Contains Nonbinding Recommendations

Draft – Not for Implementation

The Accreditation Scheme for Conformity Assessment (ASCA) Program

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

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on September 23, 2024.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions about this document regarding CDRH-regulated devices, contact the ASCA Program at ASCA@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

When final, this guidance will supersede "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff," issued September 25, 2020.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

Contains Nonbinding Recommendations

Draft – Not for Implementation

OMB Control No. 0910-0889
Current expiration date available at https://www.reginfo.gov.
See additional PRA statement in Section XIV of this guidance

Preface

Additional Copies

CDRH

Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please include the document number 17037 and the complete title of the guidance in the request.

CBER

Additional copies are available from the Center for Biologics Evaluation and Research (CBER), Office of Communication, Outreach, and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Room 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, by email, ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

Table of Contents

The Accreditation Scheme for Conformity Assessment (ASCA) Program

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

This draft guidance, when finalized, will represent 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 Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Program) 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 Program in a pilot phase.[4] FDA is concluding the ASCA pilot phase and establishing an ongoing ASCA Program, in accordance with amendments made to section 514 by section 2005 of the FDA User Fee Reauthorization Act of 2022, part of the Medical Device User Fee Amendments of 2022 (MDUFA V).[5] The establishment of the goals, scope, procedures, and a suitable framework for the voluntary ASCA Program supports the

[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] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program issued on September 25, 2020.
[5] *See* Pub. L. 117-180, Division F: "FDA User Fee Reauthorization Act of 2022" (FUFRA)

Agency's continued efforts to use its scientific resources effectively and efficiently to protect and promote public health. FDA believes the voluntary ASCA Program 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 Program does not supplant or alter any other existing statutory or regulatory requirements governing the decision-making process for premarket submissions.

When finalized, this draft guidance is intended to supersede the "The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff," issued September 25, 2020.

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

In general, FDA guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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."[7] Section 514(d) required 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. Section 514(d) was amended in 2022[8] to align language with the conformity assessment community (e.g., "results" replacing "determinations"), to modify 514(d) to reflect the processes developed during the ASCA pilot (i.e., processes for accreditation bodies), and to provide for continued operation of the ASCA Program (i.e., removal of 514(d)(3)(A-C) and 514(d)(4) Sunset).

Section 514(d) states that test results by accredited testing laboratories that support that a device conforms with a standard included as part of the ASCA Program shall be accepted by FDA for

[6] For the purposes of this guidance, the term 'standard' or 'standards' will be used to refer to 'consensus standard' or 'consensus standards'.
[7] *See* Pub. L. 115-52, section 205
[8] *See* Pub. L. 117-180, Division F: FUFRA

the purposes of demonstrating such conformity unless FDA finds that such results shall not be so accepted.[9]

The statute provides that FDA may review results by accredited testing laboratories, including by conducting periodic audits of such results or of the processes of accreditation bodies or testing laboratories.[10] 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 or recognition of an accreditation body,[11] or a request for additional information regarding a specific device.[12]

III. Overview

Under the ASCA Program'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 (detailed in any standards-specific guidance documents) associated with each FDA-recognized consensus standard and test method included in the ASCA Program.

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 included in the ASCA Program. When an ASCA-accredited testing laboratory conducts testing under the ASCA Program, it should provide to the device manufacturer all information listed in the relevant ASCA Program specifications, including an ASCA summary test report.

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 Program can then include a declaration of conformity (ASCA DOC) with any necessary supplemental documentation (e.g., an ASCA summary test report) as part of a premarket submission to FDA.

Under the ASCA Program, FDA generally will accept results from ASCA-accredited testing laboratories when accompanied by an ASCA 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)*.

---

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

[10] *See* section 514(d) of the FD&C Act. Note that this section of the Act refers to "accreditation bodies" as "accredited bodies."

[11] Section 514(d) allows FDA to take additional measures "such as suspension or withdrawal of accreditation of such testing laboratory."

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

Figure 1 illustrates the process flow for the ASCA Program as described above and in Sections X. and XI. of this guidance.

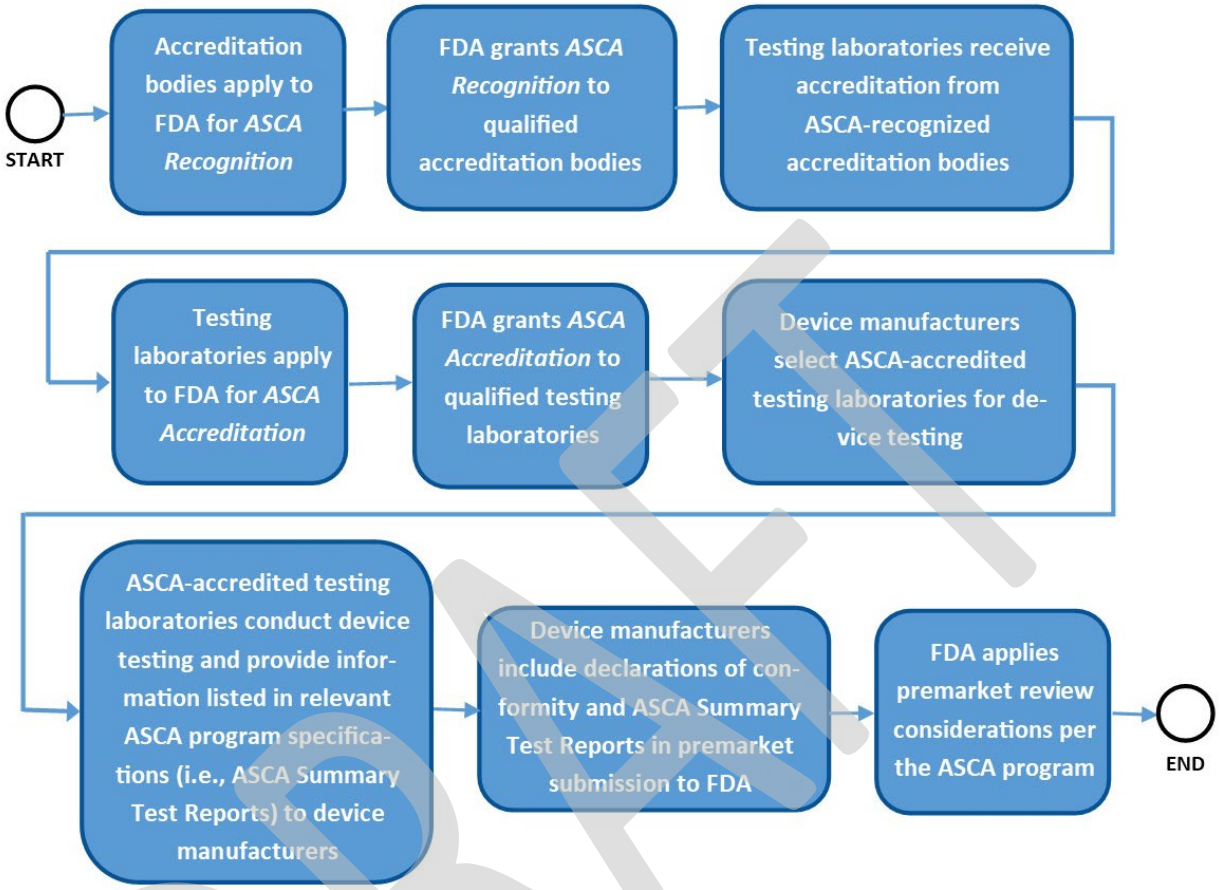

Figure 1 Process flow for the ASCA Program.

The ASCA website provides information about the ASCA Program (e.g., how to participate in the ASCA Program) as well as links to information related to the ASCA Program specifications, ASCA summary test reports, and ASCA DOC discussed in this guidance document.

IV. Scope

This guidance describes the goals and operation of the ASCA Program as required by section 514(d) of the FD&C Act. Specifically, this guidance describes the following:

- The criteria specified in guidance by the Secretary[13] used to determine whether and how an accreditation body or testing laboratory may participate in the ASCA Program. These criteria include:
    - the qualifications accreditation bodies and testing laboratories must meet to participate in the ASCA Program (*Refer to Sections X.A. and XI.A. of this guidance*);
    - the application process, including recommended application contents, for participation in the ASCA Program (*Refer to Sections X.B. and XI.B. of this guidance*); and
    - signed agreements for ASCA-recognized accreditation bodies and ASCA-accredited testing laboratories governing participation in the ASCA Program (*Refer to Appendices A and B of this guidance*).
- 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 included in the ASCA Program[14] (*Refer to Section XII of this guidance*).
- The policy regarding Agency review of results by ASCA-accredited testing laboratories: such results shall be accepted by the Secretary for purposes of demonstrating such conformity unless the Secretary finds that certain results of such tests should not be so accepted[15] (*Refer to Section XIII. of this guidance*).
- The processes and policies FDA intends to follow when conducting periodic audits of such results or of the processes of accredited bodies or testing laboratories[16] (*Refer to Sections X.D. and XI.D. of this guidance*).
- The processes and policies FDA intends to follow regarding suspension or withdrawal of *ASCA Accreditation* or *ASCA Recognition* and requesting additional information[17] (*Refer to Sections X.E., XI.E., XI.F., and XIII. of this guidance*).

The ASCA Program guidance(s) do not address all of the specific content which may be necessary to support a particular premarket submission. For more information about the use of standards for device review, visit the Standards and Conformity Assessment Program website. See also FDA's guidance, CDRH Standard Operating Procedures for the Identification and

[13] *See* section 514(d) of the FD&C Act.
[14] *See* section 514(d) of the FD&C Act.
[15] *Ibid*
[16] *Ibid*
[17] *Ibid*

Evaluation of Candidate Consensus Standards for Recognition 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. Conformity assessment resources used to develop the ASCA Program are described in Section V. of this guidance.

V. Terminology in the ASCA Program

This section provides definitions for key terms used in the ASCA Program. 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 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 Program do not make them legal or regulatory requirements. In certain circumstances, FDA has created new terminology to describe specific aspects of the ASCA Program.

- Accreditation: third-party attestation related to a conformity assessment body conveying formal demonstration of its competence to carry out specific conformity assessment tasks.[18] An accreditation body may or may not accredit a testing laboratory independent of a laboratory's participation (or desire to participate) in the ASCA Program.

- Accreditation body: authoritative body that performs accreditation.[19]

- ASCA-accredited testing laboratory: testing laboratory that has been granted *ASCA Accreditation* by FDA. ASCA-accredited testing laboratories may state their testing as having been conducted under the ASCA Program 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 state their accreditation activities as having been conducted under the ASCA Program 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

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

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 FDA-recognized consensus standards and test methods for which testing may be stated as having been conducted under the ASCA Program. *ASCA Accreditation* exists only within the ASCA Program and is separate from any accreditation that an accreditation body may provide to a testing laboratory for purposes other than the ASCA Program.

- *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 FDA-recognized consensus standards and test methods for which accreditation activities may be stated as having been conducted under the ASCA Program.

- ASCA summary test report: documentation that summarizes the testing conducted by an ASCA-accredited testing laboratory within the scope of its *ASCA Accreditation*; an ASCA summary test report is specific to the ASCA Program.

- 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.[20]

  Note: In the ASCA Program, 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.[21]

- Conformity assessment body: body that performs conformity assessment services; note that an accreditation body is not a conformity assessment body.[22]

[20] Per ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles
[21] *Ibid*
[22] *Ibid*

- Conformity assessment scheme: conformity assessment system related to specified objects of conformity assessment to which the same specified requirements, specific rules and procedures apply.[23]

- Conformity assessment system: rules, procedures, and management for carrying out conformity assessment.[24]

- Declaration of Conformity (DOC): attestation made by a 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.[25]

- Declaration of Conformity for the ASCA Program (ASCA DOC): a declaration of conformity, as described in the FDA guidance entitled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, with additional ASCA-specific content.

- Deviations[26] from FDA-recognized consensus standards: modifications to the test method and/or acceptance criteria implemented during testing that are not explicitly permitted within the FDA-recognized consensus standard. This modified testing would not be considered as conducted in conformity with the standard and therefore, a declaration of conformity would not be appropriate. See Section XII.B of this guidance for more information.

- Exclusions to Accreditation: specific clauses, subclauses, or any other section of an FDA-recognized consensus standard that are not included in a scope of accreditation, for example, due to limitations of the capabilities of the testing laboratory.

- FDA-recognized consensus standard: standards identified by FDA (consistent with section 514(c) of the FD&C Act) for device manufacturers 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 and review FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

---

[23] 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, device manufacturers), and the nature of the specific requirements being assessed (e.g., specific medical device standards).

[24] Per ISO/IEC 17000

[25] See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

[26] The FDA Bioresearch Monitoring Program, in accordance with 21 CFR part 58,– Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies Practice, uses the term "deviation" to refer to study protocol deviations, which are different and separate from the term "deviations" from FDA-recognized consensus standards. Please refer to the standards-specific ASCA Program guidance documents for more information.

- Scope of accreditation: specific conformity assessment activities for which accreditation is sought or has been granted.[27]

- 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 Program.

- 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 Program.

- Suspending *ASCA Accreditation*: putting constraints in place for one or more FDA-recognized consensus standards or test methods within a testing laboratory's scope of *ASCA Accreditation* while issues are addressed *(Refer to Section XI.E. of this guidance).*

- Suspending *ASCA Recognition*: putting constraints on an accreditation body's scope of *ASCA Recognition* while issues are addressed *(Refer to Section X.E. of this guidance).*

- Third-party attestation: issue of statement, based on a decision following review, that fulfilment of specific requirements has been demonstrated.[28]

- Updating *ASCA Accreditation:* the process, initiated by a testing laboratory, of adding or removing FDA-recognized consensus standards, test methods, and/or exclusions to a testing laboratory's scope of *ASCA Accreditation (Refer to Section XI.C. of this guidance).*

- Updating *ASCA Recognition:* the process, initiated by an accreditation body, of adding or removing FDA-recognized consensus standards and test methods to an accreditation body's scope of *ASCA Recognition (Refer to Section X.C. of this guidance).*

- Withdrawing *ASCA Accreditation*: the process, initiated by FDA, of cancelling a testing laboratory's full or partial scope of *ASCA Accreditation*; note that withdrawal of the full scope of *ASCA Accreditation* removes the organization from the ASCA Program entirely *(Refer to Section XI.F. of this guidance)*.

- Withdrawing *ASCA Recognition*: the process, initiated by FDA, of cancelling an accreditation body's full or partial scope of *ASCA Recognition*; note that withdrawal of the full scope of *ASCA Recognition* removes the organization from the ASCA Program entirely *(Refer to Section X.E. of this guidance)*.

[27] Per ISO/IEC 17011
[28] Per ISO/IEC 17000

VI. Purpose of the ASCA Program

The ASCA Program is intended to improve the efficiency of premarket review processes by building confidence in DOCs and any associated supporting documentation produced by accredited testing laboratories. Evidence of conformity to one or more FDA-recognized consensus standards is often a thorough and efficient way for a device manufacturer to address certain questions of safety and/or effectiveness. For device manufacturers and FDA to benefit from the efficiency, however, FDA must have confidence in the DOC.[29] 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 and any associated supporting documentation 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 and any associated supporting documentation described in Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices 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. 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.

VII. Specific Goals of the ASCA Program

The ASCA Program 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 device manufacturers rely on testing completed by ASCA-accredited testing laboratories.

The overarching goals of the ASCA Program are the following.

- **Enhance confidence in medical device testing**

  The ASCA Program 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

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

guidance throughout their participation in the Program.[30] 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 Program does not introduce new requirements for device manufacturers. Rather, by clearly communicating expectations for how results from ASCA-accredited testing laboratories are included and reviewed in premarket submissions, the ASCA Program works 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 Program (*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 Program will decrease the need for the FDA to request additional information regarding testing methodologies when a premarket submission includes an ASCA DOC.

- **Support international harmonization**

  FDA used elements from international conformity assessment standards in the ISO/IEC 17000 series to establish the ASCA Program. The standards within the ISO/IEC 17000 series are used worldwide by stakeholders including accreditation bodies, testing laboratories, and device manufacturers.[31] In addition, most of the FDA-recognized consensus standards and test methods selected for the ASCA Program are international voluntary consensus standards. FDA believes the experience gained in the ASCA Program could broadly inform international harmonization efforts such as standards use across jurisdictions.

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

VIII. ASCA Program Framework

A. Conformity Assessment Resources

FDA sought to maximize the use of existing frameworks and arrangements in developing the ASCA Program. This way, accreditation bodies and testing laboratories can participate in the ASCA Program by leveraging existing processes and knowledge, increasing the net benefit of participation. We also believe that, by using and extending existing paradigms, the ASCA Program output will be equally applicable to, and therefore beneficial to, other stakeholders (e.g., other regulatory authorities).

The conformity assessment scheme used in the ASCA Program generally 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)[32]**

  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.D. of this guidance*).

- **ISO/IEC 17011**

  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.D. of this guidance).*

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

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

  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 FDA-recognized consensus standard or test method to accredit testing laboratories included in the ASCA Program (*Refer to Section IX.B. of this guidance*).

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

The ASCA Program relies on FDA-recognized consensus standards and test methods. Please note that only a subset are included in the ASCA Program. FDA has sought to maximize the benefit of the ASCA Program to the public health by selecting FDA-recognized consensus standards and test methods that device manufacturers often rely upon to address significant issues of safety and/or effectiveness. These standards and test methods in the ASCA Program include both cross-cutting (horizontal) and device-specific (vertical) standards, are of public health significance, and provide a means for establishing acceptance criteria.

FDA regularly considers recognition of updated versions of consensus standards. FDA is aware that, depending on the nature of the changes to the new version, revisions to the associated ASCA Program specifications may be needed. For the version of any FDA-recognized consensus standard included in the ASCA Program, see the FDA-Recognized Consensus Standards Database.

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, device manufacturers may continue to rely on other voluntary consensus standards and provide DOCs in premarket submissions; however, these other standards will not be eligible for the premarket review benefits of the ASCA Program *(Refer to Section XIII. of this guidance)*.

C. 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 Program. The additional ASCA Program specifications for each set of FDA-recognized consensus standards and test methods, are those FDA considers necessary to ensure confidence in device testing submitted to FDA.

D. Expanding the ASCA Program

In the MDUFA V commitment letter, FDA committed to working with stakeholders for further input on programmatic improvements and/or consideration for expansion.[33] In the future, the ASCA Program may expand to include new FDA-recognized consensus standards and test methods, in which case FDA will update its FDA-Recognized Consensus Standards Database accordingly and may issue or update its guidance regarding the new FDA-recognized consensus standards and test methods. Generally, FDA intends that such guidance(s) will address the same concepts identified in the current standard-specific guidances, including (i) appropriate additional ASCA specifications for the new technical area; (ii) sufficiently detailed and streamlined test report content; and (iii) appropriate considerations for declaring conformity and supplemental documentation.

IX. Roles and Responsibilities

A. FDA Staff

FDA ASCA Program staff manage the ASCA Program, including granting *ASCA Recognition* to accreditation bodies, granting *ASCA Accreditation* to testing laboratories, conducting audits[34] 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 scope of *ASCA Recognition*) and ASCA-accredited testing laboratories (including the scope of *ASCA Accreditation*). FDA ASCA Program staff are responsible for operating the ASCA Program, including providing relevant training for testing laboratories and accreditation bodies.[35] ASCA Program processes and policies for management of the ASCA Program are described in Sections X. and XI. of this guidance.

The FDA ASCA Program staff managing the ASCA Program are separate and independent from the FDA staff conducting premarket reviews.

FDA 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 staff are responsible for applying the statute (section 514(d) of the FD&C Act), and the policies described in this guidance. ASCA Program processes and policies regarding review of testing from an ASCA-accredited testing laboratory are described in Section XIII. of this guidance.

---

[33] *See* MDUFA V Commitment Letter, pg. 17-18 at https://www.fda.gov/media/157074/download

[34] 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.

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

B. Accreditation Bodies

Under the ASCA Program, ASCA-recognized accreditation bodies accredit testing laboratories using the specifications of ISO/IEC 17025 and the ASCA Program specifications associated with each FDA-recognized consensus standard and test method included in the ASCA Program. 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 Program. ASCA Program 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 Appendix A Section E of this guidance*).

C. Testing Laboratories

ASCA-accredited testing laboratories can only perform testing for the FDA-recognized consensus standards and test methods included in the testing laboratory's scope of *ASCA Accreditation*. The testing laboratories should perform testing in accordance with the specifications of ISO/IEC 17025 and ASCA Program specifications associated with each included FDA-recognized consensus standard and test method. 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 state its testing was conducted under the ASCA Program only if the FDA-recognized consensus standards and test methods used were within its scope of *ASCA Accreditation* at the time of testing.

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 Program. ASCA Program 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 Appendix B Section E of this guidance*).

D. 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*). FDA recommends the device manufacturer develop the test plan in collaboration with the ASCA-accredited testing laboratory. It is the device manufacturer's responsibility to ensure FDA-recognized consensus standards and test methods are selected and used appropriately. The device manufacturer should ensure that the declaration of conformity for the ASCA Program (ASCA DOC) provided in a premarket

submission is appropriate, taking into account information and recommendations in the guidance, Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices and has the appropriate ASCA-specific content. ASCA Program processes and policies for device manufacturers are described in Section XII. of this guidance.

A device manufacturer's internal testing laboratory is eligible for *ASCA Accreditation*.[36] 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.

X. Processes and Policies for Accreditation Bodies

A. Qualifications for ASCA Recognition

FDA intends to 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, to the requirements of ISO/IEC 17011, 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 included 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 Program to accreditation bodies based in the United States, FDA aims to effectively use limited resources to facilitate successful program operation. For example, this approach will require fewer FDA resources for training accreditation body staff and technical assessors to the ASCA-program specifications and less resources for in-person trainings and on-site visits at the accreditation body.

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

3. Has the accreditation body executed a signed agreement as described in Section E of Appendix A of this guidance?

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

4. Has the accreditation body demonstrated competence in the FDA-recognized consensus standards and test methods included in ASCA to assess testing laboratories?

Accreditation bodies should demonstrate technical competency in the FDA-recognized consensus standards and test methods included in the ASCA Program to assess the testing laboratories. For example, technical assessors performing assessments within the ASCA Program should be knowledgeable in all of the test methods and standards they assess. Appendix A of this guidance includes a list of information that should be included in an application to demonstrate competence.

B. Accreditation Body Application Process

1. Application to FDA

An accreditation body may apply for *ASCA Recognition* by submitting documentation demonstrating how the accreditation body addresses the qualifications specified in Section X.A. of this guidance. The ASCA website provides instructions on how to apply to the ASCA Program. Appendix A of this guidance provides more information on application contents for accreditation bodies.

2. FDA Review and Assessment

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. By calendar day 60, FDA intends to grant or deny *ASCA Recognition* or request additional information from the accreditation body. The 60 calendar days will begin when all documents in Appendix A of this guidance are received. After reviewing application contents, FDA intends to notify the accreditation body of any issues that may preclude *ASCA Recognition* so the issues may be addressed (if possible). If an accreditation body fails to respond to a request for additional information within 90 calendar days, FDA intends to consider the application withdrawn. In the circumstances of either a withdrawn or denied application for *ASCA Recognition*, an accreditation body may reapply for *ASCA Recognition.* In these cases, the new application should include complete responses to the additional information request(s) and/or identify how

the previously identified issues have been addressed. Until *ASCA Recognition* is granted by FDA, an accreditation body is not a participant of the ASCA Program.

3. FDA Decision

When review is complete, FDA intends to inform the accreditation body of the decision. If *ASCA Recognition* is granted, FDA will provide a scope and renewal date (e.g., four years) for *ASCA Recognition*. Note that the scope will include only FDA-recognized consensus standards and test methods in the ASCA Program for which competence has been demonstrated. When FDA grants *ASCA Recognition* to an accreditation body, it will thereafter update the ASCA website to list the organization along with its scope of *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 will provide the rationale for the decision to the applicant.

4. ASCA Recognition Renewals

Up to six months prior to the anticipated renewal date of its *ASCA Recognition*, an accreditation body may apply to renew its *ASCA Recognition* following the same process outlined above. For renewal applications, the ASCA-recognized accreditation body should provide current documentation (i.e., the most recent version of all relevant documentation) of all items listed in Appendix A.C.1 of this guidance.

C. Updates to Scope of ASCA Recognition

FDA understands that accreditation bodies may continually adjust capabilities within their programs and their available expertise. When an accreditation body obtains additional competencies within FDA-recognized consensus standards and test methods, the accreditation body can apply to FDA to update the scope of their *ASCA Recognition*. For example, an accreditation body may initially participate in the ASCA Program by accrediting testing laboratories for MEM Elution Cytotoxicity testing. After some time, the accreditation body may obtain additional resources or competencies that can also support accrediting testing laboratories for Complement Activation Intracutaneous Reactivity testing. The accreditation body may then apply to update its *ASCA Recognition* by adding Complement Activation Intracutaneous Reactivity testing to its scope of *ASCA Recognition*.

Alternatively, if an accreditation body no longer offers accreditation to specific FDA-recognized consensus standards and test methods for which they had been recognized under the ASCA Program, the accreditation body must notify FDA and provide a brief rationale for the removal. FDA will remove those FDA-recognized consensus standards and test methods (e.g., a particular biocompatible test method) from the program, or the accreditation body as a whole will be removed if they have no remaining scope of *ASCA Recognition*. Recommended contents for applications to add to scope or notifications of removal are described in Appendix A of this guidance.

For additions or removals, FDA intends to update the scope of *ASCA Recognition* of each accreditation body on the ASCA website. As applicable, FDA intends to notify all affected ASCA-accredited testing laboratories. FDA intends to use the same *ASCA Accreditation* Body Identification Number to track all activity for a given accreditation body, including updates to *ASCA Recognition*.

D. Audits of Accreditation Bodies

FDA intends to periodically audit accreditation bodies to ensure that they are adequately fulfilling program expectations.[37] FDA intends to use a tiered-approach with three levels of audits. When practical, FDA intends to collaborate with ILAC on the status of ASCA-recognized accreditation bodies.

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.[38]

For Level 1 audits of an accreditation body, FDA may 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. For Level 1 audits of an accreditation body, FDA may also request additional information and/or ask questions to clarify the policies and processes of an accreditation body, which may include requesting relevant assessment documentation of ASCA-accredited testing laboratories.

For Level 2 audits of the accreditation body, FDA may 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 may include, but are not limited to, persistent issues with testing laboratories accredited by a particular accreditation body, a concerning trend identified 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 Program.

For Level 3 audits, FDA may initiate an on-site or remote audit of an accreditation body. This audit generally 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 situations where there is a public health concern regarding the safety of a device or when Level 1 and Level 2 audits do not

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

[38] *See* https://ilac.org/ilac-membership/membership-criteria/ for information on membership criteria for ILAC MRA Signatories.

adequately address issues concerning participation in the ASCA Program 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.

Through an audit, FDA might determine that there are grounds for suspension or withdrawal of the accreditation body's *ASCA Recognition* (see Section X.E. of this guidance below).

E. Suspension or Withdrawal of ASCA Recognition

One purpose of the ASCA Program is to increase FDA's confidence in testing results and DOCs provided in premarket submissions. FDA may identify issues, using a variety of means, that raise concerns regarding an accreditation body's ability to adequately fulfill its role in the ASCA Program. Section 514(d) of the FD&C Act provides that FDA may suspend or withdraw an accreditation body's *ASCA Recognition*. Full suspension or withdrawal affects an accreditation body's entire scope of *ASCA Recognition.* Partial suspension or withdrawal affects one or more parts of an accreditation body's scope of *ASCA Recognition.* Upon suspension or withdrawal, the accreditation body should halt all ASCA activities for the relevant suspended or withdrawn FDA-recognized consensus standards and test methods.

1. Considerations for Suspension or Withdrawal

For example, as explained in Appendix A Section E of this guidance, an accreditation body's application for *ASCA Recognition* contains a signed agreement to permit FDA to observe and assess ASCA-related activities. The application also includes a signed agreement to provide reports and notification of any changes that may impact the organization's participation in the ASCA Program. FDA may also request information about the competence of an accreditation body and its adherence to the criteria specified by FDA for participation in the ASCA Program when it reviews and compares a testing laboratory's requested scope of *ASCA Accreditation* to the scope of accreditation provided by the accreditation body.

Suspension or withdrawal of *ASCA Recognition* may be an appropriate measure when the findings from the periodic audits of an accreditation body suggest unreliable accreditation activities. Additionally, suspension or withdrawal may be appropriate when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which premarket submissions were supported by testing from an ASCA-accredited testing laboratory that was accredited by the accreditation body (*Refer to Section XIII.A. of this guidance*). If an accreditation body fails to meet the ASCA Program requirements specified in the ASCA Program guidances, FDA may suspend the accreditation body's *ASCA Recognition*.

When determining whether to suspend an accreditation body's *ASCA Recognition*, FDA generally considers whether the issues identified are of a magnitude for which a temporary constraint (e.g., by constraining the accreditation body from performing accreditation assessment activities for testing laboratories that have not yet been granted *ASCA Accreditation* during a period of suspension) on the accreditation body would appropriately address the concern.

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

- **Violation of law or violation of criteria outlined in this or any ASCA Program guidance**

  FDA's confidence in the ASCA Program 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 criteria outlined in this or any ASCA Program guidance document. For example, FDA might withdraw an accreditation body's *ASCA Recognition* if it states accreditation activities conducted outside of its scope of *ASCA Recognition* were conducted under the ASCA Program.

- **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 Program (*Refer to Appendix A Section E of this guidance*). For example, an accreditation body agrees to notify FDA of specific changes relative to the testing laboratories it has accredited for the ASCA Program. If an accreditation body repeatedly fails to provide such notifications to FDA, this may result in withdrawal of the organization's *ASCA Recognition*.

- **Information demonstrates nonconformity to the ASCA Program Specifications**

  Depending on the nature of the nonconformity identified, FDA may determine that an accreditation body should suspend ASCA-accreditation assessment activities for testing laboratories that have not yet been granted *ASCA Accreditation.*

- **Information is obtained that materially bears 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**[39]

  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

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

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 suspension or withdrawal of the accreditation body's *ASCA Recognition*.

- **Fraudulent or any other activity by an ASCA-accredited testing laboratory regarding the integrity of testing data**[40]

  For example, FDA may become aware of fraudulent activities or data integrity issues with testing data from an ASCA-accredited testing laboratory, that the accreditation body did not discover during their assessment of the testing laboratory. The fraudulent activities and/or data integrity issues may result in the suspension or withdrawal of the accreditation body's full or partial scope of *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 Program. 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 Program. 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.E.3. and XI.F.3. of this guidance)*.

- **Failure to demonstrate or maintain competence in assessment of testing laboratories**

  If an ASCA-recognized accreditation body fails to demonstrate or maintain its competence in its assessment of testing laboratories (e.g., loss of personnel with particular expertise, use of technical assessors who do not have ASCA testing-related experience, and/or have not completed FDA required training) for the scope of *ASCA Recognition*, FDA may consider withdrawing the full or partial scope of *ASCA Recognition* of the accreditation body. FDA may also consider withdrawing the full or partial scope of *ASCA Recognition* of the accreditation body if an ASCA-recognized accreditation body repeatedly accredits testing laboratories for the ASCA Program that do not meet the ASCA Program specifications.

[40] *Ibid*

Generally, while the issues resulting in suspension are addressed, the accreditation body may continue ASCA-accreditation assessment activities for testing laboratories that have been granted *ASCA Accreditation*.

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* when appropriate under section 514(d) even if the reasons are not listed above.

2. Procedures for Suspension or Withdrawal

When an accreditation body's *ASCA Recognition* is suspended or withdrawn, FDA will notify the accreditation body. The notification will include the reason for the suspension or withdrawal and, if appropriate, how the issues identified may be addressed in a future, new application for *ASCA Recognition.* The ASCA website has instructions on how to voluntarily withdraw from the ASCA Program.

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

If an accreditation body wishes to participate in the ASCA Program 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. The new application should include the *ASCA Accreditation* Body Identification Number and indicate whether the withdrawal was voluntary. If withdrawal was not voluntary, the response should include a reference to FDA's withdrawal notification and explain how all issues identified in the withdrawal notification were addressed.

F. Transfer of ASCA Accreditation

An ASCA-accredited testing laboratory may seek to transfer its accreditation from its current ASCA-recognized accreditation body to a different ASCA-recognized accreditation body (henceforth, the "new" ASCA-recognized accreditation body). In this case, the new ASCA-recognized accreditation body should notify FDA of this pending transfer with adequate information and documentation for FDA to determine whether to perform a reassessment of the testing laboratory's *ASCA Accreditation*. The notification should include the following:

- The name of the current ASCA-recognized accreditation body.
- A brief rationale for why the testing laboratory is requesting a transfer of its *ASCA Accreditation.*
- The testing laboratory's current scope of *ASCA Accreditation,* if*:*
  - The testing laboratory's new scope of *ASCA Accreditation* will be identical to the testing laboratory's current scope of *ASCA Accreditation*, the testing laboratory should submit a statement that the new scope of accreditation, which will be issued

by the new accreditation body, is identical. The draft scope of accreditation from the new accreditation body may also be helpful.
    - Transfer to another ASCA-recognized accreditation body is accompanied by changes in the scope of ASCA-accreditation, provide the necessary information, identified in Section XI.C. of this guidance, to support the updates to the *ASCA Accreditation*.
- Details of the new assessment cycle and how it relates to the current ASCA-recognized accreditation body's assessment cycle to ensure there will not be a lapse in accreditation of the testing laboratory as established through the specifications of ISO/IEC 17011.
- An overview or list of the documentation reviewed by the new ASCA-recognized accreditation body to ensure the testing laboratory has resolved any outstanding corrective actions or findings that may preclude accreditation. Documentation may include, but is not limited to, the following:
    - a complete copy of the most recent assessment report from the current accreditation body, and
    - details of any corrective actions and resolutions noted in the assessment report.

The ASCA-accredited testing laboratory should collaborate with the new ASCA-recognized accreditation body to provide the notification to FDA in a timely manner.

FDA may follow up with requests for additional documentation or information to determine whether to perform a reassessment of the testing laboratory's *ASCA Accreditation*. The new ASCA-recognized accreditation body should take appropriate steps to ensure that the testing laboratory is not transferring its accreditation for fraudulent purposes or to circumvent any negative assessments or corrective actions identified by its prior accreditation body.

XI. Processes and Policies for Testing Laboratories

Except where otherwise noted in any standards-specific ASCA guidance, FDA intends to follow the processes and policies detailed below in the management of testing laboratories participation in the ASCA Program.

A. Qualifications for ASCA Accreditation

FDA generally 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 generally 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 Program provides confidence in the testing laboratory because FDA has

795 determined the accreditation body is competent for the purposes of the ASCA Program with
796 respect to the eligible FDA-recognized consensus standards and test methods. FDA's review of
797 the testing laboratory's application to the ASCA Program and the comparison of the scope
798 requested by the testing laboratory to the scope of accreditation provided by an ASCA-
799 recognized accreditation body permits FDA to ensure that an ASCA-accredited testing
800 laboratory has met, and continues to meet, the criteria specified by FDA for participation in the
801 ASCA Program.[41]

802 ### 2. Has the testing laboratory executed the signed agreement described
803 in Section E of Appendix B of this guidance?

804 The signed agreement outlined in Appendix B Section E of this guidance is designed to ensure
805 transparency and accountability on the part of the testing laboratory in all aspects of its
806 participation in the ASCA Program. A testing laboratory may choose not to follow the terms of
807 participation at any time. However, *ASCA Accreditation* is contingent upon following such
808 terms.

809 ## B. Testing Laboratory Application Process

810 ### 1. Accreditation Body Assessment

811 Prior to applying to FDA for *ASCA Accreditation*, a testing laboratory must first obtain
812 accreditation from an ASCA-recognized accreditation body to ISO/IEC 17025 and the ASCA
813 Program specifications for which the testing laboratory is applying.

814 When an assessment is favorable, the ASCA-recognized accreditation body notifies the testing
815 laboratory of the "scope of *ASCA Accreditation*" proposed to be added to the testing laboratory's
816 accreditation. See the example in Appendix D of this guidance.

817 **NOTE:** To participate in the ASCA Program, the testing laboratory must next apply to FDA for
818 *ASCA Accreditation*. Until the testing laboratory has completed the ASCA Program application
819 process and FDA grants *ASCA Accreditation*, the testing laboratory is not part of the ASCA
820 Program.

821 ### 2. Application to FDA

822 After obtaining accreditation from an ASCA-recognized accreditation body, a testing laboratory
823 should submit an application for *ASCA Accreditation* to FDA. The testing laboratory can submit
824 an application to FDA by submitting documentation required by Appendix B of this guidance,
825 along with the proposed scope of *ASCA Accreditation* as described in Section XI.B.1. above.

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

The ASCA website provides instructions on how to apply to the ASCA Program. 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 uses the ASCA Testing Laboratory Identification Number to track all activity for a given testing laboratory.

3. FDA Decision

When its review is complete, FDA intends to inform the testing laboratory of its decision. If FDA grants *ASCA Accreditation*, FDA will provide a scope of *ASCA Accreditation* and an renewal date that aligns with the accreditation cycle scheduled by the testing laboratory's ASCA-recognized accreditation body. The ASCA-recognized accreditation body will then add the scope of *ASCA Accreditation* to the testing laboratory's certificate of accreditation. Note that the scope will include only FDA-recognized consensus standards and test methods in the ASCA Program 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 *ASCA Accreditation*.

If FDA does not grant *ASCA Accreditation*, the accreditation body should revoke and remove the testing laboratory's proposed scope of ASCA *Accreditation.* 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.

4. FDA Review and Assessment

FDA intends to review applications for *ASCA Accreditation* within 60 calendar days. By day 60, FDA intends either to grant or deny *ASCA Accreditation* or request additional information from the testing laboratory. The 60 calendar days will not begin until all documents in Appendix B of this guidance are received. If additional information is requested, FDA generally will include the testing laboratory's ASCA-recognized accreditation body in the communication and resolution of the requested information.

After reviewing application contents, FDA intends to notify the testing laboratory of any issues that may preclude granting *ASCA Accreditation* so that the issues may be addressed (if possible). If a testing laboratory fails to respond to a request for additional information within 90 calendar days, FDA intends to consider the application withdrawn. In the circumstances of either a withdrawn or denied application for *ASCA Accreditation*, a testing laboratory may reapply for *ASCA Accreditation.* In these cases, the new application should include complete responses to the additional information request(s) and/or identify how the previously identified issues have been addressed. Until *ASCA Accreditation* is granted by FDA, testing laboratories should not advertise that they are participants of the ASCA Program.

5. ASCA Accreditation Renewal

To maintain *ASCA Accreditation*, the testing laboratory should notify the ASCA Program when its ASCA-recognized accreditation body has finalized the reassessment to ISO/IEC 17025 and the ASCA specifications according to the accreditation cycle established by the accreditation body.[42] In the renewal notification to the ASCA Program, the testing laboratory should explicitly state any changes to the testing laboratory's administrative information.

An ASCA-accredited testing laboratory should notify the FDA of any delay in its scheduled reassessment at least 1 week prior to the planned reassessment date and provide any updates from its ASCA-recognized accreditation body (e.g., any extension of its accreditation pending the rescheduled reassessment). Failure to maintain accreditation to ISO/IEC 17025 and the ASCA Program specifications through an ASCA-recognized accreditation body will result in the suspension or withdrawal of the testing laboratory's *ASCA Accreditation*.

C. Update of Scope of ASCA Accreditation

FDA understands that testing laboratories may continually adjust capabilities within their programs, especially if they experience an increase or loss of facilities or internal expertise. When an testing laboratory adds FDA-recognized consensus standards or test methods, the testing laboratory can apply to update the testing laboratory's scope of *ASCA Accreditation*. For example, a testing laboratory may initially participate in the ASCA Program 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 update its *ASCA Accreditation* by adding Complement Activation testing to its scope of *ASCA Accreditation*. For additions to its scope of *ASCA Accreditation* a testing laboratory applies by following the initial application process and providing the information necessary for the new FDA-recognized consensus standards and testing methods.

Alternatively, if a testing laboratory removes specific FDA-recognized consensus standards and test methods for which they had been accredited under the ASCA Program, the testing laboratory must notify their ASCA-recognized accreditation body and FDA, and provide a brief rationale for the removal. FDA will remove the specific FDA-recognized consensus standards and test methods (e.g., a particular biocompatibility test method) from the Program, or the testing laboratory as a whole will be removed if they have no remaining scope of *ASCA Accreditation*.

Recommended contents for applications to additions to scope or notifications of removal are described in Appendix B of this guidance.

FDA intends to use the same ASCA Testing Laboratory Identification Number to track all activity for a given testing laboratory, and to make updates to the ASCA website as appropriate.

[42] *See* subclause 7.9 from ISO/IEC 17011.

D. Audits of Testing Laboratories

FDA intends to periodically audit testing laboratories to ensure that they are adequately fulfilling program expectations.[43] FDA intends to use a tiered-approach with three levels of audits. When practical, FDA intends to collaborate with the ASCA-recognized accreditation body regarding the status of ASCA-accredited testing laboratories.

In order to maintain conformance with ISO/IEC 17011, an accreditation body assesses its accredited testing laboratories at least every 2 years.[44] For Level 1 audits of the testing laboratory, FDA may 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. Additionally, for Level 1 audits of a testing laboratory, FDA may also request additional information and/or ask questions to clarify the policies and processes of a testing laboratory, which may include requesting relevant assessment documentation (e.g., complete test reports, training records).

For Level 2 audits of the testing laboratories, FDA may 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 may include, but are not limited to, persistent issues with a testing laboratory, a concerning trend identified upon review of the testing laboratory complaint logs, and a determination that Level 1 audits of the testing laboratory do not adequately address issues concerning participation in the ASCA Program.

For Level 3 audits, FDA may initiate an on-site or remote audit of the testing laboratory. This audit generally 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 only for issues of highest concern such as when Level 1 and Level 2 audits do not adequately address issues concerning participation in the ASCA Program. FDA will notify the appropriate accreditation body of the intent to initiate an 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.

---

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

[44] *See* 7.9.3 of ISO/IEC 17011: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.

Through an audit, FDA might determine that there are grounds for suspension or withdrawal of the accreditation body's *ASCA Recognition* (see Sections XI.E. and XI.F. of this guidance below).

E. Suspension of ASCA Accreditation

One purpose of the ASCA Program is to increase FDA's confidence in testing results and DOCs provided in premarket submissions. FDA may identify issues, using a variety of means, that raise concerns regarding a testing laboratory's ability to fulfill its role in the ASCA Program adequately. Section 514(d) of the FD&C Act provides that FDA may suspend a testing laboratory's participation in the ASCA Program. Suspension puts 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

For example, as explained in Appendix B Section D of this guidance, a testing laboratory application for *ASCA Accreditation* contains a signed agreement to permit FDA to conduct audits and assessment activities. The signed agreement also requires the testing laboratory to provide reports and notification of any changes that may impact the organization's participation in the ASCA Program. FDA may also request 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 test results may be unreliable. Suspension may also be appropriate when FDA becomes aware of information materially bearing on safety or effectiveness of a device for which the premarket submissions were supported by testing from the ASCA-accredited testing laboratory (*Refer to Section XIII.A. of this guidance*). If a testing laboratory fails to meet the requirements of the ASCA Program specified in the ASCA Program guidances, FDA may suspend the TL's *ASCA Accreditation*. The suspension helps to maintain confidence in the test results produced by ASCA-accredited testing laboratories.

When determining whether to suspend a testing laboratory's *ASCA Accreditation*, FDA generally considers whether the issues identified are of a magnitude for which a constraint on the testing laboratory would adequately maintain the integrity of the ASCA Program.

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 state its testing has been conducted during a period of suspension until the nonconformity is adequately addressed. The 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 Program (*Refer to Appendix B Section E of this guidance*). 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 testing to one or more of the FDA-recognized consensus standards and test methods within the testing laboratory's scope of *ASCA Accreditation.*

- **Suspension of accreditation by an ASCA-recognized accreditation body**

  An ASCA-recognized accreditation body may suspend the testing laboratory's accreditation for FDA-recognized consensus standards and test methods under the ASCA Program. Such a suspension violates the signed agreement in Appendix B of this guidance which indicates that a testing laboratory must obtain accreditation from an ASCA-recognized accreditation body. Therefore, FDA will suspend that testing laboratory's *ASCA Accreditation* until the issues are addressed. Prior to lifting a testing laboratory's suspension, FDA may request additional information from the testing laboratory's accreditation body and/or ask the accreditation body questions to clarify the resolution of nonconformities that affect ASCA-related activities.

- **Information is obtained that materially bears on safety or effectiveness of a device for which a premarket submission included testing from the testing laboratory[45]**

  FDA may become aware of information materially bearing on study conduct or quality for which stating that test results have been conducted during a period of suspension is necessary to maintain confidence in the ASCA Program. 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 Program, 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 state the affected test results have been conducted during a period of suspension.

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

- **Fraudulent activities of an ASCA-accredited testing laboratory or information bearing on integrity of testing data**

  FDA may become aware of fraudulent activities or data integrity issues with testing data from an ASCA-accredited testing laboratory. FDA may coordinate with the testing laboratory's associated accreditation body to determine appropriate actions and may suspend the testing laboratory's *ASCA Accreditation*.

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

  FDA relies on ASCA-recognized accreditation bodies to accredit testing laboratories for the ASCA Program. If the accreditation body that accredited a testing laboratory is withdrawn from the ASCA Program, FDA may 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 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.E.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* when appropriate under section 514(d) even if the reasons are not listed above.

2. Implications for ASCA activities

When a testing laboratory's *ASCA Accreditation* is suspended, constraints are put on how the testing laboratory may state its testing relative to the ASCA Program while the issues resulting in the suspension are addressed. 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 stated as having been conducted during a period of suspension.

A device manufacturer indicates in their ASCA 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 XII.C. of this guidance*). In such circumstances, the submitted ASCA Summary Test Report may not be adequate to support the ASCA DOC and FDA staff may ask additional questions to determine whether the test results can be used to support a decision on a premarket submission. 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 Appendix B Section D of this guidance*).

Suspension of a testing laboratory's *ASCA Accreditation* may affect the accreditation body that accredited it for the ASCA Program, depending on the reasons for suspension (*Refer to Section X.E.1. of this guidance).* At a minimum, FDA will discuss with the accreditation body the reasons for suspension as well as any plans for resolution, including any timelines and actions to address the issue(s). 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 Program while the issue(s) resulting in the suspension are addressed.

3. Procedures

a. Initiating Suspension

When FDA suspends a testing laboratory's *ASCA Accreditation*, FDA intends to notify the testing laboratory. The notification will include the suspended FDA-recognized consensus standards or test methods and how the issues resulting in suspension may be addressed.

Upon suspension of a testing laboratory's *ASCA Accreditation*, FDA will update the ASCA website as appropriate to reflect the constraint on the impacted FDA-recognized consensus standards and test methods within the testing laboratory's scope of *ASCA Accreditation*. FDA also intends to notify the testing laboratory's ASCA-recognized accreditation body. The appropriate ASCA-specific section from the testing laboratory's scope of accreditation should be immediately removed by their accreditation body. Considerations for the accreditation body are discussed in Section X.E.1. of this guidance.

b. Lifting Suspension

To pursue lifting a suspension of *ASCA Accreditation*, a testing laboratory should submit documentation demonstrating how all issues resulting in suspension were resolved. To avoid delays, the documentation should include the ASCA Testing Laboratory Identification Number and include reference to FDA's initial suspension notification. If a suspension was initiated by the testing laboratory's ASCA-recognized accreditation body, documentation demonstrating the suspension by that accreditation body has been lifted should be included in the submission to FDA. If necessary, FDA may contact the testing laboratory's ASCA-recognized accreditation body to request documentation to demonstrate issues have been resolved.

Once FDA has determined that the testing laboratory has adequately addressed the issues that resulted in suspension, FDA will lift the suspension and corresponding constraints. The accreditation body will also be notified that the suspension is lifted, and will reinstate the ASCA-specific section of the testing laboratory's scope of accreditation. FDA will update the ASCA website as appropriate to accurately reflect the scope of *ASCA Accreditation*.

F. Withdrawal of ASCA Accreditation

One purpose of the ASCA Program is to increase FDA's confidence in testing results and DOCs provided in premarket submissions. FDA may identify issues, using a variety of means, that raise concerns regarding a testing laboratory's ability to fulfill its role in the ASCA Program adequately. Section 514(d) 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 or partial scope of *ASCA Accreditation*. A full withdrawal removes the organization from the ASCA Program entirely.

1. Considerations for Withdrawal

For example, as explained in Appendix B Section E of this guidance, the signed agreement included in a testing laboratory's application for *ASCA Accreditation* contains an agreement to permit FDA to conduct audits 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 Program. 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. 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 suspension cannot, or can no longer, adequately maintain the integrity of the ASCA Program (e.g., repeated failure to correct nonconformities).

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 criteria outlined in this or any ASCA Program guidance document**

  FDA's confidence in the ASCA Program 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 criteria outlined in this or any ASCA Program guidance document. For example, FDA may withdraw a testing laboratory's *ASCA Accreditation*, thereby removing it from the ASCA Program, if it states testing results conducted outside of its scope were conducted under the ASCA Program.

- **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 Program *(Refer to Appendix B Section E of this guidance*). For example, a testing laboratory agrees to notify FDA of changes that may affect its participation in the ASCA Program. If a testing laboratory repeatedly fails to provide such notifications to FDA, this may result in withdrawal of the organization's *ASCA Accreditation*.

- **Information is obtained that materially bears on safety or effectiveness of a device for which a premarket submission included testing from the testing laboratory**[46]

  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 Program and fails to correct such issues, FDA may withdraw that testing laboratory's *ASCA Accreditation*.

- **Fraudulent or any other activity by an ASCA-accredited testing laboratory regarding the integrity of testing data**

  FDA may become aware of fraudulent activities or data integrity issues with testing data from an ASCA-accredited testing laboratory. 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 Program**

  FDA relies on ASCA-recognized accreditation bodies to accredit testing laboratories for the ASCA Program. If the accreditation body that accredited a testing laboratory is withdrawn from the ASCA Program and the testing laboratory is unable to transfer their ASCA Accreditation to another ASCA-recognized accreditation body (see Section XI.G. of this guidance) before their current certificate expires, FDA will withdraw a testing laboratory's *ASCA Accreditation*. Note that FDA intends to notify affected testing

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

laboratories if their accreditation body's *ASCA Recognition* is withdrawn *(Refer to Section X.E.3. of this guidance*).

- **Failure to demonstrate or maintain competence in testing by an ASCA-accredited testing laboratory**

  If an ASCA-accredited testing laboratory fails to demonstrate or maintain its competence in testing for FDA-recognized consensus standards and test methods in the ASCA Program (e.g., loss of personnel with particular expertise) for the scope of *ASCA Accreditation*, FDA may consider withdrawing the full or partial scope of *ASCA Accreditation* of the testing laboratory.

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* when appropriate under section 514(d) even if the reasons are not listed above.

2. Implications for ASCA activities

Withdrawal of a testing laboratory's *ASCA Accreditation* removes the testing laboratory from the ASCA Program for the full or partial scope of *ASCA Accreditation*. Any activities performed after withdrawal of the full or partial scope of *ASCA Accreditation* should not be identified as being performed as part of the ASCA Program.

Withdrawal of a testing laboratory's *ASCA Accreditation* may affect the accreditation body that accredited it for the ASCA Program, depending on the reasons for withdrawal *(Refer to Section X.E.1. of this guidance)*. Premarket review considerations for testing conducted after withdrawal of a testing laboratory's *ASCA Accreditation* are provided in Section XIII.C. 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 continue to accredit the testing laboratory; however, FDA would no longer recognize that accreditation for purposes of the ASCA Program.

3. Procedures

When a testing laboratory's *ASCA Accreditation* is withdrawn, FDA will notify the testing laboratory. The notification 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*.

For voluntary withdrawals, the ASCA website provides instructions on how to withdraw from the ASCA Program.

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 Program. The ASCA-specific section from the testing laboratory's scope of

accreditation should be immediately removed by their accreditation body. Considerations for the accreditation body are discussed in Section X.E.1. of this guidance.

If a testing laboratory wishes to participate in the ASCA Program 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 notification and explain how all issues identified in the withdrawal notification were addressed.

G. Transfer of ASCA Accreditation

At any given time, the testing laboratory must be accredited by an ASCA-recognized accreditation body to participate in the ASCA Program. However, an ASCA-accredited testing laboratory may transfer its accreditation from its current ASCA-recognized accreditation body to another ASCA-recognized accreditation body. The testing laboratory should work collaboratively with its new ASCA-recognized accreditation body to ensure that the information and documentation referenced in Section X.F. of this guidance is provided to FDA in a timely manner. A testing laboratory should not seek to transfer its *ASCA Accreditation* to circumvent or obfuscate any negative assessments or corrective actions identified by their prior accreditation body. Such a transfer may undermine the confidence in test results for purposes of the ASCA Program, warranting withdrawal or suspension of *ASCA Accreditation*.

After a testing laboratory receives accreditation from another accreditation body, the testing laboratory notifies FDA of this transfer of accreditation by providing proof of accreditations described above from the new ASCA-recognized accreditation body. If transfer to another ASCA-recognized accreditation body is accompanied by changes in the scope of *ASCA Accreditation,* the testing lab should follow the process outlined in Section XI.C. of this guidance and provide the necessary information to support the changes.

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 the scope of their *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 Program 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, FDA recommends a device manufacturer work with them in developing a test plan for the device. FDA encourages a collaborative relationship between the device manufacturer and testing laboratory wherever possible. FDA recommends that development of a test plan for conduct by an ASCA-accredited testing laboratory consider the following:

- **Supplementary Information Sheets (SIS)**

  FDA recommends that the device manufacturer and the ASCA-accredited testing laboratory consult the Supplementary Information Sheet (SIS) for each FDA-recognized consensus standard(s) to be included in the test plan. The SIS includes the extent of recognition and relevant FDA guidance and/or supportive publications which may better inform the device manufacturer's test plan development.

- **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 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)[47] does not meet the criteria for inclusion in the ASCA Program and the premarket review considerations described in Section XIII. of this guidance do not

[47]See https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

apply. This is because, under the ASCA Program, device manufacturers may include in their premarket submissions ASCA DOCs based on testing from ASCA-accredited testing laboratories.[48] 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, an ASCA DOC would not be appropriate. Note that the testing performed using deviations to an FDA-recognized consensus standard 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***

  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 and any other relevant ASCA Program 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 Program 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.

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 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 included in the ASCA Program and in accordance with the ASCA Program specifications for that standard and test method. The ASCA Program 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. FDA recommends that device manufacturers review FDA's guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices." Rather, this guidance document describes how a device

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

manufacturer may incorporate testing results from an ASCA-accredited testing laboratory into its premarket submissions, including the use of ASCA DOCs and, where applicable, supplemental documentation to support the ASCA DOC.

A premarket submission with ASCA documentation should include the following elements:

1. a cover letter (with a summary of ASCA information),
2. ASCA DOC(s), and
3. ASCA summary test report(s).

Please see Appendix C of this guidance for more detail on the elements above which should be included in a premarket submission with ASCA documentation.

XIII. Processes and Policies for FDA 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 Program, 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 test results from an ASCA-accredited testing laboratory if FDA finds that certain results of such tests should not be so accepted.[49] FDA will not discuss contents of a premarket submission with an ASCA-accredited testing laboratory without permission from the device manufacturer. 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 Sections X.D. and XI.D. of this guidance)*;[50]
- if FDA becomes aware of information that would result in suspension or withdrawal of a testing laboratory's *ASCA Accreditation*;
- if FDA becomes aware of information that would result in withdrawal of the associated accreditation body's *ASCA Recognition*;
- if FDA becomes aware of information materially bearing on the study conduct or quality, or data integrity, or related issues of non-compliance with 21 CFR Part 58 (e.g., if the testing laboratories under the purview of 21 CFR Part 58 receive from FDA

[49] *See* section 514(d) of the FD&C Act.
[50] *Ibid*

Bioresearch Monitoring Program a Form 483 with Official Action Indicated (OAI) classification, an untitled letter, or a warning letter);

- if FDA becomes aware of information materially relevant to safety or effectiveness for the device [51] (e.g., if specific use issues of public health concern are identified for a device type during total product lifecycle reviews);
- if FDA becomes aware of information related to potential fraudulent behavior of a testing laboratory that may affect ASCA-related activities;
- if the ASCA summary test report indicates an issue with the testing or device[52] (e.g., controls do not work as expected or test results signal a possible issue with safety or performance);
- if basic administrative information is missing (e.g., product identification information or dates of testing); or
- if supplemental documentation to support the ASCA DOC (e.g., ASCA summary test report) is incomplete.

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.E.1. of this guidance, FDA will suspend a testing laboratory's *ASCA Accreditation* when specific issues are identified. If the testing laboratory's *ASCA Accreditation* was suspended at the time of testing, an ASCA DOC may not be submitted for the suspended FDA-recognized consensus standards and test methods. 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 constraints of the suspension. Depending on the issues resulting in suspension, FDA may be unable to rely solely on the 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.F. of this guidance, FDA will withdraw a testing laboratory's *ASCA Accreditation* in certain situations. A device manufacturer may still include in their premarket submission a DOC for testing conducted at the testing laboratory. In these cases, an ASCA DOC would not be appropriate and 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).

[51] *See* section 514(d) of the FD&C Act.
[52] *Ibid*

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 suspension or 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 Sections XI.E.1. and XI.F.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[53] 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,
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 (To find the current expiration date, search for this OMB control number available at https://www.reginfo.gov).

[53] Rounded to the nearest whole number.

Appendix A: Application for ASCA Recognition

An application from an accreditation body seeking *ASCA Recognition* should include the components described below. All information in the application should be provided in English. If the documents are not originally written in English, the accreditation body must provide the following:

- native language documents,
- certified English translations of the documents (refer to ISO 17100, ISO/IEC 17050-2, and ASTM F2575 for additional information), and
- details of the document control process for native language document approval and related release of the certified document.

A. Administrative Information

- organization name and address;
- designated point of contact: first and last name, title, phone number, email address; and
- alternate point of contact: first and last name, title, phone number, 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 Program (more than one standard and test method may be identified).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Program:

- Proof of signatory status as International Laboratory Accreditation Cooperation (ILAC) MRA with scope that includes 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 FDA-recognized consensus standards or test methods in the ASCA Program.
- An example scope of accreditation that is typically used by the accreditation body, and information indicating to what extent it will be modified to address accreditation for the ASCA Program.
- A detailed description of the process to accredit testing laboratory applicants to ISO/IEC 17025 and ASCA Program specifications, including awareness, training, and accreditation activities.
- A detailed description of the accreditation body's approach used to demonstrate technical competency of testing laboratories consistent with ASCA Program specifications, including guidances associated with the ASCA Program. This includes a detailed

description of the qualifications for each technical assessor for the requested scope of *ASCA Recognition*. It also includes training records to demonstrate competence for assessing all FDA-recognized consensus standards and test methods for the requested scope of *ASCA Recognition* for which they will perform the assessment. For each technical assessor, include resumes, CVs, summary of experience, relevant technical training, etc., from personnel already identified.

- If applicable, a detailed description of the accreditation body's outsourcing activities, as permitted under IEC/ISO 17011, related to obtaining and training additional outsourced resources to complete assessments. Details should include how outsourcing activities will be managed; whether outsourcing will include individual contractors, entire organizations, or both; and how records related to supplier management and training are maintained. Note: if a detailed description of outsourcing activities is not provided in an application for *ASCA Recognition*, an application to amend the accreditation body's *ASCA Recognition*, with the details described above, must be submitted and approved before outsourcing may be used to conduct assessments under the ASCA Program.
- 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. Renewal, Updates to the Scope of ASCA Recognition, and Amendments

In addition to the contents outlined below, FDA recommends that all renewals, updates to the scope of *ASCA Recognition*, and amendments 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 updated in its scope of *ASCA Recognition*, as applicable.

1. Renewal

For renewal applications, the ASCA-recognized accreditation body should provide current documentation (i.e., the most recent version of all relevant documentation) of all items listed in Appendix A Section B.

2. Updates to the Scope of ASCA Recognition

For additions to the scope of *ASCA Recognition*, accreditation bodies should follow the initial application process described in Appendix A. For removals from the scope of ASCA *Recognition*, a notification to FDA is required, along with a brief rationale. For detailed information related to updates to the scope of *ASCA Recognition* see Section X.C. of this guidance.

3. Amendments

For amendments to existing *ASCA Recognition* (i.e., changes that do not update the scope of *ASCA Recognition)*, such as outsourcing, the amendment application should include only the relevant changes from the most recently approved initial or renewal application.

E. Signed Agreement

The signed agreement is an agreement executed by the accreditation body. It includes confirmation that the accreditation body has read, understood, and agrees to adhere to the following for its ASCA Program-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 Program.
- Retain a copy of all records used during an assessment of a testing laboratory for the ASCA Program until the next accreditation cycle.
- Maintain a current list and description of any accreditation services offered for which the scope includes any FDA-recognized consensus standards or test methods in the ASCA Program and reassess ASCA-accredited testing laboratories per the accreditation body's renewal schedule.
- Follow the guidelines and processes detailed in the ASCA Program guidance documents regarding which FDA-recognized consensus standards and test methods to assess when accrediting a testing laboratory for the ASCA Program.
- Provide all ASCA documentation to FDA in a timely manner upon request.
- Maintain all ASCA documentation in a clear, complete, and detailed manner such that a trained individual could follow them.
- Produce all ASCA documentation in English, as described at the beginning of Appendix A.
- 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.
- Communicate any changes in *ASCA Recognition* status to affected testing laboratories.
- When notified by FDA of a testing laboratory's full or partial withdrawal from the ASCA Program, remove any scope of *ASCA Accreditation* from applicable documentation.
- Commit to minimize and address the accreditation of fraudulent testing laboratories.

- Notify FDA of investigations of potential fraud with adequate information and documentation for FDA to determine if suspension or withdrawal of the testing laboratory's *ASCA Accreditation* is appropriate.
- Maintain due diligence to minimize accreditation of testing laboratories that misleadingly or fraudulently represent competencies, for instance by conducting searches on publicly available information and investigating complaints filed by stakeholders.

- Commit that all relevant FDA training will be completed by appropriate individuals prior to providing any accreditation to testing laboratories under the ASCA Program and maintain up-to-date records of all ASCA training.
  - Notify FDA of new personnel who need FDA training. Commit to not assign personnel in ASCA-related activities until training is complete.
  - Commit to maintaining competence and capacity for the requested scope of *ASCA Recognition*.
- Establish and maintain appropriate communication with FDA. An accreditation body should not hesitate to contact FDA regarding the ASCA Program. FDA expects that appropriate communication includes the following:
  - Notification to FDA within five calendar days via written notification of any changes that may impact the accreditation body's participation (e.g., change to scope of signatory status to ILAC MRA)
  - Notification to FDA within five calendar days via written notification of any changes that may impact the participation of any of the testing laboratories that the accreditation body has accredited. The relevant testing laboratory also should be included in this notification.
  - 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 Program activities:
    - complaint handling report, including number of complaints received, a short description of each complaint, investigation of the complaints, conclusion, and any corrective actions;
    - total number and list of testing laboratories the accreditation body has accredited, including dates of accreditation, names of the assessors, upcoming assessments and/or reassessments;
    - number and description of non-conformities the accreditation body has observed during accreditation or auditing of testing laboratories, including names of the testing laboratories, description of corrective actions and resolution of non-conformities;
    - number of suspensions issued by the accreditation body for testing laboratories;

1542 ▪ training records for all FDA training; and
1543 ▪ results of the accreditation body's management reviews.

1544 • Establish and maintain policies and procedures that incorporate feedback from FDA.

1545 • FDA may suspend or withdraw *ASCA Recognition* at any time, as warranted.

1546 • Confirm, to the best of your knowledge, all information submitted to FDA is truthful and
1547 accurate and that no material fact has been omitted.

1548

1549

Appendix B: Application for ASCA Accreditation

An application from a testing laboratory seeking *ASCA Accreditation* should 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. All information in the application should be provided in English. If the documents are not originally written in English, the testing laboratory must provide the following:

- native language documents,
- certified translation to English (refer to ISO 17100, ISO/IEC 17050-2, and ASTM F2575 for additional information), and
- details of the document control process for native language document approval and related release of the certified document.

A. Administrative Information

- organization name and address;
- designated point of contact: first and last name, title, phone number, email address;
- alternate designated point of contact: first and last name, title, phone number, email address; and
- planned assessment schedule per the testing laboratory's established accreditation cycle (with target dates of next assessment, when possible).

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 Program (more than one may be chosen).

C. Information in Support of Competence

Information demonstrating ability to participate in the ASCA Program should include the following:

- Accreditation is from an ASCA-recognized accreditation body, including the ASCA-recognized accreditation body's ASCA Identification Number and current status.
- Proof of accreditation under ISO/IEC 17025 and to the relevant standards and test methods in the ASCA Program.
- The scope of *ASCA Recognition* for the accreditation body, which must include the scope for which they accredited the testing laboratory.
- The proposed scope of *ASCA Accreditation* provided by the ASCA-recognized accreditation body to the testing laboratory, which must match the testing laboratory's requested scope of *ASCA Accreditation*.
- A copy of any relevant ASCA test-related documents (e.g., test method SOPs, protocol templates, test report templates, work instructions, general SOPs that address ASCA

Program specifications, data collection worksheets, training information) applicable to any testing of FDA-recognized consensus standards and test methods included in the requested scope of *ASCA Accreditation.*[54]

D. Renewal and Updates to the Scope of ASCA Accreditation

For renewal notifications to FDA, the ASCA-accredited testing laboratory should provide a copy of the renewed scope of *ASCA Accreditation* from their ASCA-recognized accreditation body. The testing laboratory should explicitly state if there are any changes to the testing laboratory's administrative information and/or if the testing laboratory is applying for an updated scope of *ASCA Accreditation*.

For additions to the scope of *ASCA Accreditation*, testing laboratories should follow the initial application process described in Appendix B and provide the information necessary for the new standards and testing methods (more than one may be included). For removals from the scope of A*SCA Recognition*, a notification to FDA is required, along with a brief rationale. For detailed information related to updates to the scope of *ASCA Accreditation*, see Section XI.C. of this guidance. In addition to the contents outlined above, FDA recommends that these renewal notifications or updates to the scope of *ASCA Accreditation* 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

E. Signed Agreement

The signed agreement is an agreement executed by the testing laboratory. It includes confirmation that the testing laboratory has read, understood, and agrees to adhere to the following for its ASCA Program-related activities:

- Operate in accordance with generally accepted professional and ethical business practices.
- 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.
- Maintain status of accreditation by an ASCA-recognized accreditation body. If accreditation by ASCA-recognized accreditation body is suspended or withdrawn, *ASCA Accreditation* will also be suspended or withdrawn.

---

[54] Please review the ASCA website for more information. For example, FDA generally only conducts review of SOPs and any relevant ASCA test-related documents in the initial application for *ASCA Accreditation*. After the initial *ASCA Accreditation*, FDA might rely on the accreditation renewal conducted by the ASCA-recognized accreditation body.

- Confirm that the certificate with the scope of included standard(s) and/or testing method(s) provided by the ASCA-recognized accreditation body is accurate to the requested scope of *ASCA Accreditation*.
- Abide by the ASCA Program specifications to achieve and maintain status as an ASCA-accredited testing laboratory.
- Follow the guidelines and processes detailed in in the ASCA Program guidance documents regarding which FDA-recognized consensus standards and test methods to use when conducting testing under the ASCA Program.
- Maintain document control and ensure that the testing laboratory's ASCA documentation provided to an ASCA-recognized accreditation body is consistent with ASCA documentation provided to the FDA.
- Provide all ASCA documentation (e.g., complaint logs, issue tracking, test procedures) to FDA in a timely manner upon request.
- Provide all ASCA documentation as outlined in Appendix B Section C (Information in Support of Competence) to FDA in a timely matter upon request.
- Maintain all ASCA documentation in a clear, complete, and detailed manner, such that a trained individual could follow them.
- Produce all ASCA documentation in English as described above.
- Allow FDA to conduct audits upon request. Audits may include observations of testing activities and documentation review.
- Allow FDA to include the testing laboratory's ASCA-recognized accreditation body in communications requesting any additional information, granting or denying ASCA Accreditation. Communicate any changes in scope of *ASCA Accreditation* or status within ASCA Program to the testing laboratory's ASCA-recognized accreditation body.
- Establish and maintain appropriate communication with FDA. A testing laboratory should not hesitate to contact FDA regarding the ASCA Program. FDA expects that appropriate communication includes the following at a minimum:
    - Written notification to FDA and the accreditation body within five calendar days of any changes that may impact the testing laboratory's participation.
    - Attend 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 Program.
- Ensure that proprietary information is protected per client agreements.

- Ensure ASCA summary test report(s) include the elements in the ASCA Program guidances.
- Provide all information listed in the relevant ASCA Program specifications, including ASCA summary test report(s) and complete testing reports to the device manufacturer.
- Attest that the laboratory has not conducted fraud or any activities that impact data integrity. .
- Acknowledge that FDA may suspend or withdraw *ASCA Accreditation* at any time, as warranted.
- C, to the best of your knowledge, all information submitted to FDA is truthful and accurate and that no material fact has been omitted.

Appendix C: ASCA Content for Premarket Submission

The ASCA Program tailors the contents of an ASCA DOC and supplemental documentation. A premarket submission with ASCA documentation should include the following elements:

A. Cover Letter

The cover letter should include:

- 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), and
- FDA-recognized consensus standard and test methods used during testing and a statement that they are within the testing laboratory's scope of *ASCA Accreditation.*

Note: if the testing laboratory's *ASCA Accreditation* was suspended or withdrawn at the time of testing, an ASCA DOC may not be submitted for the suspended or withdrawn FDA-recognized consensus standards and test methods. However, the submitter may submit a DOC as outlined in FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

B. Declarations of Conformity for the ASCA Program (ASCA DOC)

The content of an ASCA DOC expands on the content of a DOC described in FDA's guidance entitled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.

Submitters should include the content detailed in the example ASCA DOCs in their premarket submission. The example ASCA DOCs can be found in the ASCA Program guidances.[55]

C. Supplemental Documentation Supporting ASCA DOC (i.e., ASCA Summary Test Reports)

The submitter should include ASCA summary test report(s) associated with their ASCA testing in the premarket submission to support their ASCA DOC. The ASCA-accredited testing laboratory provides all information listed in the relevant ASCA Program specifications, including ASCA summary test report(s) to the device manufacturer. The unadulterated ASCA summary test report(s) should be included in the premarket submission as provided by the ASCA-accredited testing laboratory (i.e., with no changes, additions, and/or deletions).

The ASCA Program specifications detailed in the ASCA Program guidances provide recommendations for supplemental documentation that may be needed for testing conducted by

[55] *See* https://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca

an ASCA-accredited testing laboratory (including the expected contents of ASCA summary test report(s).

Appendix D: "Proposed Scope of ASCA Accreditation" Example and Considerations

Note: This example is intended to illustrate the minimum information that should be documented by an ASCA-recognized accreditation body following a favorable assessment of ISO/IEC 17025 and the additional ASCA Program specifications.

The example separates the scope of accreditation by standards family.

Basic Safety and Essential Performance

FDA Recognition Number	Standard Developing Organization and Designation Number	Test Method & Procedure	Exclusions
19-46	ANSI AAMI ES60601-1	All test methods	**Excluding subclauses 9.5.2, 10.1, 11.4, and Annex G
19-36	IEC 60601-1-2	All test methods	
3-123	IEC 80601-2-30	All test methods	Excluding subclauses 211.8.3.1
…	…	…	…

Biocompatibility

FDA Recognition Number	Standard Developing Organization and Designation Number	Test Method & Procedure	Exclusions
2-248	ISO 10993-4	Direct and Indirect Hemolysis [SOP XXX]	N/A
2-250	ASTM F756-17		
2-191	ISO 10993-12	Sample preparation and reference materials [SOP XXX]	N/A
…	…	…	…

**Note: Exclusions listed for ANSI AAMI ES60601-1 also apply to other collaterals and particulars in the 60601/80601 family of standards except where otherwise stated.

A. Considerations for Scope of ASCA Accreditation

Accreditation bodies and testing laboratories should consider the following when documenting the scope of *ASCA Accreditation* to be included in a testing laboratory's application to the ASCA Program.

Before completing the assessment by the ASCA-recognized accreditation body, the accreditation body and testing laboratory should ensure that all listed FDA-recognized consensus standards and test methods are included in the ASCA Program by checking the FDA-Recognized Consensus Standards Database (note that individual test methods are contained within standards). The accreditation body should not list any FDA-recognized consensus standards or test methods in the scope of ASCA *Accreditation* that are not included in the ASCA Program.

The FDA Recognition Numbers from the FDA-Recognized Consensus Standards Database should be included to identify the specific versions of the ASCA standards included in the scope of *ASCA Accreditation*. Older versions of standards in the FDA database may have a transition date listed on the Supplementary Information Sheet (SIS) which denotes the date after which the standard version will be withdrawn from FDA recognition. These standards should be removed in subsequent assessments or reassessments from the scope of *ASCA Accreditation* following the transition period for the applicable standard.

When multiple versions of the same FDA-recognized consensus standard are added to a scope of *ASCA Accreditation*, the standards should be listed with each version as separate line items including the FDA Recognition Number for each version. Each version of a standard has its own unique FDA Recognition Number.

Different families of FDA-recognized consensus standards should be grouped together and explicitly separated in a scope of *ASCA Accreditation* (i.e., basic safety and essential performance standards being separated from biocompatibility test methods and associated standards). The example above shows a separate table for each family.

Exclusions listed for any FDA-recognized consensus standards should be listed by clause, subclause, or annex.

Exclusions may be listed in a separate table, column, or sequentially, but should always cite the specific clause, subclause, or annex.

If excluded clauses and/or subclauses from one standard are referenced throughout a family of standards (i.e., clauses/subclauses in ANSI AAMI ES60601-1), these excluded clauses and/or subclauses should be noted to be applicable throughout the scope of accreditation (e.g., other collaterals and particulars in the 60601/80601 family). In the example above, this is achieved by adding a footnote to the scope of accreditation clarifying that the excluded clauses in 60601-1 also apply to the applicable collaterals and particulars in this family of standards.