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The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff

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Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Preface

Public Comment

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The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program

Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

The Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot) is authorized under section 514(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).[1] In accordance with amendments made to section 514 by the FDA Reauthorization Act of 2017 (FDARA),[2] and as part of the enactment of the Medical Device User Fee Amendments of 2017 (MDUFA IV),[3] FDA was directed to issue a guidance regarding the goals and implementation of the ASCA Pilot.[4] The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Pilot supports the Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Pilot may further encourage international harmonization of medical device regulation because it incorporates elements, where appropriate, from a well-established set of international conformity assessment practices and standards (e.g., ISO/IEC 17000 series). The voluntary ASCA Pilot does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

[1] 21 U.S.C. 360d(d)
[2] *See* Pub. L. 115-52
[3] *See also* MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download
[4] *See* section 514(d)(3)(B) of the FD&C Act.

This guidance refers to voluntary consensus standards.[5] For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database.[6] For more information regarding use of standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices[7] and Standards Development and the Use of Standards in Regulatory Submissions Reviewed in CBER.[8]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

FDARA amended section 514 of the FD&C Act by adding a new subsection (d) titled "Pilot Accreditation Scheme for Conformity Assessment."[9] Subsection 514(d) requires FDA to establish a pilot program under which testing laboratories may be accredited by accreditation bodies meeting criteria specified by FDA to assess the conformance of a device within certain FDA-recognized consensus standards. Determinations by accredited testing laboratories that a device conforms with an eligible standard included as part of the pilot program shall be accepted by FDA for the purposes of demonstrating such conformity unless FDA finds that a particular such determination shall not be so accepted.[10]

The statute provides that FDA may review determinations by accredited testing laboratories, including by conducting periodic audits of such determinations or processes of accreditation bodies or testing laboratories.[11] Following such a review, or if FDA becomes aware of information materially bearing on safety or effectiveness of a device tested by an accredited testing laboratory, FDA may take additional measures as determined appropriate, including suspension or withdrawal of accreditation of a testing laboratory[12] or a request for additional information regarding a specific device.[13]

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[5] For the purposes of this guidance, the term 'standard' or 'standards' will be used to refer to 'consensus standard' or 'consensus standards'.
[6] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[7] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
[8] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation
[9] *See* Pub. L. 115-52, section 205
[10] *See* section 514(d)(1)(B) of the FD&C Act.
[11] *See* section 514(d)(2)(A) of the FD&C Act.
[12] Section 514(d)(2)(B) allows FDA to take additional measures "such as suspension or withdrawal of accreditation of such testing laboratory." As used in this guidance, the term "accreditation" refers to the "*ASCA Accreditation"* granted by FDA and not the accreditation granted by an accreditation body.
[13] *See* section 514(d)(2)(A)-(B) of the FD&C Act.

III. Overview

Under the ASCA Pilot's conformity assessment scheme, ASCA-recognized accreditation bodies accredit testing laboratories using ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* and the ASCA program specifications associated with each FDA-recognized consensus standard and test method included in the ASCA Pilot. The FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot and the ASCA program specifications are provided in the relevant standards-specific ASCA Pilot guidance documents which can be accessed from the ASCA website.[14]

ASCA-accredited testing laboratories may conduct testing to provide data used to determine conformance of a device with one or more of the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot.

When an ASCA-accredited testing laboratory conducts testing under the ASCA Pilot, it should provide to the device manufacturer all information listed in the relevant ASCA program specifications, including an ASCA summary test report. Example ASCA summary test reports for the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot are provided in the associated standards-specific ASCA Pilot guidance documents.

Device manufacturers may choose to use an ASCA-accredited testing laboratory to conduct testing for premarket submissions to FDA. A device manufacturer that uses an ASCA-accredited testing laboratory to perform testing in accordance with the provisions of the ASCA Pilot can then include a declaration of conformity (DOC) with any necessary supplemental documentation (e.g., an ASCA summary test report) as part of a premarket submission to FDA. Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using an FDA-recognized consensus standard and test method eligible for inclusion in the ASCA Pilot and in accordance with the ASCA program specifications for that standard.

During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories (i.e., test results) when accompanied by a DOC and appropriate supplemental documentation (e.g., an ASCA summary test report) and when the standard and test methods are within the testing laboratory's scope of *ASCA Accreditation* at the time of testing *(Refer to Section XIII. of this guidance)*.

As part of the enactment of MDUFA IV,[15] FDA committed to publish the following information on FDA's publicly-accessible ASCA website:

- A list of ASCA-recognized accreditation bodies including the FDA-recognized consensus standards and test methods within the scope of each accreditation body's *ASCA Recognition*;

[14] ASCA website: https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca
[15] MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download

- A list of ASCA-accredited testing laboratories including the FDA-recognized consensus standards and test methods within the scope of each testing laboratory's *ASCA Accreditation*.

To further promote transparency, FDA intends to also identify an expiration date for each accreditation body's *ASCA Recognition*, and for each testing laboratory's *ASCA Accreditation,* on the publicly-accessible ASCA website. Figure 1 illustrates the process flow for the ASCA Pilot as described above and in Sections IX and X of this guidance.

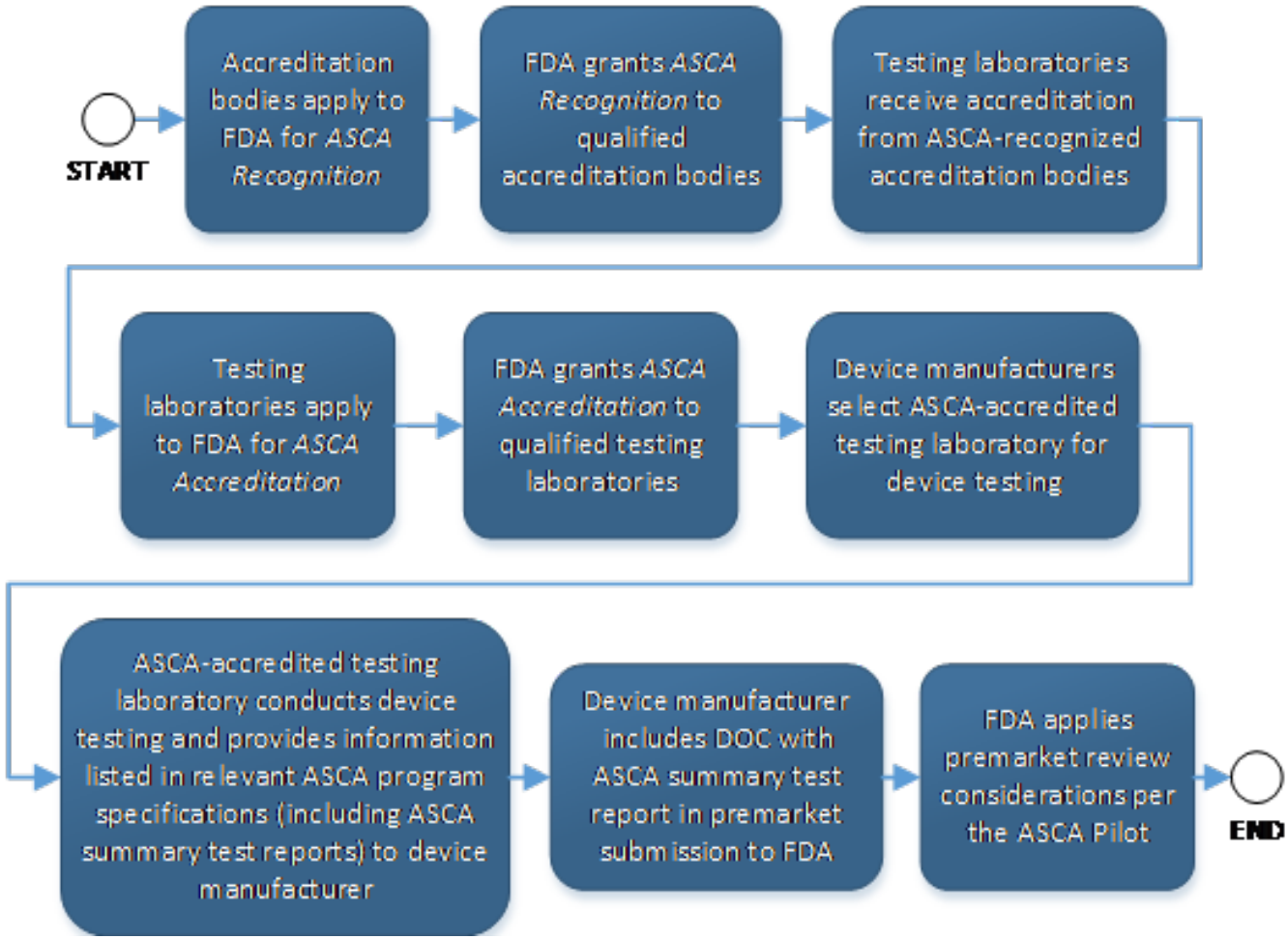

Figure 1 Process flow for the ASCA Pilot.

IV. Scope

Several complementary guidance documents are being used to implement the ASCA Pilot. This guidance describes the goals and implementation of the ASCA Pilot as required by section 514(d)(3)(B) of the FD&C Act. Specifically:

- The "criteria specified by the Secretary"[16] used to determine whether and how an accreditation body or testing laboratory may participate in the ASCA Pilot. These criteria include:
    - Qualifications FDA intends to consider when reviewing applications from accreditation bodies and testing laboratories to participate in the ASCA Pilot (*Refer to Sections X.A. and XI.A. of this guidance*);
    - Processes FDA intends to follow, including recommended application contents, in granting *ASCA Recognition* to accreditation bodies and granting *ASCA Accreditation* to testing laboratories (*Refer to Sections X.B. and XI.B. of this guidance*);
    - Terms of participation to which ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories agree (*Refer to Section D of Appendices A and B of this guidance*); and
    - ASCA program specifications associated with each eligible FDA-recognized consensus standard and test method developed to communicate expectations for how ASCA-recognized accreditation bodies accredit testing laboratories in the ASCA Pilot.
        - This guidance document provides a description of how the ASCA program specifications were developed (*Refer to Section VIII.D. of this guidance*). ASCA program specifications are located in the relevant standards-specific ASCA Pilot guidance documents.
- The "certain standards recognized under [section 514]"[17] eligible for inclusion in the ASCA Pilot.
    - This guidance document provides a description of how FDA-recognized consensus standards and test methods were selected for the ASCA Pilot, including considerations articulated in the MDUFA IV Commitment Letter[18] (*Refer to Section VIII.C. of this guidance*). The FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot are located in the relevant standards-specific ASCA Pilot guidance documents.
- The process by which device manufacturers may incorporate testing from ASCA-accredited testing laboratories in a submission to FDA for the purpose of demonstrating conformance of a device with FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot[19] (*Refer to Section XII. of this guidance*).
- The policy regarding Agency review of determinations (i.e., test results) by ASCA-accredited testing laboratories. Such determinations "shall be accepted by the Secretary for purposes of demonstrating such conformity under this section unless the Secretary finds that a particular such determination shall not be so accepted"[20] (*Refer to Section XIII. of this guidance*).

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[16] *See* section 514(d)(1)(A) of the FD&C Act.
[17] *See* section 514(d)(1)(A) of the FD&C Act.
[18] *See* MDUFA IV Commitment Letter pg. 14: https://www.fda.gov/media/100848/download
[19] *See* section 514(d)(1)(B) of the FD&C Act.
[20] *See* section 514(d)(1)(B) of the FD&C Act.

- The processes and policies FDA intends to follow when "conducting periodic audits of such determinations or processes of accredited bodies or testing laboratories"[21] (*Refer to Sections X.E. and XI.E. of this guidance*).
- The processes and policies FDA intends to follow regarding "suspension or withdrawal of accreditation" or "requesting additional information"[22] (*Refer to Sections X.F., XI.F., XI.G., and XIII.B. of this guidance*).

The FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot are identified in the relevant 'standards-specific' ASCA Pilot guidance documents. These guidance(s) were developed for the purpose of being able to implement the framework described in this guidance and provide more detailed information for the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot. Each standards-specific ASCA Pilot guidance document includes the following information:

- Detailed list of FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot for assessment of the particular subject matter (e.g., biocompatibility testing);
- ASCA program specifications associated with such standards and test methods;
- Recommended premarket submission contents specific to such standards and test methods when testing is conducted by an ASCA-accredited testing laboratory;
- Example ASCA summary test report(s) for such standards and test methods; and
- Example DOC for such standards and test methods.

The ASCA Pilot guidance documents do not address specific content for a particular premarket submission. For more information about the use of standards for device review, visit the Standards and Conformity Assessment Program website.[23] See also FDA's guidance, CDRH Standard Operating Procedures for the Identification and Evaluation of Candidate Consensus Standards for Recognition[24] FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, and FDA's guidance Standards Development and the Use of Standards in Regulatory Submissions Reviewed in CBER.

This guidance document is not intended to be a complete resource for understanding conformity assessment. Key conformity assessment resources used to develop the ASCA Pilot are described in Section V. of this guidance.

V. Terminology in the ASCA Pilot

This section provides definitions for key terms used in the ASCA Pilot. Where possible, FDA has used terms already defined in the international standard ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles (hereafter referred to as "ISO/IEC 17000") and

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[21] *See* section 514(d)(2)(A) of the FD&C Act.
[22] *See* section 514(d)(2)(A) and 514(d)(2)(B) of the FD&C Act.
[23] Available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program
[24] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cdrh-standard-operating-procedures-identification-and-evaluation-candidate-consensus-standards-0

ISO/IEC 17011 ISO/IEC 17011:2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies* (hereafter referred to as "ISO/IEC 17011"). Footnotes in this section indicate when a term is identical to one used in ISO/IEC 17000 or ISO/IEC 17011. Some definitions within ISO/IEC 17000 and ISO/IEC 17011 refer to "requirements;" FDA's references to them for the ASCA Pilot do not make them legal or regulatory requirements. In certain circumstances, FDA has created new terminology to describe specific aspects of the ASCA Pilot.

- Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.[25] An accreditation body may or may not accredit a testing laboratory independent of a laboratory's participation (or desire to participate) in the ASCA Pilot.
- Accreditation body: authoritative body that performs accreditation.[26]
- ASCA-accredited testing laboratory: testing laboratory that has been granted *ASCA Accreditation* by FDA. ASCA-accredited testing laboratories may label their testing as having been conducted under the ASCA Pilot if the FDA-recognized consensus standards and test methods were within their scope of *ASCA Accreditation* at the time of testing. ASCA-accredited testing laboratories attend training, communicate with FDA, receive periodic audits, and agree to follow the other processes and policies outlined in this guidance (*Refer to Section XI. of this guidance*).
- ASCA-recognized accreditation body: accreditation body that has been granted *ASCA Recognition* by FDA. ASCA-recognized accreditation bodies may label their accreditation activities as having been conducted under the ASCA Pilot if the FDA-recognized consensus standards and test methods were within their scope of *ASCA Recognition* at the time of accreditation; ASCA-recognized accreditation bodies attend training, communicate with FDA, receive periodic audits, and agree to follow the other processes and policies outlined in this guidance (*Refer to Section X. of this guidance*).
- *ASCA Accreditation*: status granted by FDA to testing laboratories that demonstrate competence in testing via the application process (*Refer to Section XI.B. of this guidance*). ASCA-accredited testing laboratories are granted a scope of *ASCA Accreditation* indicating the standards and test methods for which testing may be labeled as having been conducted under the ASCA Pilot. *ASCA Accreditation* exists only within the ASCA Pilot and is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Pilot.
- *ASCA Recognition*: status granted by FDA to accreditation bodies that demonstrate competence in accreditation activities via the application process (*Refer to Section X.B. of this guidance*). ASCA-recognized accreditation bodies are granted a scope of *ASCA Recognition* indicating the standards and test methods for which accreditation activities may be labeled as having been conducted under the ASCA Pilot.
- ASCA summary test report: documentation that summarizes the testing conducted by an ASCA-accredited testing laboratory within the scope of its *ASCA Accreditation*; an

[25] Per ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles
[26] *Ibid*

ASCA summary test report is specific to the ASCA Pilot and should include the information recommended in the standards-specific ASCA Pilot guidance documents.

- Audit: systematic, independent, documented process for obtaining records, statements of fact or other relevant information and assessing them objectively to determine the extent to which specified requirements are fulfilled.[27]
    - In the ASCA Pilot, FDA uses the term "audit" to refer also to evaluations and assessments.
- Conformity assessment: demonstration that specified requirements relating to a product, process, system, person, or body are fulfilled; note that the subject field of conformity assessment may include testing, inspection, and certification, as well as accreditation of conformity assessment bodies.[28]
- Conformity assessment body: body that performs conformity assessment services; note that an accreditation body is not a conformity assessment body.[29]
- Conformity assessment scheme: conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules and procedures apply.[30]
- Conformity assessment system: rules, procedures, and management for carrying out conformity assessment.[31]
- Declaration of conformity (DOC): attestation made by a medical device manufacturer, in accordance with section 514(c)(1)(B) of the FD&C Act, regarding whether a device conforms with an FDA-recognized consensus standard.[32]
- Determinations by testing laboratories:[33] test results.
- Extending accreditation: adding conformity assessment activities to the scope of accreditation.[34]
- Extending *ASCA Accreditation:* adding FDA-recognized consensus standards and test methods to a testing laboratory's scope of *ASCA Accreditation (Refer to Section XI.C. of this guidance).*
- Extending *ASCA Recognition:* adding FDA-recognized consensus standards and test methods to an accreditation body's scope of *ASCA Recognition (Refer to Section X.C. of this guidance).*

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[27] *Ibid*
[28] *Ibid*
[29] *Ibid*
[30] Per ISO/IEC 17000, conformity assessment scheme setup varies based on the object of conformity assessment (e.g., medical device), the users of the scheme (e.g., regulators, medical device manufacturers), and the nature of the specific requirements being assessed (e.g., specific medical device standards).
[31] Per ISO/IEC 17000
[32] See FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.
[33] The term "determinations by testing laboratories" is used in sections 514(d)(1)(b), 514(d)(2), and 514(d)(4) of the FD&C Act.
[34] Per ISO/IEC 17011

- FDA-recognized consensus standard: standards identified by FDA (per section 514(c) of the FD&C Act) as appropriate for manufacturers of products to declare conformance to meet relevant requirements under the FD&C Act, including premarket submission requirements. For more information on the standards recognition process, please visit the Standards and Conformity Assessment Program website[35] and review FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.
- Request for Clarification: request submitted to FDA for clarification of one or more specific ASCA program specifications from an ASCA-recognized accreditation body (*Refer to Section X.D. of this guidance)* or an ASCA-accredited testing laboratory (*refer to Section XI.D. of this guidance)*. A Request for Clarification presents a question relative to implementation of ASCA program specifications. It does not include suggestions or requests for modifications to the ASCA Pilot or hypothetical issues.
- Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted.[36]
- Scope of *ASCA Accreditation*: list of FDA-recognized consensus standards and test methods for which a testing laboratory has demonstrated competence to FDA, through the application process, for conducting testing for the ASCA Pilot.
- Scope of *ASCA Recognition*: list of FDA-recognized consensus standards and test methods for which an accreditation body has demonstrated competence to FDA, through the application process, for accrediting testing laboratories for the ASCA Pilot.
- Suspending *ASCA Accreditation*: putting temporary constraints in place for one or more FDA-recognized consensus standards or test methods within a testing laboratory's scope of *ASCA Accreditation (Refer to Section XI.F. of this guidance).*
- Third-party attestation: issue of statement, based on a decision following review, that fulfilment of specific requirements has been demonstrated.[37]
- Withdrawing accreditation: cancelling accreditation for the full scope.[38]
- Withdrawing *ASCA Accreditation*: cancelling a testing laboratory's full scope of *ASCA Accreditation*; withdrawal of *ASCA Accreditation* removes the organization from the ASCA Pilot entirely *(Refer to Section XI.G. of this guidance)*.
- Withdrawing *ASCA Recognition*: cancelling an accreditation body's full scope of *ASCA Recognition*; withdrawal of *ASCA Recognition* removes the organization from the ASCA Pilot entirely *(Refer to Section X.F. of this guidance)*.

VI. Purpose of the ASCA Pilot

Evidence of conformity to one or more FDA-recognized consensus standards is often a thorough and efficient way for a manufacturer to address certain questions of safety and/or effectiveness.

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[35] Available at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program
[36] Per ISO/IEC 17011
[37] Per ISO/IEC 17000
[38] Per ISO/IEC 17011

For manufacturers and FDA to benefit from the efficiency, however, FDA must have confidence in the DOC.[39] DOCs are discussed in section 514(c)(1)(B) of the FD&C Act and FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices. These resources indicate that a device manufacturer may provide a DOC to one or more FDA-recognized consensus standards in a premarket submission to be reviewed by FDA.

A device manufacturer may declare conformity to an FDA-recognized consensus standard based on test results; however, there may be variability in how this testing is conducted. Given this variability, and because medical devices are increasingly complex and can involve high risks to patients, DOCs are not always sufficient to fully address FDA's questions regarding safety and effectiveness for premarket submissions. As a result, FDA reviewers may need to request additional information and review supplemental documentation as described in FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices. In some instances, a device manufacturer may decide to repeat or revise testing based on FDA input. These interactions and requests for modifications in test methodology can result in delays and additional costs, but are needed to provide FDA with the necessary confidence in a DOC for its intended purpose.

As required by FDARA[40] and as part of the enactment of MDUFA IV,[41] FDA committed to the establishment of the ASCA Pilot with stakeholder input.[42] FDA held a public workshop to obtain input and recommendations from stakeholders regarding the goals, scope, procedures, and requirements for the ASCA Pilot. The feedback sought from stakeholders (*Refer to Section VIII.A. of this guidance*) was directed to the ultimate purpose of improving the efficiency of the premarket review process by building confidence in DOCs through the use of accredited testing laboratories.

VII. Specific Goals of the ASCA Pilot

The ASCA Pilot is intended to support FDA's public health mission by providing increased confidence in testing results from ASCA-accredited testing laboratories, as well as potentially decreasing the burden of individual premarket submissions when manufacturers rely on testing completed by ASCA-accredited testing laboratories.

The overarching goals of the ASCA Pilot are intended to:

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[39] *See* section 514(c)(1)(B) of the FD&C Act.
[40] *See* sections 514(d)(1) and 514(d)(3)(A) of the FD&C Act
[41] *See also* MDUFA IV Commitment Letter: https://www.fda.gov/media/100848/download
[42] 83 FR 2165, available at https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug

- Enhance confidence in medical device testing

  The ASCA Pilot includes application processes and periodic audits of accreditation bodies and testing laboratories as well as the processes that will be followed for suspension or withdrawal. These processes and audits are intended to increase confidence in the testing performed by ASCA-accredited testing laboratories by ensuring that ASCA-recognized accreditation bodies meet the criteria specified by FDA in this guidance and any relevant standards-specific ASCA Pilot guidance documents throughout their participation in the program.[43] The increased confidence in testing may be particularly helpful for premarket submissions that rely on DOC to FDA-recognized consensus standards using test results from ASCA-accredited testing laboratories.

- Promote consistency and predictability in the premarket review process

  The ASCA Pilot does not introduce new requirements for medical device manufacturers. Rather, by clearly communicating expectations for how results from ASCA-accredited testing laboratories are included and reviewed in premarket submissions, the ASCA Pilot intends to promote consistency and predictability in all of FDA's premarket submission programs.

- Encourage effective use of FDA resources

  The increased acceptance of DOCs under the ASCA Pilot (*Refer to Section XIII. of this guidance)* allows FDA to direct scientific and regulatory resources to other priorities.

- Enhance regulatory efficiency

  By virtue of a testing laboratory's *ASCA Accreditation*, device manufacturers can be more confident early in the product development lifecycle that testing to the FDA-recognized consensus standards and test methods within the laboratory's scope *of ASCA Accreditation* is likely to meet FDA's regulatory requirements. FDA expects that the application process, periodic audits, and clear communication among participants in the ASCA Pilot will decrease the need for the FDA to request additional information regarding testing methodologies when a premarket submission includes DOCs to a FDA-recognized consensus standard eligible for inclusion in the ASCA Pilot.

- Support international harmonization

  FDA used elements from international conformity assessment standards in the ISO/IEC 17000 series to establish the ASCA Pilot. The standards within the ISO/IEC 17000 series are used worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers.[44] In addition, most of the FDA-recognized consensus standards and test methods selected for the ASCA Pilot are international consensus

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[43] *See* section 514(d)(1)(A) of the FD&C Act.
[44] *See* NIST SP 2000-01 ABCs of Conformity Assessment (2018) available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-01.pdf

standards. FDA believes the experience gained in the ASCA Pilot could broadly inform international harmonization efforts such as standards use across jurisdictions.

VIII. Development of the ASCA Pilot

A. Stakeholder Input

FDA has developed the framework of the ASCA Pilot with the support and participation of stakeholders from industry, the conformity assessment community, and technical experts from the National Institute of Standards and Technology (NIST).

In addition, FDA published a *Federal Register* notice[45] requesting comments on a set of questions designed to gain insight regarding the development and overall design/approach of the ASCA Pilot including goals, pilot FDA-recognized consensus standards and test methods, design concepts, and overall program approach. Comments received in response to this notice were reviewed and considered in the development of this guidance. These comments were also informative to the public meeting required by section 514(d)(3)(A).[46]

As required by FDARA,[47] FDA held a public workshop titled "Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration Recognized Standards" on May 22-23, 2018,[48] to discuss and obtain input and recommendations from stakeholders about the ASCA Pilot, including its goals and scope as well as a suitable framework and procedures to facilitate implementation. The workshop is discussed on FDA's "Workshop and Conferences" website.[49]

Input from each of these resources has been informative in the design of the conformity assessment scheme and selection of the initial FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot as discussed in this guidance as well as the standards-specific ASCA Pilot guidance documents.

B. Conformity Assessment Resources

FDA sought to maximize the use of existing frameworks and arrangements in developing the ASCA conformity assessment scheme. This way, accreditation bodies and testing laboratories can participate in the ASCA Pilot by leveraging existing processes and knowledge, increasing the net benefit of participation. We also anticipate that, by using and extending existing

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[45] 82 FR 22548 (May 16, 2017).
[46] ASCA Public Workshop website: https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/public-workshop-accreditation-scheme-conformity-assessment-asca-medical-devices-fda-recognized
[47] *See* section 514(d)(3)(A) of the FD&C Act.
[48] 83 FR 2165, available at https://www.federalregister.gov/documents/2018/01/16/2018-00551/accreditation-scheme-for-conformity-assessment-of-medical-devices-to-food-and-drug
[49] Available at https://www.fda.gov/medical-devices/news-events-medical-devices/workshops-conferences-medical-devices

paradigms, the lessons learned from the ASCA Pilot will be equally applicable, and therefore beneficial, to other stakeholders (e.g., other regulatory authorities).

The conformity assessment scheme used in the ASCA Pilot leverages the following well-established set of international conformity assessment standards and arrangements that are used worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers:

- International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)[50]

  ILAC is an international organization for accreditation bodies that accredit conformity assessment bodies including testing laboratories. The accreditation bodies that are signatories to the ILAC MRA are peer evaluated in accordance with the specifications of ISO/IEC 17011 to demonstrate their competence. The ILAC MRA provides an internationally recognized process used to accept accredited test reports. One qualification for *ASCA Recognition* is whether the accreditation body is a signatory to the ILAC MRA (*Refer to Section X.A. of this guidance*). FDA intends to leverage ILAC MRA policies and procedures regarding accreditation body peer evaluations by reviewing peer evaluation reports and/or participating as an observer during these activities (*Refer to Section X.E. of this guidance*).

- ISO/IEC 17011

  This international consensus standard describes the specifications for accreditation bodies accrediting, among others, testing laboratories. Accreditation bodies conform to ISO/IEC 17011 in order to be a signatory to the ILAC MRA, a qualification for *ASCA Recognition* of an accreditation body (*Refer to Section X.A. of this guidance*). FDA intends to leverage the assessments conducted by accreditation bodies per ISO/IEC 17011 by reviewing assessment reports and/or participating as an observer during these activities (*Refer to Section X.E. of this guidance).*

- ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* (hereafter referred to as "ISO/IEC 17025")

  This international consensus standard contains specifications for laboratories to operate competently and generate valid results. Accreditation bodies use ISO/IEC 17025 along with the ASCA program specifications associated with each eligible FDA-recognized consensus standard or test method to accredit testing laboratories for the ASCA Pilot (*Refer to Section IX.A. of this guidance*).

In addition to the above resources, FDA also leveraged the following NIST documents, which provide an overview of conformity assessment, in the design, development, and implementation

[50] For more information about ILAC, visit https://ilac.org/about-ilac/

scheme of the ASCA Pilot as outlined in this guidance document: NIST SP 2000-01 ABCs of Conformity Assessment (2018)[51] and NIST SP 2000-02 Conformity Assessment Considerations for Federal Agencies (2018).[52]

C. Selection of FDA-Recognized Consensus Standards and Test Methods

When deciding which FDA-recognized standards and test methods to include in the ASCA Pilot, FDA sought to maximize the benefit of the ASCA Pilot to the public health by selecting FDA-recognized consensus standards and test methods that manufacturers often rely upon to address significant issues of safety and/or effectiveness. FDA identified FDA-recognized consensus standards and test methods as eligible for the ASCA Pilot based on input from stakeholders at the public workshop and provided in response to the *Federal Register* notice requesting comments. In accordance with the MDUFA IV commitment letter,[53] these standards and test methods include both cross-cutting (horizontal) and device-specific (vertical) standards, are of public health significance, and have or are able to provide the means for establishing acceptance.

FDA regularly considers recognition of updated editions of standards. FDA is aware that, depending on the nature of the changes to the new edition, revisions to the associated ASCA program specifications may be needed. For the edition of the FDA-recognized consensus standard(s) included in the ASCA Pilot, see the FDA Recognized Consensus Standards Database.[54]

As allowed under section 514(c) of the FD&C Act and further explained in FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, manufacturers may continue to rely on other standards and provide DOC in premarket submissions; however, other standards will not be eligible for the premarket review benefits of the ASCA Pilot *(Refer to Section XIII. of this guidance)*.

D. ASCA Program Specifications Development

ISO/IEC 17025 includes "general requirements for the competence of testing and calibration laboratories." Sections of the standard discuss impartiality, confidentiality, organizational structure, resources (e.g., personnel, facilities, equipment), processes (e.g., selection and verification of methods, validation of methods, sampling, reporting of results), and management systems (e.g., corrective actions, control of records, management reviews). The ASCA program specifications are used *in addition to* ISO/IEC 17025 by ASCA-recognized accreditation bodies for accreditation of testing laboratories for the ASCA Pilot. In developing the ASCA program specifications for each set of FDA-recognized consensus standards and test methods, FDA

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[51] Available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-01.pdf
[52] Available at https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.2000-02.pdf
[53] *See* MDUFA IV Commitment Letter, pg. 14 at https://www.fda.gov/media/100848/download
[54] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

sought to ensure that the ASCA program specifications include only those aspects of testing laboratory competence that are necessary *above and beyond* those already provided in ISO/IEC 17025 in order to ensure confidence in device testing submitted to FDA. FDA carefully considered previous and current concerns with testing submitted to the FDA as well as potential implementation challenges for accreditation bodies and testing laboratories. Stakeholder input on the ASCA program specifications was received at a public workshop[55] (*Refer to Section VIII.A. of this guidance)* as well as during the guidance process.

The ASCA program specifications are located in the standards-specific ASCA Pilot guidance documents.

IX. Roles and Responsibilities

A. Accreditation Bodies

Under the ASCA Pilot, ASCA-recognized accreditation bodies accredit testing laboratories using the specifications of ISO/IEC 17025 and the ASCA program specifications associated with each eligible FDA-recognized consensus standard and test method eligible for inclusion in the ASCA Pilot (*Refer to standards-specific ASCA Pilot guidance documents*). Upon granting *ASCA Recognition* to an accreditation body, FDA intends to provide to the accreditation body a scope of *ASCA Recognition* describing the extent to which the accreditation body has demonstrated competence in accreditation for purposes of the ASCA Pilot. ASCA Pilot processes and policies for accreditation bodies are described in Section X. of this guidance.

The responsibilities of an accreditation body (also referred to as "terms of participation") are identified in the signed agreement section of the accreditation body application (*Refer to Section D of Appendix A of this guidance*).

B. Testing Laboratories

ASCA-accredited testing laboratories perform testing in accordance with the specifications of ISO/IEC 17025 and ASCA program specifications associated with each eligible FDA-recognized consensus standard and test method included in the testing laboratory's scope of *ASCA Accreditation*. A testing laboratory may work with the device manufacturer to develop a test plan (*Refer to Section XII.B. of this guidance*). After testing is complete, the testing laboratory provides the information listed in the relevant ASCA program specifications (including an ASCA summary test report) to the device manufacturer. A testing laboratory may label its testing as having been conducted under the ASCA Pilot only if the FDA-recognized consensus standards and test methods used were within its scope of *ASCA Accreditation* at the time of testing.

[55] Public workshop titled "Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards" on May 22-23, 2018

Upon granting *ASCA Accreditation*, FDA intends to provide the testing laboratory with a scope of *ASCA Accreditation* describing the extent to which the testing laboratory has demonstrated competence in testing for purposes of the ASCA Pilot. ASCA Pilot processes and policies for testing laboratories are described in Section XI. of this guidance.

The responsibilities of a testing laboratory (also referred to as "terms of participation") are identified in the signed agreement section of the testing laboratory application (*Refer to Section D of Appendix B of this guidance*).

C. Device Manufacturers

Device manufacturers may voluntarily choose to use an ASCA-accredited testing laboratory to conduct testing to be included in premarket submissions to FDA. The device manufacturer is responsible for including the appropriate information regarding device testing in its premarket submission (*Refer to Section XII.C. of this guidance*). It is the manufacturer's responsibility to ensure FDA-recognized consensus standards and test methods are selected and used appropriately and that the DOC provided in a premarket submission is consistent with the guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices and the standards-specific ASCA Pilot guidance documents. ASCA Pilot processes and policies for device manufacturers are described in Section XII. of this guidance.

As noted in the MDUFA IV Commitment Letter,[56] a device manufacturer's internal testing laboratory is eligible for *ASCA Accreditation*. In determining whether to grant *ASCA Accreditation* to a device manufacturer's internal testing laboratory, FDA intends to consider the same factors used in determining whether to grant *ASCA Accreditation* to any other testing laboratory (*Refer to Section XI.A. of this guidance*). Any ASCA-accredited testing laboratory (including a device manufacturer's internal testing laboratory) is expected to follow the processes and policies of this guidance and fulfill the roles and responsibilities described in Section XI. of this guidance.

D. FDA Staff

FDA ASCA program staff manage the ASCA Pilot, including granting *ASCA Recognition* to accreditation bodies, granting *ASCA Accreditation* to testing laboratories, conducting audits[57] of ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories, and reviewing information submitted by ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories per their terms of participation. FDA ASCA program staff are also responsible for the ASCA website, which provides an up-to-date listing of ASCA-recognized accreditation bodies (including the scopes of and expiration dates for *ASCA Recognition*) and ASCA-accredited testing laboratories (including the scopes of and expiration dates for *ASCA*

[56] See MDUFA IV Commitment Letter pg. 14: https://www.fda.gov/media/100848/download

[57] Per NIST SP 2000-01 ABCs of Conformity Assessment (2018): "Audit activities use an organized, predictable process for assessing records and other information to determine whether requirements have been fulfilled." FDA staff's audits will determine whether the processes and policies of this guidance document have been fulfilled.

Accreditation). FDA ASCA program staff are responsible for ensuring consistent implementation of the processes and policies in this guidance document and providing any training to ASCA Pilot participants necessary to (a) maintain FDA's confidence in the testing submitted by ASCA-accredited testing laboratories and to (b) ensure that ASCA-recognized accreditation bodies meet the criteria specified by FDA for participation in the ASCA Pilot and continue to satisfy those criteria throughout their participation in the program.[58] ASCA Pilot processes and policies for management of the ASCA Pilot are described in Sections X. and XI. of this guidance.

FDA review staff conduct reviews of premarket submissions in accordance with existing statutes, regulations, and guidance. When premarket submissions include testing from an ASCA-accredited testing laboratory, FDA review staff are responsible for applying the statute, section 514(d) of the FD&C Act, and the policies described in this guidance. ASCA Pilot processes and policies regarding review of testing from an ASCA-accredited testing laboratory are described in Section XIII. of this guidance.

The FDA ASCA program staff managing the ASCA Pilot are separate and independent from the FDA review staff conducting premarket reviews.

X. Processes and Policies for Accreditation Bodies

A. Qualifications for *ASCA Recognition*

FDA will consider the following factors in determining whether to grant *ASCA Recognition* to an accreditation body :

1. Does the accreditation body have a scope of 'signatory status' of Testing: ISO/IEC 17025 to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA)?

This factor relies on the well-established set of international standards and arrangements for conducting conformity assessment activities *(Refer to Section VIII.B. of this guidance)*. Signatories to the ILAC MRA are peer-reviewed by other ILAC signatories for competence in accrediting conformity assessment bodies, which provides confidence that testing laboratories accredited by ILAC signatories are competent in their implementation of ISO/IEC 17025 and the ASCA program specifications associated with each eligible FDA-recognized consensus standard and test method.

2. Is the accreditation body based in the United States?

Many accreditation bodies exist within and outside of the United States to support global conformity assessment activities. By limiting the ASCA Pilot to accreditation bodies based in the

[58] *See* section 514(d)(1)(A) of the FD&C Act.

United States, FDA aims to effectively use limited resources to facilitate successful program implementation during the pilot.

3. Has the accreditation body agreed in writing to the terms of participation described in Section D of Appendix A of this guidance?

The terms and conditions outlined in Section D of Appendix A of this guidance are designed to ensure transparency and accountability on the part of the accreditation body in all aspects of its participation in the ASCA Pilot. An accreditation body may choose not to follow the terms of participation at any time; however, *ASCA Recognition* is contingent upon following such terms.

B. Accreditation Body Application Process

An accreditation body may apply for *ASCA Recognition* by submitting, via email to ASCA@fda.hhs.gov, documentation demonstrating how the applicant organization addresses the qualifications specified in Section X.A. of this guidance. Appendix A of this guidance provides more information on application contents for accreditation bodies. FDA intends to acknowledge receipt of the application and provide a unique ASCA Accreditation Body Identification Number to the accreditation body and a unique submission number used solely for tracking the application.

FDA intends to review applications for *ASCA Recognition* within 60 calendar days. After reviewing application contents, FDA intends to notify the accreditation body via email of the issues, if any, that may preclude *ASCA Recognition* so that any issues may be addressed (if possible). When review is complete, FDA intends to inform the accreditation body via email of our decision. If *ASCA Recognition* is granted, FDA will provide a scope of and expiration date (e.g., two years) for *ASCA Recognition*. Note that the scope will include only FDA-recognized consensus standards and test methods in the ASCA Pilot for which competence has been demonstrated. When FDA grants *ASCA Recognition* to an accreditation body, it will update the ASCA website to list the organization along with its scope of and expiration date for *ASCA Recognition*.

FDA's decision to grant *ASCA Recognition* to an accreditation body is discretionary. FDA may decide not to grant *ASCA Recognition* to an accreditation body, e.g., for reasons of public health or administrative efficiency. If FDA does not grant *ASCA Recognition* to an accreditation body, FDA intends to provide a rationale for the decision to the applicant.

Up to six months prior to the expiration of its *ASCA Recognition*, an accreditation body may apply to renew its *ASCA Recognition* following the same process outlined above.

C. Extension of *ASCA Recognition*

FDA understands that accreditation bodies may continually add capabilities to their programs and increase their internal expertise. FDA encourages accreditation bodies to extend their *ASCA Recognition* by adding FDA-recognized consensus standards and test methods to their scope of *ASCA Recognition* when additional competencies are attained. For example, an accreditation body may initially participate in the ASCA Pilot by accrediting testing laboratories for MEM

Elution Cytotoxicity testing. After some time, the accreditation body may obtain additional resources that can also support accrediting testing laboratories for Complement Activation testing. The accreditation body may then apply to extend its *ASCA Recognition* by adding Complement Activation testing to its scope of *ASCA Recognition*. In such a situation, the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot would not change, only the FDA-recognized consensus standards and test methods in the individual accreditation body's scope of *ASCA Recognition*.

An accreditation body may apply to extend its *ASCA Recognition* by following the same procedures used for its initial application for *ASCA Recognition*. That is, an accreditation body may submit documentation indicating how it meets the qualifications specified in Section X.A. of this guidance with respect to the additional FDA-recognized consensus standards or test methods via email to ASCA@fda.hhs.gov. Recommended application contents are described in Appendix A of this guidance. In addition to the contents outlined in this appendix, FDA recommends that the application include the following:

- the ASCA Accreditation Body Identification Number for the accreditation body;
- the current scope of *ASCA Recognition* for the accreditation body; and
- the FDA-recognized consensus standards or test methods that the accreditation body requests be added to its scope of *ASCA Recognition*.

FDA intends to use the same ASCA Accreditation Body Identification Number to track all activity for a given accreditation body, including extensions to *ASCA Recognition*.

FDA intends to update the scope of *ASCA Recognition* of each accreditation body on the ASCA website as appropriate.

D. Requests for Clarification

A Request for Clarification is a request submitted to FDA for clarification of one or more specific ASCA program specifications from an ASCA-recognized accreditation body. A Request for Clarification presents a question relative to implementation of ASCA program specifications. It does not include suggestions or requests for modifications to the ASCA Pilot or hypothetical issues.

A Request for Clarification may be submitted to ASCA@fda.hhs.gov.

E. Audits of Accreditation Bodies

FDA intends to periodically audit accreditation bodies to ensure that they are adequately fulfilling program expectations. [59] FDA intends to use a tiered-approach with three levels of audits.

As an ILAC MRA signatory, an accreditation body must agree to maintain conformance to ISO/IEC 17011 and agrees to periodic monitoring that includes re-evaluations conducted every four years, although shorter intervals can be determined by ILAC if needed.[60] For Level 1 audits of an accreditation body, FDA intends to leverage the existing arrangement of ILAC evaluations by requesting a copy of the most recent re-evaluation report. Upon review of the report, FDA may request clarification or additional information. FDA intends to follow the established 4-year schedule of the ILAC MRA. FDA may request a copy of the most recent evaluation report if the next peer evaluation is scheduled after the currently identified sunset of the ASCA Pilot. [61]

For Level 2 audits of the accreditation body, FDA intends to participate as an observer during the next scheduled ILAC peer re-evaluation and request a copy of the re-evaluation report for review. FDA will notify an accreditation body of the intent to participate and make the appropriate arrangements for an on-site visit. FDA intends to use Level 2 audits if there is a reason to believe Level 1 audits would be insufficient. Reasons to conduct a Level 2 audit could include, but are not limited to, observing persistent issues with testing laboratories accredited by a particular accreditation body, observing a trend upon review of the testing laboratory and/or accreditation body complaint logs, or if Level 1 audits of the accreditation body do not adequately address issues concerning participation in the ASCA Pilot.

For Level 3 audits, FDA intends to initiate an on-site or remote audit of an accreditation body. This audit will not follow the ILAC MRA peer-evaluation schedule. FDA will work with the accreditation body to make the appropriate arrangements for an FDA-initiated audit. Reasons to conduct a Level 3 audit could include, but are not limited to if there is a public health concern regarding the safety of a device or when Level 1 and Level 2 audits do not adequately address issues concerning participation in the ASCA Pilot by the accreditation body.

Note that FDA may request additional information from an accreditation body as a result of any of the audits discussed above.

Failure to comply with the policies and processes outlined in this guidance and other related standards-specific ASCA Pilot guidances can lead to withdrawal of an accreditation body's *ASCA Recognition* as described in Section X.F. of this guidance.

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[59] *See* section 514(d)(2)(A) of the FD&C Act.
[60] *See* https://ilac.org/ilac-membership/membership-criteria/ for information on membership criteria for ILAC MRA Signatories.
[61] *See* section 514(d)(4) of the FD&C Act.

F. Withdrawal of *ASCA Recognition*

One purpose of the ASCA Pilot is to increase FDA's confidence in testing results and DOCs provided in premarket submissions. In certain circumstances, and as authorized in section 514(d)(2) of the FD&C Act, FDA may withdraw an accreditation body's *ASCA Recognition* to maintain confidence in the results submitted under the ASCA Pilot. Withdrawal of *ASCA Recognition* cancels the accreditation body's full scope of *ASCA Recognition* and removes the organization from the ASCA Pilot entirely.

1. Considerations for Withdrawal

FDA may identify issues, using a variety of mechanisms, that raise concerns regarding an accreditation body's ability to adequately fulfill its role in the ASCA Pilot. As explained in Section D of Appendix A of this guidance, the signed agreement included in an accreditation body application for *ASCA Recognition* contains an agreement to permit FDA to observe and assess ASCA-related activities. A complete accreditation body application also includes an agreement to provide reports and notification of any changes that may impact the organization's participation in the ASCA Pilot. FDA may also obtain information about the competence of an accreditation body and its adherence to the criteria specified by FDA for participation in the ASCA Pilot when it reviews and compares a testing laboratory's requested scope of *ASCA Accreditation* to the scope of accreditation provided by the accreditation body.

Withdrawal of *ASCA Recognition* may be an appropriate measure when the findings from the periodic audits of an accreditation body suggest unreliable accreditation activities 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 that was accredited by the accreditation body (*Refer to Section XIII.A. of this guidance*).

The examples below describe additional issues that might decrease FDA's confidence in an accreditation body and, therefore, result in withdrawal of its *ASCA Recognition*. This list is not intended to be exhaustive.

- Violation of law or violation of policies outlined in this guidance or other standards-specific ASCA Pilot guidances.

  FDA's confidence in the ASCA Pilot relies on the integrity of ASCA-recognized accreditation bodies. FDA may consider withdrawing *ASCA Recognition* if, based on credible evidence, the organization likely committed or participated in a violation of law or a violation of the policies outlined in this or any standards-specific ASCA Pilot guidance document. For example, FDA may withdraw an accreditation body's *ASCA Recognition* if it labels accreditation activities conducted outside of its scope of *ASCA Recognition* as having been conducted under the ASCA Pilot.

- Failure to correct nonconformity.

  If an ASCA-recognized accreditation body fails to satisfactorily correct a nonconformity after notification(s), FDA may withdraw the organization's *ASCA Recognition* depending

on the nature of the nonconformity. For example, FDA may withdraw *ASCA Recognition* if, after FDA notification, the organization continually fails to address nonconformities.

- Failure to adhere to signed agreement.

  The application for *ASCA Recognition* includes several items that accreditation bodies agree to do as part of their participation in the ASCA Pilot (*Refer to Section D of Appendix A*). For example, an accreditation body agrees to notify FDA of specific changes relative to the testing laboratories it has accredited for the ASCA Pilot. If an accreditation body repeatedly fails to provide appropriate notifications to FDA, this may result in withdrawal of the organization's *ASCA Recognition*.

- Information materially bearing on safety or effectiveness of a device for which the premarket submission included testing from an ASCA-accredited testing laboratory that was accredited by the accreditation body.[62]

  FDA may obtain information about safety and effectiveness of a device that reasonably relates to the laboratory that tested the device and, by association, the accreditation body that accredited the testing laboratory. For example, a device performance issue may reveal that an ASCA-accredited testing laboratory failed to execute the device manufacturer's test plan correctly. A testing laboratory's repeated failure to correctly execute test plans could raise concerns with the competence of the accreditation body providing its accreditation; these concerns, especially if observed in multiple testing laboratories accredited by the same accreditation body, may result in withdrawal of the accreditation body's *ASCA Recognition*.

- Withdrawal or suspension of *ASCA Accreditation* for a testing laboratory that was accredited by the accreditation body.

  FDA relies on ASCA-recognized accreditation bodies to accredit testing laboratories for the ASCA Pilot. If *ASCA Accreditation* of a testing laboratory is suspended or withdrawn, FDA may consider withdrawing the *ASCA Recognition* of the accreditation body that accredited that testing laboratory for the ASCA Pilot. FDA will carefully consider the reasons for suspension or withdrawal of *ASCA Accreditation* from a testing laboratory when determining whether and what action (e.g., withdrawal of *ASCA Recognition*) to take with the associated accreditation body. FDA intends to notify accreditation bodies when *ASCA Accreditation* is suspended or withdrawn from testing laboratories they have accredited *(Refer to Section XI.F.3. and XI.G.3. of this guidance)*.

As with the initial decision to grant *ASCA Recognition* to an accreditation body, the decision to withdraw *ASCA Recognition* is discretionary. FDA may decide to withdraw *ASCA Recognition* for other reasons not listed above.

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[62] *See* section 514(d)(2)(B) of the FD&C Act.

2. Implications for ASCA activities

Withdrawal of an accreditation body's *ASCA Recognition* removes the accreditation body from the ASCA Pilot. Any activities performed after withdrawal of *ASCA Recognition* should not be identified as being performed as part of the ASCA Pilot.

Withdrawal of an accreditation body's *ASCA Recognition* may affect the testing laboratories it accredited for the ASCA Pilot *(Refer to Section XI.F.1. and XI.G.1. of this guidance).* As described in Section XIII.B. of this guidance, withdrawal of an accreditation body's *ASCA Recognition* affects FDA premarket review only indirectly in that the withdrawal may result in suspending or withdrawing the associated testing laboratory's *ASCA Accreditation.*

3. Procedures

When an accreditation body's *ASCA Recognition* is withdrawn (and the organization is, therefore, removed from the ASCA Pilot), FDA intends to send a withdrawal letter via email to the contact on record for the accreditation body. The letter will include the reason for the withdrawal and, if appropriate, how the issues identified may be addressed in a future, new application for *ASCA Recognition.*

An accreditation body may voluntarily request to withdraw its *ASCA Recognition* by submitting an email to ASCA@fda.hhs.gov. To facilitate processing, FDA recommends that an accreditation body's request to withdraw its *ASCA Recognition* include the ASCA Accreditation Body Identification Number. FDA intends to confirm the withdrawal with the contact on record within 14 calendar days of receipt of a request for voluntary withdrawal.

Upon withdrawal of an accreditation body's *ASCA Recognition*, FDA will update the ASCA website as appropriate and notify all ASCA-accredited testing laboratories who received their accreditation from the affected accreditation body. Considerations for the ASCA-accredited testing laboratories are discussed in Section XI.F.1. and XI.G.1. of this guidance.

If an accreditation body wishes to participate in the ASCA Pilot after withdrawal of its *ASCA Recognition*, the organization should submit a new application for *ASCA Recognition* following the same procedures for an initial application as outlined in this guidance. FDA recommends that the new application include the ASCA Accreditation Body Identification Number and indicate whether the withdrawal was voluntary. If withdrawal was not voluntary, FDA recommends the response include reference to FDA's letter and explain how all issues identified in the withdrawal letter were addressed.

XI. Processes and Policies for Testing Laboratories

A. Qualifications for *ASCA Accreditation*

FDA intends to consider the following factors in determining whether to grant *ASCA Accreditation* to a testing laboratory:

1. Is the testing laboratory's requested scope of *ASCA Accreditation* consistent with the scope of accreditation provided by an ASCA-recognized accreditation body?

This factor relies on the process for granting *ASCA Recognition* to accreditation bodies and ensures that the testing laboratory is appropriately accredited. Accreditation by an ASCA-recognized accreditation body to FDA-recognized consensus standards and test methods included in the ASCA Pilot provides confidence in the testing laboratory because FDA has determined the accreditation body is competent for the purposes of the ASCA Pilot with respect to the eligible FDA-recognized consensus standards and test methods. FDA's review of the testing laboratory's requested scope of *ASCA Accreditation* and its comparison to the scope of accreditation provided by an ASCA-recognized accreditation body permits FDA to ensure that an ASCA-accredited testing laboratory has met, and continues to meet, the criteria specified by FDA for participation in the ASCA Pilot.[63]

2. Has the testing laboratory agreed in writing to the terms of participation described in Section D of Appendix B of this guidance?

The terms and conditions outlined in Section D of Appendix B of this guidance are designed to ensure transparency and accountability on the part of the testing laboratory in all aspects of its participation in the ASCA Pilot. A testing laboratory may choose not to follow the terms of participation at any time; however, *ASCA Accreditation* is contingent upon following such terms.

B. Testing Laboratory Application Process

A testing laboratory may apply for *ASCA Accreditation* by submitting, via email to ASCA@fda.hhs.gov, documentation demonstrating how they address the qualifications specified in Section XI.A. of this guidance. Appendix B of this guidance provides more information on application contents for testing laboratories. FDA intends to acknowledge receipt of the application and provide a unique ASCA Testing Laboratory Identification Number to the testing laboratory and a unique submission number used solely for tracking the application.

FDA intends to review applications for *ASCA Accreditation* within 60 calendar days. After reviewing application contents, FDA intends to notify the testing laboratory via email of the issues, if any, that may preclude granting *ASCA Accreditation* so that any issues may be addressed (if possible). When review is complete, FDA intends to inform the testing laboratory via email of our decision. If *ASCA Accreditation* is granted, FDA will provide a scope of and expiration date (e.g., two years) for *ASCA Accreditation*. Note that the scope will include only FDA-recognized consensus standards and test methods in the ASCA Pilot for which competence in testing has been demonstrated. When FDA grants *ASCA Accreditation* to a testing laboratory, it will update the ASCA website to list the organization along with its scope of and expiration date for *ASCA Accreditation*.

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[63] *See* section 514(d)(1)(A) of the FD&C Act.

FDA's decision to grant *ASCA Accreditation* to a testing laboratory is discretionary. FDA may decide not to grant *ASCA Accreditation* to a testing laboratory, e.g., for reasons of public health or administrative efficiency. If FDA does not grant *ASCA Accreditation* to a testing laboratory, FDA intends to provide a rationale for the decision to the applicant.

Up to six months prior to expiration of its *ASCA Accreditation*, a testing laboratory may apply to renew its *ASCA Accreditation* following the same process outlined above.

C. Extension of *ASCA Accreditation*

FDA understands that testing laboratories may continually add capabilities to their programs and increase their internal expertise. FDA encourages testing laboratories to extend their *ASCA Accreditation* by adding FDA-recognized consensus standards and test methods to their scope of *ASCA Accreditation* when additional competencies are attained. For example, a testing laboratory may initially participate in the ASCA Pilot by conducting MEM Elution Cytotoxicity testing. After some time, the testing laboratory may obtain additional equipment and resources that can also support Complement Activation testing. The testing laboratory may then apply to extend its *ASCA Accreditation* by adding Complement Activation testing to its scope of *ASCA Accreditation*. In such a situation, the FDA-recognized consensus standards and test methods eligible for inclusion in the ASCA Pilot would not change, only the FDA-recognized consensus standards and test methods in the individual testing laboratory's scope of *ASCA Accreditation*.

A testing laboratory may apply to extend its *ASCA Accreditation* by following the same procedures used for its initial application. That is, a testing laboratory may submit documentation indicating how it meets the qualifications specified in Section XI.A. of this guidance with respect to the additional FDA-recognized consensus standards or test methods via email to ASCA@fda.hhs.gov. Recommended application contents are described in Appendix B of this guidance. In addition to the contents outlined in this appendix, FDA recommends that the application include the following:

- the ASCA Testing Laboratory Identification Number of the testing laboratory;
- the current scope of *ASCA Accreditation* for the testing laboratory; and
- the FDA-recognized consensus standards or test methods that the testing laboratory requests be added to its scope of *ASCA Accreditation*.

FDA intends to use the same ASCA Testing Laboratory Identification Number to track all activity for a given testing laboratory, including extensions to *ASCA Accreditation*.

FDA intends to update the scope of *ASCA Accreditation* on the ASCA website as appropriate.

D. Requests for Clarification

A Request for Clarification is a request submitted to FDA for clarification of one or more specific ASCA program specifications from an ASCA-accredited testing laboratory. A Request for Clarification presents a question relative to implementation of ASCA program specifications. It does not include suggestions or requests for modifications to the ASCA Pilot or hypothetical issues.

A Request for Clarification may be submitted to ASCA@fda.hhs.gov.

E. Audits of Testing Laboratories

FDA intends to periodically audit testing laboratories to ensure that they are adequately fulfilling program expectations.[64] FDA intends to use a tiered-approach with three levels of audits.

In order to maintain conformance with ISO/IEC 17011, an accreditation body assesses its accredited testing laboratories at least every 2 years. [65] For Level 1 audits of the testing laboratory, FDA intends to leverage the existing arrangement of assessments between accreditation bodies and testing laboratories by requesting a copy of the most recent assessment report of the testing laboratory. Upon review of the report, FDA may request clarification or additional information. FDA intends to follow the established schedule of accreditation body assessments of the testing laboratory.

For Level 2 audits of the testing laboratories, FDA intends to participate as an observer during the next scheduled assessment of the testing laboratory by the accreditation body and request a copy of the report for review. FDA will notify the accreditation body and testing laboratory of the intent to participate and make the appropriate arrangements for an on-site visit. FDA intends to use Level 2 audits if there is a reason to believe Level 1 audits would be insufficient. Reasons to use a Level 2 audit could include, but are not limited to, observing persistent issues with a testing laboratory, observing a trend upon review of the testing laboratory complaint logs, if Level 1 audits of the testing laboratory do not adequately address issues concerning participation in the ASCA Pilot.

For Level 3 audits, FDA intends to initiate an on-site or remote audit of the testing laboratory. This audit will not follow the assessment schedule established by the accreditation body. FDA will work directly with the testing laboratory to make the appropriate arrangements for an FDA-initiated audit. Level 3 audits will typically be used for only issues of highest concern such as when Level 1 and Level 2 audits do not adequately address issues concerning participation in the ASCA Pilot Program. FDA will notify the appropriate accreditation body of the intent to initiate on-site or remote audit of the testing laboratory.

Note that FDA may request additional information from the testing laboratory as a result of any of the audits discussed above.

Failure to comply with the policies and processes outlined in this guidance and any other related ASCA program guidance can lead to changes to a testing laboratory's *ASCA Accreditation* as described in Section XI.F. and XI.G. of this guidance.

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[64] *See* section 514(d)(2)(A) of the FD&C Act .
[65] *See* 7.9.3 of ISO/IEC 17011: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

F. Suspension of *ASCA Accreditation*

Section 514(d)(2) of the FD&C Act provides that FDA may suspend a testing laboratory's *ASCA Accreditation*. Suspension puts temporary constraints on one or more FDA-recognized consensus standards or test methods in a testing laboratory's scope of *ASCA Accreditation* while the issues resulting in the suspension are addressed.

1. Considerations for Suspension

FDA may identify issues, using a variety of mechanisms, that raise potential concerns regarding a testing laboratory's ability to adequately fulfill its role in the ASCA Pilot. As explained in Section D of Appendix B of this guidance, the signed agreement included in a testing laboratory application for *ASCA Accreditation* contains an agreement to permit FDA to observe and assess ASCA-related activities. A complete testing laboratory application also includes an agreement to provide reports and notification of any changes that may impact the organization's participation in the ASCA Pilot. FDA may also obtain information about the competence of a testing laboratory when it reviews information from the accreditation body or testing results from the testing laboratory included in premarket submissions.

Suspending *ASCA Accreditation* may be an appropriate measure when the findings from the periodic audits of the testing laboratories suggest that testing results may be unreliable or when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which the premarket submissions included testing from the ASCA-accredited testing laboratory (*Refer to Section XIII.A. of this guidance*). The suspension allows FDA to maintain confidence in the ASCA Pilot while adapting to the needs and abilities of ASCA-accredited testing laboratories.

When determining whether to suspend a testing laboratory's *ASCA Accreditation*, FDA considers whether the issues identified are of a magnitude for which a temporary constraint can adequately maintain confidence in the ASCA Pilot. Suspending a testing laboratory's *ASCA Accreditation* is used when confidence in the ASCA Pilot can be maintained by constraining the testing laboratory to label its testing as having been conducted during a period of suspension (e.g., temporary loss and then repair of specific test-related resources). By labeling its testing as having been conducted during a period of suspension, the testing laboratory clearly communicates to the device manufacturer, who then communicates to FDA via the premarket submission, that FDA may need to conduct additional review of the results (*Refer to Section XIII.B. of this guidance).* This clear communication about the status of the testing laboratory during testing maintains confidence in the ASCA Pilot.

FDA will only put a temporary constraint on the FDA-recognized consensus standards and test methods within a testing laboratory's scope of *ASCA Accreditation* that are impacted by the issues resulting in suspension.

FDA may consider withdrawing the testing laboratory's *ASCA Accreditation* if the issues identified are of a magnitude for which constraining the testing laboratory to label the testing as having been conducted during a period of suspension is inadequate to maintain confidence in the

ASCA Pilot (e.g., repeated failure to correct nonconformities or follow policies and procedures of this guidance) (*Refer to Section XI.G. of this guidance)*.

The examples below describe situations in which FDA might suspend a testing laboratory's *ASCA Accreditation*. This list is not intended to be exhaustive.

- Existence of nonconformity.

  Depending on the nature of the nonconformity identified, FDA may determine that a testing laboratory needs to label its testing as having been conducted during a period of suspension until the nonconformity is adequately addressed. The labeling constraint would apply only to testing conducted using the FDA-recognized consensus standards and test methods affected by the nonconformity.

- Inadequate completion of training or communication with FDA.

  The application for *ASCA Accreditation* includes several items that testing laboratories agree to do as part of their participation in the ASCA Pilot (*Refer to Section D of Appendix B*). For example, a testing laboratory agrees to attend FDA training and communicate with FDA. If a testing laboratory fails to complete training or submit information to FDA, FDA may suspend its *ASCA Accreditation* until such training is completed or information is submitted. Depending on the nature of the incomplete training or unsubmitted information, FDA may choose to constrain labeling of testing to one or more of the FDA-recognized consensus standards and test methods within the testing laboratory's scope of *ASCA Accreditation.*

- Information materially bearing on safety or effectiveness of a device for which a premarket submission included testing from the testing laboratory.[66]

  FDA may become aware of information materially bearing on study conduct or quality for which labeling of testing results as having been conducted during a period of suspension is necessary to maintain confidence in the ASCA Pilot. For example, if an ASCA-accredited testing laboratory under the purview of 21 CFR 58 receives from the FDA Bioresearch Monitoring Program a warning letter including issues that impact its testing under the ASCA Pilot, FDA may suspend that testing laboratory's *ASCA Accreditation* until the issues are addressed. During the period of suspension (e.g., until the warning letter is adequately addressed), the testing laboratory would label the affected testing results as having been conducted during a period of suspension.

- Withdrawal of *ASCA Recognition* from the accreditation body that accredited the testing laboratory for the ASCA Pilot.

  FDA relies on ASCA-recognized accreditation bodies to accredit testing laboratories for the ASCA Pilot. If the accreditation body that accredited a testing laboratory is

[66] *See* section 514(d)(2)(B) of the FD&C Act.

withdrawn from the ASCA Pilot, FDA may suspend (or withdraw) a testing laboratory's *ASCA Accreditation* while the testing laboratory seeks accreditation from an alternative ASCA-recognized accreditation body. FDA will carefully consider the reasons for withdrawal of *ASCA Recognition* from the accreditation body when determining whether and what action (e.g., suspension or withdrawal of *ASCA Accreditation*) to take regarding the associated testing laboratories. Note that FDA intends to notify affected testing laboratories if their accreditation body's *ASCA Recognition* is withdrawn *(Refer to Section X.F.3. of this guidance*).

As with the initial decision to grant ASCA *Accreditation* to a testing laboratory, the decision to suspend ASCA *Accreditation* is discretionary. FDA may decide to suspend *ASCA Accreditation* for other reasons not listed above.

2. Implications for ASCA activities

When a testing laboratory's *ASCA Accreditation* is suspended, temporary constraints are put on how it may label its testing relative to the ASCA Pilot. FDA will indicate to the testing laboratory the FDA-recognized consensus standards and test methods within the organization's scope of *ASCA Accreditation* for which testing (including the ASCA summary test report) should be labeled as having been conducted during a period of suspension.

A device manufacturer indicates in their DOC whether the FDA-recognized consensus standards and test methods used by the testing laboratory were impacted by suspension of the testing laboratory's *ASCA Accreditation* (*Refer to Section XIII.C.2. of this guidance*). Premarket review considerations for testing conducted during a period of suspension are provided in Section XIII.B. of this guidance.

While *ASCA Accreditation* is suspended, FDA expects that the testing laboratory will continue to adhere to the signed agreement (*Refer to Section D of Appendix B of this guidance*) as well as the policies and processes of this guidance and any other relevant standards-specific ASCA Pilot guidance documents.

Suspension of a testing laboratory's *ASCA Accreditation* may affect the accreditation body that accredited it for the ASCA Pilot, depending on the reasons for suspension (*Refer to Section X.F.1. of this guidance).* At a minimum, FDA will likely discuss with the accreditation body the reasons for suspension as well as any plans for resolution. If FDA suspends a testing laboratory's *ASCA Accreditation*, an accreditation body's own decision regarding that laboratory is not necessarily affected. An accreditation body may continue to accredit the testing laboratory; however, FDA would no longer recognize that accreditation for purposes of the ASCA Pilot.

3. Procedures

a. Initiating Suspension

When FDA suspends a testing laboratory's *ASCA Accreditation*, we intend to send a letter via email to the contact on record for the testing laboratory. The letter will include the FDA-recognized consensus standards or test methods for which testing (including ASCA summary test

reports) should be labeled as having been conducted during a period of suspension and how the issues resulting in suspension may be addressed.

A testing laboratory may also voluntarily request that its *ASCA Accreditation* be suspended. Such a request should be submitted to ASCA@fda.hhs.gov and include the following information.

- the issues resulting in suspension of *ASCA Accreditation*;
- the planned timeline and/or actions to address the issues resulting in *ASCA Accreditation*;
- the FDA-recognized consensus standards and test methods for which the temporary labeling constraint applies; and
- the testing laboratory's ASCA Testing Laboratory Identification Number.

FDA intends to confirm requests to voluntarily suspend *ASCA Accreditation* with the contact on record within 14 calendar days of receipt of a request.

Upon suspension of a testing laboratory's *ASCA Accreditation*, FDA will update the ASCA website to reflect the temporary constraint on the impacted FDA-recognized consensus standards and test methods within the testing laboratory's scope of *ASCA Accreditation*. FDA will also notify the accreditation body that accredited that testing laboratory. Considerations for the accreditation body are discussed in Section X.F.1. of this guidance.

b. Lifting Suspension

To lift a suspension of *ASCA Accreditation*, a testing laboratory should send a response to ASCA@fda.hhs.gov documenting how all issues resulting in suspension were resolved. To facilitate processing, FDA recommends that the response include the ASCA Testing Laboratory Identification Number and indicate whether the suspension was voluntary. If suspension was not voluntary, FDA recommends the response include reference to FDA's suspension letter.

Once the issues that resulted in suspension have been adequately addressed to FDA's satisfaction, the agency intends to send a letter via email to the contact on record indicating that the testing laboratory's *ASCA Accreditation* is no longer suspended and the temporary constraints have been lifted. FDA will update the ASCA website to ensure that it accurately reflects the scope of *ASCA Accreditation*.

G. Withdrawal of *ASCA Accreditation*

Section 514(d)(2) of the FD&C Act provides that FDA may withdraw a testing laboratory's ASCA Accreditation. Withdrawal of ASCA Accreditation cancels the testing laboratory's full scope of ASCA Accreditation and removes the organization from the ASCA Pilot entirely.

1. Considerations for Withdrawal

FDA may identify issues, using a variety of mechanisms, that raise concerns regarding a testing laboratory's ability to adequately fulfill its role in the ASCA Pilot. As explained in Section D of Appendix B of this guidance, the signed agreement included in a testing laboratory's application for *ASCA Accreditation* contains an agreement to permit FDA to observe and assess ASCA-

related activities. A complete testing laboratory application also includes an agreement to provide reports and notification of any changes that may impact the organization's participation in the ASCA Pilot. FDA may also obtain information about the competence of a testing laboratory when it reviews information from the accreditation body or testing results from the testing laboratory included in premarket submissions.

Withdrawal of a testing laboratory's *ASCA Accreditation* may be an appropriate measure depending on the findings from periodic audits of testing laboratories or when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which a premarket submission included testing from an ASCA-accredited testing laboratory (*Refer to Section XIII.A. of this guidance)*.

When determining whether to withdraw a testing laboratory's *ASCA Accreditation*, FDA intends to consider whether the issues identified are of a magnitude for which a temporary constraint cannot adequately maintain confidence in the ASCA Pilot. Withdrawal of a testing laboratory's *ASCA Accreditation* is used when confidence in the ASCA Pilot cannot be maintained by constraining the testing laboratory to label its testing as having been conducted during a period of suspension (e.g., repeated failure to correct nonconformities or follow policies and procedures of this guidance).

The examples below describe situations in which FDA may consider withdrawing a testing laboratory's *ASCA Accreditation*. This list is not intended to be exhaustive.

- Violation of law or violation of policies outlined in this guidance and other standards-specific ASCA Pilot guidances.

  FDA's confidence in the ASCA Pilot relies on the integrity of ASCA-accredited testing laboratories. FDA may consider withdrawing a testing laboratory's *ASCA Accreditation* if, based on credible evidence, the organization likely committed or participated in a violation of law or a violation of the policies outlined in this or any standards-specific ASCA Pilot guidance document. For example, FDA may withdraw a testing laboratory's *ASCA Accreditation*, thereby removing it from the ASCA Pilot, if it labels testing results conducted outside of its scope as having been conducted under the ASCA Pilot.

- Failure to correct nonconformity.

  If an ASCA-accredited testing laboratory fails to satisfactorily correct a nonconformity after notification(s) by either their accreditation body or FDA, FDA may consider withdrawing its *ASCA Accreditation* depending on the nature of the nonconformity.

- Failure to adhere to signed agreement.

  The application for *ASCA Accreditation* includes several items that testing laboratories agree to do as part of their participation in the ASCA Pilot *(Refer to Section D of Appendix B*). For example, a testing laboratory agrees to notify FDA of changes that may affect its participation in the ASCA Pilot. If a testing laboratory repeatedly fails to

provides appropriate notifications to FDA, this may result in withdrawal of the organization's *ASCA Accreditation*.

- Information materially bearing on safety or effectiveness of a device for which a premarket submission included testing from the testing laboratory.[67]

  FDA may become aware of information materially bearing on study conduct or quality. For example, if an ASCA-accredited testing laboratory under the purview of 21 CFR 58 receives from the FDA Bioresearch Monitoring Program a warning letter including issues that impact its testing under the ASCA Pilot and fails to correct such issues, FDA may withdraw that testing laboratory's *ASCA Accreditation*.

- Withdrawal of *ASCA Recognition* from the accreditation body that accredited the testing laboratory for the ASCA Pilot.

  FDA relies on ASCA-recognized accreditation bodies to accredit testing laboratories for the ASCA Pilot. If the accreditation body that accredited a testing laboratory is withdrawn from the ASCA Pilot, FDA may withdraw (or suspend) a testing laboratory's *ASCA Accreditation* while the testing laboratory seeks accreditation from an alternative ASCA-recognized accreditation body. FDA will carefully consider the reasons for withdrawal of *ASCA Recognition* from the accreditation body when determining whether and what action (e.g., withdrawal of suspension of *ASCA Accreditation*) to take regarding the associated testing laboratories. Note that FDA intends to notify affected testing laboratories if their accreditation body's *ASCA Recognition* is withdrawn *(Refer to Section X.F.3. of this guidance*).

As with the initial decision to grant *ASCA Accreditation* to a testing laboratory, the decision to withdraw *ASCA Accreditation* is discretionary. FDA may decide to withdraw *ASCA Accreditation* for other reasons not listed above.

2. Implications for ASCA activities

Withdrawal of a testing laboratory's *ASCA Accreditation* removes the testing laboratory from the ASCA Pilot. Any activities performed after withdrawal of *ASCA Accreditation* should not be identified as being performed as part of the ASCA Pilot.

Withdrawal of a testing laboratory's *ASCA Accreditation* may affect the accreditation body that accredited it for the ASCA Pilot, depending on the reasons for withdrawal *(Refer to Section X.F.1. of this guidance)*. Premarket review considerations for testing conducted after withdrawal of a testing laboratory's *ASCA Accreditation* are provided in Section XIII.B. of this guidance.

If FDA withdraws a testing laboratory's *ASCA Accreditation*, an accreditation body's own decision regarding that laboratory is not necessarily affected. An accreditation body may

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[67] *See* section 514(d)(2)(B) of the FD&C Act.

continue to accredit the testing laboratory; however, FDA would no longer recognize that accreditation for purposes of the ASCA Pilot.

3. Procedures

When a testing laboratory's *ASCA Accreditation* is withdrawn (and the organization is, therefore, removed from the ASCA Pilot), FDA intends to send a withdrawal letter via email to the contact on record for the testing laboratory. The letter will include the reason for the withdrawal and, if appropriate, how the issues identified may be addressed in a future, new application for *ASCA Accreditation*. A testing laboratory may voluntarily request withdrawal of its *ASCA Accreditation* by submitting an email to ASCA@fda.hhs.gov. To facilitate processing, FDA recommends that a testing laboratory's request to withdraw from the ASCA Pilot include the ASCA Testing Laboratory Identification Number. FDA intends to confirm the withdrawal with the contact on record within 14 calendar days of receipt of a request for voluntary withdrawal.

Upon withdrawal of a testing laboratory's *ASCA Accreditation*, FDA will update the ASCA website as appropriate and notify the accreditation body that accredited that testing laboratory for the ASCA Pilot. Considerations for the accreditation body are discussed in Section X.F.1. of this guidance.

If a testing laboratory wishes to participate in the ASCA Pilot after withdrawal of its *ASCA Accreditation,* the organization should submit a new application for *ASCA Accreditation* following the same procedures for an initial application as outlined in this guidance. FDA recommends that the new application for *ASCA Accreditation* include the ASCA Testing Laboratory Identification Number and indicate whether the withdrawal was voluntary. If withdrawal was not voluntary, FDA recommends the application include reference to FDA's letter and explain how all issues identified in the withdrawal letter were addressed.

XII. Processes and Policies for Device Manufacturers

A. Selection of an ASCA-accredited Testing Laboratory

Device manufacturers may voluntarily choose to use an ASCA-accredited testing laboratory to conduct testing included in a premarket submission. The ASCA website provides an up-to-date listing of ASCA-accredited testing laboratories (including their scopes of and expiration dates for *ASCA Accreditation*). In selecting an ASCA-accredited testing laboratory, FDA recommends that a device manufacturer consider the FDA-recognized consensus standards and test methods within a testing laboratory's scope of *ASCA Accreditation* in comparison to the testing the device manufacturer plans. A device manufacturer may wish to stipulate in their contract with an ASCA-accredited testing laboratory that the testing laboratory notify the device manufacturer if the testing laboratory's *ASCA Accreditation* is suspended or withdrawn.

B. Development of a Test Plan

The ASCA Pilot does not alter the device manufacturer's responsibility to ensure FDA-recognized consensus standards and test methods are selected and used appropriately as

described in FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices. Given an ASCA-accredited testing laboratory's expertise, a manufacturer may choose to work with them in developing a test plan for their device. FDA recommends that development of a test plan for conduct by an ASCA-accredited testing laboratory consider the following:

- Other FDA guidance and FDA-recognized consensus standards.

  FDA recommends that a test plan consider all relevant FDA guidance (e.g., device type guidance, scientific area guidance, submission type guidance) and FDA-recognized consensus standards. For example, FDA recommends that a test plan for basic safety and essential performance consider the collateral and particular standards to determine the most efficient and appropriate test plan. As another example, FDA's guidance Bone Anchors- Premarket Notification (510(k)) Submissions[68] provides specific recommendations for a bone anchor 510(k) submission, including performance test recommendations such as biocompatibility testing.

- Impact of deviations from FDA-recognized consensus standards.

  Modifications to the methods and/or acceptance criteria included within an FDA-recognized consensus standard may be appropriate for a specific device based on its intended use. When a standard permits such modifications, the modifications do not affect compliance with the standard and, therefore, a DOC is appropriate. However, if the standard does not permit the modifications used during testing, the modifications would be considered deviations and the testing would not be considered to have been conducted in compliance with the standard. A DOC would not be appropriate for testing that includes deviations. Testing that includes deviations (and for which a DOC would not be appropriate)[69] does not meet the criteria for inclusion in the ASCA Pilot and the premarket review considerations described in Section XIII. of this guidance do not apply. This is because, under the ASCA Pilot, device manufacturers may include in their premarket submissions DOCs based on testing from ASCA-accredited testing laboratories.[70] Deviations (i.e., modifications not specifically allowed by the FDA-recognized consensus standard) necessarily indicate that a device does not conform to the standard; therefore, a DOC would not be appropriate. Note that the testing may still be appropriate for general use of consensus standards as described in FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

- Testing outside of a testing laboratory's scope of *ASCA Accreditation.*

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[68] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bone-anchors-premarket-notification-510k-submissions

[69] *See* section IV.B. of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices

[70] *See* section 514(d)(1)(B) of the FD&C Act.

A test plan may include some methods that are and some methods that are not included in a testing laboratory's scope of *ASCA Accreditation*. The processes and policies within this guidance and other relevant standards-specific ASCA Pilot guidances, including the ASCA program specifications applicable to the specific FDA-recognized consensus standards and test methods, apply to all testing conducted within a testing laboratory's scope of *ASCA Accreditation*. The premarket review considerations discussed in Section XIII. of this guidance apply only to testing conducted by an ASCA-accredited testing laboratory within their scope of *ASCA Accreditation*. Section XII.C. of this guidance describes how to clarify in a premarket submission which testing was conducted within the ASCA Pilot and which was not. For testing not within a testing laboratory's scope of *ASCA Accreditation*, please see FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

- Q-Submission.

  A device manufacturer may follow the policies and procedures in FDA's guidance Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program[71] to receive feedback from FDA regarding a proposed test plan.

C. Contents of a Premarket Submission

Testing performed by an ASCA-accredited testing laboratory can be used to support a premarket submission for any device if the testing was conducted using an FDA-recognized consensus standard and test method eligible for inclusion in the ASCA Pilot and in accordance with the ASCA program specifications for that standard and test method. The ASCA Pilot does not alter the device manufacturer's responsibility to address relevant information in the premarket submission. This includes the responsibility to document how testing supports premarket authorization, even when such testing is performed by an ASCA-accredited testing laboratory.

As mentioned in Section IV. of this guidance, this guidance document does not address specific content for a particular premarket submission. Rather this guidance document describes how a device manufacturer may incorporate testing results from an ASCA-accredited testing laboratory into its premarket submissions. Device manufacturers should also review FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, which further describes recommended premarket submission content when an FDA-recognized consensus standard is used.

1. Cover Letter

FDA recommends that manufacturers include the following information in the cover letter for a premarket submission containing testing results from an ASCA-accredited testing laboratory.

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[71] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

- Clear identification of the term "ASCA"
- Name(s) and location(s) of the testing laboratory(ies) where testing was conducted
- ASCA Testing Laboratory Identification Number(s)
- FDA-recognized consensus standard(s) (and specific test methods) used during testing. Note: The premarket review considerations in Section XIII. of this guidance apply only to FDA-recognized consensus standards (and specific test methods) within the laboratory's scope of *ASCA Accreditation* at the time of testing.

2. Declaration of Conformity (DOC)

Section IV.A. of FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices recommends contents for a DOC to an FDA-recognized consensus standard. For testing from an ASCA-accredited testing laboratory, additional items are recommended for inclusion in a DOC depending upon the FDA-recognized consensus standards and test methods used. For example, FDA recommends that the DOC indicate whether the FDA-recognized consensus standards and test methods used were included in the testing laboratory's scope of *ASCA Accreditation* at the time of testing. Example DOCs are provided in the standards-specific ASCA Pilot guidance documents. These examples illustrate how one DOC might incorporate results from testing using FDA-recognized consensus standards and test methods under the ASCA Pilot and outside of the ASCA Pilot.

3. Supplemental Documentation to Support a DOC

FDA's guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices describes when supplemental documentation (e.g., summary test report, complete test report) is needed to support a DOC to an FDA-recognized consensus standard. Recommended contents for supplemental documentation for testing conducted by an ASCA-accredited testing laboratory are provided in the standards-specific ASCA Pilot guidance documents. Note that the ASCA-accredited testing laboratory provides to the device manufacturer all information listed in the relevant ASCA program specifications (including the ASCA summary test report). The device manufacturer then includes appropriate supplemental documentation (e.g., ASCA summary test report) with its own DOC in a premarket submission to FDA.

XIII. Processes and Policies for FDA Review Staff

Use of a conformity assessment scheme to grant *ASCA Recognition* to accreditation bodies, grant *ASCA Accreditation* to testing laboratories, and communicate with and audit both accreditation bodies and testing laboratories provides FDA increased confidence in the methods used and results reported by ASCA-accredited testing laboratories when testing is performed within the testing laboratory's scope of *ASCA Accreditation*.

A. General Premarket Review Policy

As part of their participation in the ASCA Pilot, ASCA-accredited testing laboratories agree to use methodologies consistent with the FDA-recognized consensus standards and test methods in their scope of *ASCA Accreditation* and the relevant ASCA program specifications. For this

reason, FDA generally intends to rely on the results from ASCA-accredited testing laboratories for the purpose of premarket review without the need for additional information related to conformance with a standard. However, FDA retains the discretion not to accept determinations (i.e., test results) from an ASCA-accredited testing laboratory if FDA "finds that a particular such determination shall not be so accepted."[72] The following are examples of circumstances where FDA is likely to question the validity of test methods within a testing laboratory's scope of *ASCA Accreditation*:

- As part of periodic audits (*Refer to Section X.E. and XI.E. of this guidance)*;[73] or
- If FDA becomes aware of information that would result in suspension or withdrawal of a testing laboratory's *ASCA Accreditation*; or
- If FDA becomes aware of information that would result in withdrawal of the associated accreditation body's *ASCA Recognition*; or
- If FDA becomes aware of information materially bearing on the study conduct or quality (e.g., if the testing laboratories under the purview of 21 CFR 58 receive from FDA Bioresearch Monitoring Program a warning letter including issues that could potentially impact the testing in their scope of *ASCA Accreditation*); or
- If FDA becomes aware of information materially relevant to safety or effectiveness for the device [74] (e.g., if specific use issues of public health concern are identified for a device type during total product lifecycle reviews); or
- If the ASCA summary test report indicates an issue with the testing or device[75] (e.g., controls do not work as expected or test results signal a possible issue with safety or performance); or
- If basic administrative information is missing (e.g., product identification information or dates of testing);
- If supplemental documentation to support the DOC (e.g., ASCA summary test report) is incomplete; or
- As noted in the standards-specific ASCA Pilot guidance documents for certain instances.

In these cases, additional questions may be asked to determine whether the test results can be used to support a decision on a premarket submission.

B. Impact of Suspension of *ASCA Accreditation*

As discussed in Section XI.F.1. of this guidance, FDA will suspend a testing laboratory's *ASCA Accreditation* when specific issues are identified that raise potential concerns with the results from that specific laboratory. When evaluating testing results conducted during a period of suspension, FDA intends to carefully consider the issues resulting in the suspension as well as which FDA-recognized consensus standards and test methods were subject to the temporary labeling constraints of the suspension. Depending on the issues resulting in suspension and which standards or test methods were suspended, FDA may be unable to rely solely on the

[72] *See* section 514(d)(1)(B) of the FD&C Act.
[73] *See* section 514(d)(2)(A) of the FD&C Act .
[74] *See* section 514(d)(2)(B) of the FD&C Act.
[75] *See* section 514 (d)(1)(B) of the FD&C Act.

testing results provided in the premarket submission. In these cases, FDA may need to review additional information and/or ask questions to determine whether the test results can be used to support a decision on a premarket submission.

C. Impact of Withdrawal of *ASCA Accreditation*

As discussed in Section XI.G.1. of this guidance, FDA will withdraw a testing laboratory's *ASCA Accreditation* when FDA no longer believes the premarket review benefits of the ASCA Pilot are appropriate for testing conducted at the testing laboratory. A manufacturer may still include in their premarket submission a DOC for testing conducted at the testing laboratory. In these cases, FDA would apply the policies described in FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, regarding review of the associated DOCs (and the need for supplemental documentation to support a DOC).

Withdrawal of a testing laboratory's *ASCA Accreditation* may indicate the need for FDA to take postmarket action. FDA intends to carefully consider the reason for withdrawal when determining what postmarket action, if any, is appropriate for closed premarket submissions that included testing results from an ASCA-accredited testing laboratory from which *ASCA Accreditation* has been withdrawn. For example, if the nature and severity of the reasons for withdrawal might have impacted the testing results supporting the submission decision, FDA may engage with the device manufacturer to better understand device performance and evaluation, review Medical Device Reports (MDRs) for signs of post market performance issues, or conduct other compliance actions. In all cases, FDA intends to carefully weigh the benefits and risks to patients when considering what, if any, action should be taken.

Note that withdrawal of an accreditation body's *ASCA Recognition* affects FDA review indirectly in that the withdrawal may result in suspension or withdrawal of the associated testing laboratory's *ASCA Accreditation* (*Refer to Section XI.F.1. and XI.G.1. of this guidance).*

XIV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521).

The time required to complete this information collection is estimated 76 to average 95 hours per response for accreditation bodies and 47 hours for testing laboratories. Send comments regarding this burden estimate or suggestions for reducing this burden to:

FDA PRA Staff,
Office of Operations,
Food and Drug Administration,

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[76] Rounded to the nearest whole number.

PRAStaff@fda.hhs.gov

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0889 (expires 06-30-2023).

Appendix A: Application for *ASCA Recognition*

FDA recommends that an application from an accreditation body seeking *ASCA Recognition* include the following components:

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of *ASCA Recognition*

Indication of the requested scope of *ASCA Recognition* from the list of FDA-recognized consensus standards and test methods in the ASCA Pilot (more than one standard and test method may be identified).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Pilot.

- Proof of signatory status as International Laboratory Accreditation Cooperation (ILAC) MRA with scope that includes testing: ISO/IEC 17025.
- Confirmation that accreditation body is based in the United States.
- A current list and description of any accreditation services offered for which the scope includes any of the FDA-recognized consensus standards or test methods in the ASCA Pilot.
- An example scope of accreditation that is typically used by the accreditation body, and to what extent it will be modified to address accreditation for the ASCA Pilot.
- A detailed description of the process to accredit testing laboratory applicants to ISO/IEC 17025 and ASCA program specifications to include awareness, training, and accreditation activities.
- A detailed description of the approach to assess procedures and corrective actions as related to the most recent inspection findings noted by FDA Bioresearch Monitoring Program per 21 CFR Part 58 – Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies for testing laboratory applicants with biological

evaluation of medical device standards and test methods in their scope of accreditation.[77]

- A detailed description of the accreditation body's approach used to determine technical competency of testing laboratories consistent with ASCA program specifications. This includes a detailed description of the qualifications for technical assessors for the requested scope of *ASCA Recognition*. A description could include resumes, CVs, summary of experience, relevant technical training, etc., from personnel already identified.
- A detailed description of the policy and processes concerning corrective actions and the approach for responding to, investigating, and resolving complaints against testing laboratories.

D. Signed Agreement

Confirmation that the accreditation body has read, understood, and agrees to adhere to the following for its ASCA Pilot-related activities:

- Maintain scope of signatory status to International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) that includes ISO/IEC 17025.
- Verify conformance with ISO/IEC 17025 and ASCA program specifications when accrediting testing laboratories for the ASCA Pilot.
- Follow the expectations (outlined in the standards-specific ASCA Pilot guidance documents) regarding which FDA-recognized consensus standards and test methods to assess when accrediting and assessing a testing laboratory for the ASCA Pilot.
- Provide all ASCA Pilot accreditation documentation to FDA upon request.
- Allow FDA to participate as an observer during the accreditation body's ILAC MRA peer evaluation(s).
- Allow FDA to participate as an observer during the accreditation body's assessment of a testing laboratory.
- Commit that all relevant FDA training will be completed by appropriate individuals prior to providing any accreditation to testing laboratories under the ASCA Pilot.
- Establish and maintain appropriate communication with FDA. An accreditation body should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
    - Notification to FDA within five calendar days via email of any changes that may impact the accreditation body's participation (e.g., change to scope of signatory status to ILAC MRA).

[77] As discussed at the public workshop titled "Accreditation Scheme for Conformity Assessment of Medical Devices to Food and Drug Administration-Recognized Standards," biocompatibility testing conducted under the ASCA Pilot will be conducted in accordance with 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations.

  - Notification to FDA within five calendar days via email of any changes that may impact the participation of any of the testing laboratories that the accreditation body has accredited.
  - Attendance at regularly scheduled teleconferences with FDA as requested.
  - Provision of status updates annually or upon request to FDA including the following information regarding the accreditation body's ASCA Pilot activities:
    - Complaint handling;
    - Total number and list of testing laboratories the accreditation body has accredited, including dates of accreditation;
    - Number and nature of non-conformities the accreditation body has observed during accreditation or auditing of testing laboratories;
    - Number of suspensions issued by the accreditation body for testing laboratories; and
    - Results of the accreditation body's management reviews.
- Establish and maintain policies and procedures that incorporate feedback from FDA.
- Acknowledge that FDA maintains complete discretion regarding granting *ASCA Recognition* to an accreditation body. FDA may withdraw *ASCA Recognition* at any time.
- Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.

Appendix B: Application for *ASCA Accreditation*

FDA recommends that an application from a testing laboratory seeking *ASCA Accreditation* include the following components. If a testing laboratory application will be for multiple testing sites, documentation should be clear with respect to the site to which it applies.

A. Administrative Information

- Organization name and address
- Designated point of contact: first and last name, title, phone number, and email address
- Alternate designated point of contact: first and last name, title, phone number, and email address

B. Scope of *ASCA Accreditation*

Indication of the requested scope of *ASCA Accreditation* from the list of FDA-recognized consensus standards and test methods in the ASCA Pilot (more than one standard and test method may be chosen).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Pilot.

- Proof of testing laboratory accreditation that shows:
  - The accreditation is from an ASCA-recognized accreditation body.
  - The scope of *ASCA Recognition* for the accreditation body includes the scope for which they accredited the testing laboratory.
  - The scope of accreditation provided by the ASCA-recognized accreditation body to the testing laboratory matches the testing laboratory's requested scope of *ASCA Accreditation*.

- A copy of the Index of SOPs and any relevant ASCA test-related documents (e.g., SOPs, work instructions, master protocols, test-specific protocols, data collection worksheets, training information) applicable to any biocompatibility testing of medical device standards and test methods if included in the requested scope of *ASCA Accreditation*.

D. Signed Agreement

Confirmation that the testing laboratory has read, understood, and agrees to adhere to the following for its ASCA Pilot-related activities:

- Conduct testing in accordance with ISO/IEC 17025, and the relevant ASCA program specifications

- Be aware of and consider recommendations made in any relevant FDA guidance documents.
- Abide by the ASCA program specifications to achieve and maintain status as an ASCA-accredited testing laboratory.
- Provide all ASCA Pilot documentation (e.g., complaint logs, issue tracking, test procedures) to FDA upon request.
- Allow FDA to conduct audits upon request; audits may include observations of testing activities and documentation review.
- Establish and maintain appropriate communication with FDA. A testing laboratory should not hesitate to contact FDA regarding the ASCA Pilot. FDA expects that appropriate communication includes the following at a minimum:
    - Notification to FDA within five calendar days via email of any changes that may impact the testing laboratory's participation.
    - Attendance at regularly scheduled teleconferences with FDA as requested. Regular interactions between testing laboratories and FDA are intended to provide the opportunity for discussions about ASCA implementation issues, e.g., training needs, possible improvements and other program-related topics. FDA plans to hold these teleconferences with testing labs as a group, not with individual laboratories.
    - Provision of annual reports of complaint handling to FDA.
- Commit that all relevant FDA training will be completed by appropriate individuals prior to conducting testing under the ASCA Pilot.
- Ensure that proprietary information is protected per client agreements.
- Acknowledge that FDA maintains complete discretion regarding granting *ASCA Accreditation* in the ASCA Pilot. FDA may suspend or withdraw *ASCA Accreditation* at any time.
- Confirm, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.