4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-1067]

# Request for Comments on Food and Drug Administration Accreditation Scheme for Conformity Assessment Pilot Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA or the Agency), Center for Devices and Radiological Health (CDRH), is establishing a public docket to request comments related to the FDA Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program. The purpose is to gain insight regarding the development and overall design/approach of the ASCA pilot program including program goals, pilot standards, design concepts, and overall program approach. The Agency is interested in gathering additional information to increase the efficiency of the ASCA Program.

DATES: Submit either electronic or written comments or information by [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments received by mail/hand

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: https://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to https://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on https://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2017-N-1067 for "Request for Comments on FDA Accreditation Scheme for Conformity Assessment Pilot Program." Received comments, those filed in a timely manner (see DATES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Scott Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5514, Silver Spring, MD 20993, 301-796-6287, standards@cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

## I. Background

Voluntary consensus standards are technical standards developed among different parties including governments and standard setting organizations, which play an important role in establishing the safety and performance criteria for many aspects of medical device design and manufacturing. These standards help to support claims of safety and quality of technical information in premarket review. FDA has authority to recognize voluntary consensus standards for use in establishing safety and performance criteria for medical device design and manufacturing. Sponsors can include a "Declaration of Conformity" to attest to which consensus standards they used in their premarket applications to meet premarket requirements for their devices. However, the appropriate use of an FDA recognized consensus standard via a

declaration of conformity has not been consistently applied by sponsors in submissions. Many standards are highly complex and require substantial specialized knowledge to interpret and apply correctly. This is a challenge for manufacturers and FDA alike. During the Medical Device User Fee Act reauthorization negotiations, FDA and Industry agreed to establish an FDA Accreditation Scheme for Conformity Assessment (ASCA) Program for recognizing accredited testing laboratories that evaluate medical devices according to certain FDA-recognized standards. This initiative will benefit sponsors of submissions who can have the tests conducted at recognized accredited test labs and submit to FDA a determination from the test laboratory that their device conforms to the standards tested. FDA intends to rely on the results from the recognized accredited Test Laboratory for the purpose of premarket review without the need to address further questions related to standards conformance. Once developed, the ASCA will ease a regulatory burden on industry by allowing them to use recognized accredited test laboratories to ensure accurate conformance with the consensus standard.

FDA is requesting comments to gain insight regarding the development and overall design/approach of the ASCA pilot program, including program goals, pilot standards, design concepts, and overall program approach. FDA is not endorsing any of the models proposed at this time. The Agency is open to considering other options or models for the ASCA pilot program and invites comments on any additional options or suggestions that may assist FDA in its decision making.

FDA is also considering using private sector accreditation bodies to increase the efficiency of the ASCA Program. As a result, FDA is considering a number of different models to serve this purpose. FDA is not endorsing any of these models at this time and is open to considering other options or models for the ASCA pilot program.

## II. Request for Comments

The Agency invites comments on the ASCA pilot program, in general, and on the following questions, in particular. Each individual question is numbered; please clearly delineate which questions each of your comments are addressing in the written response.

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?
    b. What impact/efficiencies would you like to see from the pilot program?
    c. What does success of the pilot program look like?
    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?
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?
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.

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

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?

Dated: May 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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