that the test laboratories included are broad enough to allow manufacturers sufficient flexibility in choosing an appropriate laboratory.

Finally, MITA Members have unique challenges, given the size and scope of the capital equipment that they produce. Large capital equipment testing at an outside laboratory is difficult given transportation and installation needs. It is especially important for manufacturers’ laboratories to be accredited for medical imaging manufacturers to reap the full benefits of the ASCA program.

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

MITA believes that full success of the ASCA program will be realized when all procodes have one or more standards that are included in the program. Additionally, only after the initial pilot phase, MITA recommends that the Agency consider including standards that rely at least partly on risk management criteria for the program.

*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?*

MITA believes that inconsistent certification reports could be problematic and encourages the Agency to work with stakeholders to develop templates for the program.

*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?*

FDA should include methods to accept an organization’s history in dealing with the following programs, especially if the organization is participating in the ASCA program:

* IECEE CB Scheme
* European Union Medical Device Directive Annex 2, QM-system-certification
* UL COMPASS program
* CSA category certification program

Additionally, MITA members express strong interest in relying upon ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories* when defining criteria for the eligibility of testing laboratories.

*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 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.*

Overall whether FDA uses private sector accreditation bodies or performs the activities themselves, an organization seeking ASCA acceptance must be evaluated from a Quality Management perspective as well as a technical competency perspective, with respect to the standards within their ASCA scope of accreditation application. The “bar” should be set sufficiently high enough to weed out lesser quality testing facilities. Whether private sector organizations are used or not FDA must provide sufficient capabilities to ensure ASCA can be granted to an organization in a timely manner.

MITA also believes that the ASCA program will allow FDA to utilize a least burdensome approach to conformance with recognized standards while moving toward harmonized requirements. In order to fully realize these benefits, MITA encourages the FDA to consider including international facilities and laboratories in the program.

*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?*

If FDA implemented a model under which it would serve as the accreditation body, MITA would be concerned that FDA does not have the resources, including appropriate skills and test equipment for technical competency evaluations. FDA does not seem to have sufficient experience in conducting technical competency evaluations, whereas private sector organizations do. This approach would be especially critical as there is already a well-structured process to assess the technical competency of testing labs. An approach whereby the FDA served as the accreditation body would need to ensure that it did not conflict with or duplicate the existing process.

*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?*

MITA Member companies have a number of accredited laboratories with expertise in a large number of standards, including those with IECEE recognition. Those labs are generally required to complay with ISO/IEC 17025 and ISO 15189 is specifically applicable to medical laboratories.

*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?*

MITA Member companies report reliance on a variety of standards for quality management purposes, including:

* ISO 13485, *Medical devices -- Quality management systems -- Requirements for regulatory purposes*
* The ISO 9001 series of standards for quality management systems
* The ISO 14000 series of standards for environmental management
* The ISO 27000 series of standards for information security management

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

In addition to standards mentioned previously in these comments, MITA Members indicate ability to test to a variety of consensus standards, including:

* NEMA UD2, *Acoustic Output Measurement Standard*
* IEC 61689, *Ultrasonics: Physiotherapy Systems*
* IEC 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*
* IEC 62359, *Ultrasonics - Field characterization - Test methods for the determination of thermal and mechanical indices related to medical diagnostic ultrasonic fields*

*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?*

FDA should evaluate a firm’s ability to conduct those additional assessments. Specific conformity assessment techniques should be developed in collaboration with standards development organizations (SDOs).

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

MITA Member companies are interested in participation in the ASCA program. Some companies express interest in having their test laboratories accredited, especially for standards aligned with the IECEE scope. Some companies expressed interest in utilizing the program for their 510(k) applications. Some Member companies expressed a need for additional information or clarification before making a decision about participation.

*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?*

FDA should accept ISO 17025 / ISO 15189 accreditations already granted by existing accreditation organizations, and then find private sector organizations that can perform the competency evaluations. FDA should strongly consider accepting or relying on a manufacturers testing facility’s technical competency to recognized standards based on privileges already granted by other similar programs, such as the IECEE CB Scheme, UL COMPASS, EU MDD Annex 2 certification, CSA Category Certification, etc., especially if the firm granting these privileges is also entered into the ASCA program. MITA strongly encourages the FDA to leverage existing conformity assessment work and to ensure that additional burdens are not being added to companies already participating in similar efforts.

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MITA Member companies count on careful consideration of this response and look forward to an outcome that meets their expectations. Further, MITA would be eager to continue its dialog with FDA as the ASCA program proceeds and to help actively with the many tasks before us. If you have any questions, please contact Megan Hayes, Director, Regulatory and Standards Strategy at 703-841-3285 or by email at [mhayes@medicalimaging.org](mailto:mhayes@medicalimaging.org).

Sincerely,



Patrick Hope

Executive Director, MITA

*MITA is the collective voice of medical imaging equipment and radiopharmaceutical manufacturers, innovators and product developers. It represents companies whose sales comprise more than 90 percent of the global market for medical imaging technology. These technologies include: magnetic resonance imaging (MRI), medical X-Ray equipment, computed tomography (CT) scanners, ultrasound, nuclear imaging, radiopharmaceuticals, radiation therapy equipment, and imaging information systems. Advancements in medical imaging are transforming health care through earlier disease detection, less invasive procedures and more effective treatments. The industry is extremely important to American healthcare and noted for its continual drive for innovation, fast-as-possible product introduction cycles, complex technologies, and multifaceted supply chains. Individually and collectively, these attributes result in unique concerns as the industry strives toward the goal of providing patients with the safest, most advanced medical imaging currently available.*