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Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Program

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Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.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draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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, 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 Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment – Standards Specific Information for the Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program, 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

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See additional PRA statement in Section VII of this guidance

Preface

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Draft Guidance for Industry, Accreditation Bodies, Testing Laboratories, and Food and Drug Administration Staff

I. Introduction

This guidance provides information regarding how basic safety and essential performance standards are incorporated into the Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Program). The ASCA Program is described in FDA's guidance on The Accreditation Scheme for Conformity Assessment (ASCA) Program.

For the edition of FDA-recognized consensus standard(s) included in the ASCA Program, see the FDA Recognized Consensus Standards Database. For more information regarding use of FDA-recognized consensus standards in regulatory submissions, please refer to FDA's guidances entitled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices, Safety and Performance Based Pathway, and Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research.

FDA's 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. Scope

This guidance includes the following:

- the ASCA Program specifications for the FDA-recognized consensus standards and test methods for basic safety and essential performance;
- assessment and accreditation of Testing Laboratories by ASCA-recognized Accreditation Bodies; and
- the recommended premarket submission contents specific to FDA-recognized consensus standards and test methods for basic safety and essential performance when testing is conducted by an ASCA-accredited testing laboratory.

FDA guidance The Accreditation Scheme for Conformity Assessment (ASCA) Program describes how accreditation bodies, testing laboratories, device manufacturers, and FDA staff participate in the ASCA Program as well as how FDA-recognized consensus standards and test methods are selected and how Program specifications are developed.

III. FDA-Recognized Consensus Standards in the ASCA Program for Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

Evaluation of safety is critical for electrically powered medical devices. The IEC 60601/80601[1] series of standards applies to devices used in patient care settings, while the IEC 61010 series applies to devices used in laboratory settings. FDA encourages the use of these standards to support device safety in the majority of premarket submissions for electrically powered medical devices. These standards take an "all-hazards approach" to device safety, encompassing electrical, mechanical, and radiation hazards, among others, in addition to hazards posed by the environment of use. Besides addressing the wide range of generic safety requirements, the IEC 60601/80601 and IEC 61010 series include close to 100 "particular standards" with safety requirements for specific types of devices, such as clinical thermometers, infusion pumps, infant incubators, and laboratory centrifuges.

The FDA Recognized Consensus Standards Database lists all FDA-recognized consensus standards, including those included in the ASCA Program for basic safety and essential performance of medical devices and laboratory equipment (note that individual test methods are contained within standards). Any activities carried out by the testing laboratory under its scope of *ASCA Accreditation* to assess the conformity of a product to one or more of these standards is within the scope of the ASCA Program. The extent of FDA recognition (complete or partial) is provided in the Supplemental Information Sheet (SIS) for each standard included in the ASCA Program listed in the FDA Recognized Consensus Standards Database. The SIS provides additional information to consider when using FDA-recognized consensus standards , such as relevant guidance documents that provide clarity on FDA recommendations for testing to support premarket submissions.

IV. Accreditation and Assessment of Testing Laboratories

A. Scope of Assessments

Clause 7 of ISO/IEC 17011: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies* (hereafter referred to as "ISO/IEC 17011") describes processes by which accreditation bodies assess testing laboratories. In order to maintain conformance to ISO/IEC 17011, an accreditation body assesses a sample of the scope of accreditation of its accredited testing laboratories at least every two years.[2] An accreditation body also performs a reassessment of its accredited testing laboratories before

[1] In this document, the reference to the IEC 60601/80601 series of standards includes the ANSI/AAMI ES 60601-1, the IEC and US adopted collaterals [6060-1-xx], the IEC 60601-2-xx particulars, and the IEC or ISO 80601-2-xx particulars.

[2] *See* 7.9.3 of ISO/IEC 17011: 2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*.

the end of the accreditation cycle that confirms the competence of each testing laboratory for all the requirements of the consensus standards within the laboratory's scope of accreditation.[3] There are no additional expectations for assessments under the ASCA Program for basic safety and essential performance standards. That is, in the ASCA Program, ASCA-recognized accreditation bodies may assess a sample of the basic safety and essential performance standards to ensure competence across the testing laboratory's entire scope of *ASCA Accreditation*.

B. ASCA Program Specifications for Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

The ASCA Program specifications in this section provide expectations for the accreditation of testing laboratories for basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment under the ASCA Program. ASCA-recognized accreditation bodies, following the processes of ISO/IEC 17011, accredit testing laboratories to ISO/IEC 17025:2017: *General requirements for the competence of testing and calibration laboratories* (hereafter referred to as "ISO/IEC 17025") as well as to the ASCA Program specifications identified in this section.Throughout the ASCA Program specifications below, the term "will" before each action for testing laboratories is used to convey that they they are able to provide supportive documentation or information demonstrating competence to each of the ASCA Program specifications below when undergoing assessments by ASCA -recognized accrediting bodies. ASCA-recognized accreditation bodies will assess the laboratories to the specifications to ensure ASCA Program specifications are met.

In addition, all testing should be conducted considering the recommendations of relevant FDA guidance documents (*refer to Section III. of this guidance*). For readability and ease of reference, the numbering and nomenclature (including the term "requirements")[4] below correspond to the numbering and nomenclature of clauses/subclauses in ISO/IEC 17025.

ISO/IEC 17025 Clause 4 "General requirements"

For the purposes of the ASCA Program, testing laboratories inspect the device manufacturer's risk management file to the extent necessary to assess compliance with the expectations of IEC 60601/80601 or IEC 61010. The testing laboratories do not make judgments concerning the adequacy of the device manufacturer's risk management process. Nor do they make judgments concerning the acceptability of risk or the adequacy of the device manufacturer's decisions concerning risk. Each time a clause or subclause of IEC 60601/80601 or IEC 61010 calls for inspection of the risk management policy, plan, or

[3] *See* 7.9.4 of ISO/IEC 17011: 2017: *Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies*.

[4] Some definitions within FDA-recognized consensus standards refer to 'requirements.' FDA's references to them for the ASCA Program do not make them legal or regulatory requirements unless specifically identified as such.

records (i.e., the risk management file), the testing laboratory is to check to see if a related IEC 60601/80601 or IEC 61010 expectation has been complied with.

4.1 Impartiality

If any services, such as consulting, design, or research, are offered by the testing laboratory, it will have a policy and procedure for maintaining impartiality through separation of those services from its testing activities.

A device manufacturer's internal testing laboratory will have policies and procedures that specifically ensure and protect the impartiality of the laboratory to test or otherwise evaluate devices manufactured by the laboratory's parent organization and, if applicable, other device manufacturers without regard to the impact of the test results on the parent organization's business interests.

4.2 Confidentiality

There are no additional specifications above those set forth in ISO/IEC 17025.

ISO/IEC 17025 Clause 5 "Structural requirements"

There are no additional specifications above those set forth in ISO/IEC 17025.

ISO/IEC 17025 Clause 6 "Resource requirements"

6.1 General

There are no additional specifications above those set forth in ISO/IEC 17025.

6.2 Personnel

a) The testing laboratory will maintain technical personnel who are qualified and competent to:
   - Establish and perform the appropriate test methods required for the standard.
   - Understand and apply the specifications and underlying rationale (including such concepts as basic safety and essential performance).
   - Understand other normative references in the relevant standards forming part of the requested scope of accreditation.
   - Assure the suitability of means used to confirm the basic safety and essential performance of the medical device under test.

b) The testing laboratory will:
   - Document and maintain a program for the initial and ongoing training of technical personnel, including procedures for applying new/updated test methods and performing required tests.

- Provide ongoing training of technical personnel at specified intervals or when test standards or methods are updated or developed, as well as when responsibilities have changed.
- Conduct training through appropriate training mechanisms, such as on-the-job training or formal classroom training.
- Document and maintain records of training for technical personnel.

c) The testing laboratory will maintain job descriptions that specify and document the responsibilities and required competencies of managerial, technical, and key support personnel involved in requested scope of accreditation.

6.3 Facilities and environmental conditions

There are no additional specifications to those set forth in ISO/IEC 17025.

6.4 Equipment

a) The testing laboratory will ensure that all equipment used for testing and evaluating devices is available and in proper working order for the requested scope of accreditation.

b) The testing laboratory will ensure that its procedures specify the steps for establishing calibration intervals for each type or item of equipment, and specify criteria, steps, and approvals for extending the calibration interval of an instrument.

c) The testing laboratory will ensure that its procedures address adding, deleting, modifying, or maintaining information in equipment records in an accurate and timely manner, and specify the personnel responsible for these tasks.

d) The testing laboratory will have procedures to examine the effects of defective or out-of-tolerance equipment on calibrations and tests. The testing laboratory further agrees that procedures will identify the personnel responsible for such examinations, specify their responsibilities, and provide the steps for the examination, including:
- Determining whether the effects are unacceptable (including the accept/reject criteria);
- Identifying the devices affected;
- Analyzing the particular tests impacted for these devices; and determining whether retesting is required;
- Preparing a report of the examination;
- Notifying customers when retesting is required; and
- Specifying the steps to follow to perform the retesting.

6.5 Metrological traceability

There are no additional specifications to those set forth in ISO/IEC 17025.

6.6 Externally provided products and services

There are no additional specifications to those set forth in ISO/IEC 17025.

ISO/IEC 17025 Clause 7 "Process requirements"

7.1 Review of requests, tenders, and contracts

a) The testing laboratory will have contracts with customers that require the customer to:
   - Identify those tests and test results that are intended to be used to support premarket submissions to the FDA;
   - Identify special test conditions and additions or modifications to test methods and/or acceptance criteria as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4; and
   - Indicate that per the risk management requirements of IEC 60601/80601 and IEC 61010 the customer maintains responsibility for specifying and documenting acceptance criteria.

7.2 Selection, verification and validation of methods

a) The testing laboratory agrees that its management system will include procedures governing the development, maintenance, and use of test procedures (including associated records in paper or electronic format such as test data forms and checklists). The testing laboratory further agrees that these management system procedures will include steps for:
   - Ensuring that test procedures are documented and reviewed prior to use;
   - Identifying the personnel responsible for developing, reviewing, and maintaining test procedures;
   - Ensuring that new and revised test procedures are reviewed by personnel who are competent and trained in the applicable standard(s); and
   - Specifying the criteria for review.

b) The testing laboratory agrees that test procedures and project-specific test plans will include or specify, as appropriate, the following information:
   - Unique identification of the test procedure or plan, including title, document number, revision, and effective date;
   - Specific test equipment to use or the salient performance characteristics required of the equipment to be used;
   - Warnings/caution statements to alert the operators of potential hazards;
   - Normal and any unusual ambient conditions (including tolerances) for tests;
   - Test data to be obtained and recorded;
   - Objective acceptance criteria for results including the essential performance required to be maintained;
   - Testing techniques required to ensure consistent results;
   - Instructions on equipment operation and on handling and preparation of test samples (including instructions on multiple sample marking, if applicable); and

- The methods to be used to assess or monitor the performance of the test sample.

c) The testing laboratory will ensure that relevant contextual information from the intended use of the device's essential performance specifications, including any metrological stability, are reflected in the relevant test procedure or project-specific test plan.

d) The testing laboratory will ensure that each test procedure adequately addresses all the applicable requirements of the standard for the equipment under test.

e) The testing laboratory will give preference to using test methods in the requested scope of accreditation. Modified test methods as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4 may be used within the ASCA Program as long as details of the rationale for the modification, test method, and results are provided.

Note: Recommendations for how to report the modified test method can be found in FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

f) The testing laboratory will include relevant sections of the test report in the ASCA Summary Test Report as necessary to explain any testing to address risks that are different or in addition to those found in the FDA-recognized consensus standard.

g) Where a clause or subclause of the FDA-recognized consensus standard requires inspection of the risk management file to obtain objective evidence, the testing laboratory agrees, at a minimum, to include pass/fail criteria in the inspection procedure and record the list of documents examined during the inspection in the testing laboratory's records.

7.3 Sampling

There are no additional specifications to those set forth in ISO/IEC 17025.

7.4 Handling of test or calibration items

There are no additional specifications to those set forth in ISO/IEC 17025.

7.5 Technical records

There are no additional specifications to those set forth in ISO/IEC 17025.

7.6 Evaluation of measurement uncertainty

There are no additional specifications to those set forth in ISO/IEC 17025.

7.7 Ensuring the validity of results

There are no additional specifications to those set forth in ISO/IEC 17025.

7.8 Reporting of results

a) The testing laboratory will have procedures to record and report all required information in ISO/IEC 17025 for each test conducted, including the following:
   - A statement of the extent to which the articles that were tested complied or did not comply with the specifications of each clause or subclause that were part of the standard tested;
   - A detailed description of the medical device tested including accessories, options, software versions, and configurations tested;
   - A test plan including reference to the device manufacturer's stated intended use and essential performance claims monitored during testing, any additional device-specific acceptance criteria (beyond those detailed in specific consensus standards) monitored during testing, reporting of the operational state(s) of the equipment during each test, as well as, if needed, any modified test methods as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4.

     Note: Recommendations for how to report the modified test methods can be found in the guidance document Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

   - The date and location of the test(s) performed;
   - The test report's unique identifier;
   - The signatures and printed names of the personnel responsible for the test results;
   - The test conditions, e.g., supply voltage, ambient temperature or humidity, when relevant to the test;
   - All of the applicable data required for equipment under test according to the standard;
   - A statement of the estimated uncertainty of measurement, when it is relevant to the validity or application of the test results, when a customer's instructions so requires or when the uncertainty affects compliance to a specification limit; and
   - A statement that test report meets ASCA Program specifications.

b) The testing laboratory agrees not to report test results in a "simplified way" as mentioned in subclause 7.8.1.3. Instead, the testing laboratory will report to the customer all information listed in subclauses 7.8.2 through 7.8.7 to the extent applicable (Subclause 7.8.4 is for calibration certificates and is not applicable when testing to the requirements of IEC 60601).

c) The testing laboratory will convey to the customer, in writing, all opinions and interpretations, including concerns about basic safety and essential performance such as:
   - Anomalous test results noted during any part of the testing that were not resolved to the testing laboratory's satisfaction; and
   - Concerns regarding any other aspect of conformity to the standard.

d) The testing laboratory will require that testing conducted by subcontractors will also comply with the above test report specifications, as applicable.

e) The testing laboratory agrees that an ASCA Summary Test Report including the content specified in this guidance will be submitted to the customer at the end of testing activities.

f) The testing laboratory will convey to the customer, in writing, all observations recorded during execution of a project test plan.

   Note. An observation is a device behavior that is not directly related to the pass/fail assessment being made at that time. An observation is recorded to make the customer aware of a device behavior that, while it might be out-of-scope for the test plan being executed, could indicate a potential quality issue. It is the customer's responsibility to assess this further.

7.9 Complaints

There are no additional specifications to those set forth in ISO/IEC 17025.

7.10 Nonconforming work

There are no additional specifications to those set forth in ISO/IEC 17025.

7.11 Control of data and information management

There are no additional specifications to those set forth in ISO/IEC 17025.

ISO/IEC 17025 Clause 8 "Management system requirements"

8.1 Options

Regardless of the option selected (i.e., ISO/I"aEC 17025 Option A or Option B), the testing laboratory will maintain an index of standard operating procedures (SOPs) and any relevant ASCA test-related documents (i.e., SOPs, test methods, work instructions, master protocols, test-specific protocols, data collection worksheets, training information, completed ASCA Summary Test Reports, and associated complete test reports) applicable to any of the relevant FDA-recognized consensus standards included in the ASCA Program for basic safety and essential performance of medical devices and laboratory equipment and the associated specifications detailed in this document.

C. Scope of Accreditation Issued by Accreditation Bodies Including ASCA Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment Standards

Once testing laboratories have been assessed by an ASCA-recognized accreditation body to ISO/IEC 17025 and the ASCA Program specifications identified in Section IV.B of this guidance, the accreditation body will issue a proposed scope of accreditation under the ASCA Program to the testing laboratory (see sample in Appendix D of ASCA Program guidance document). The testing laboratory should work with their accreditation body to ensure the applicable exclusions are accurately and clearly listed in the ASCA section of the scope of accreditation.

Appendix D of the ASCA Program guidance document highlights that the scope of *ASCA Accreditation A*should accurately capture when excluded clauses and/or subclauses of one standard may also apply to others within the scope of accreditation. For example, excluded subclauses of ANSI AAMI ES60601-1 (referred to as the "general standard" throughout the collaterals and particulars of the 60601/80601 series of standards) will also apply to the applicable collateral and particular standards in the scope of accreditation that reference the excluded clauses/subclauses (e.g., particulars can state "Clause 11 of the general standard applies," or "Clause 8 of the general standard applies except as follows…" adding an additional subclause or requirement that could be excluded if Clause 8 or subclause 8.x.x.x is excluded in ANSI AAMI ES60601-1). The testing laboratory should work with their accreditation body to ensure these types of exclusions are accurately and clearly captured in the conditional and any subsequently updated accreditation.

Testing laboratories should also consider the recommendations in Appendix B of this guidance, regarding representing exclusions to the scope of accreditation under the ASCA Program in the Clauses/Subclauses Tested section of the ASCA Summary Test Report.

V. Recommendations for Participation in the ASCA Program

A. Test plan development as a collaboration between device manufacturers and testing laboratories

As described in the draft ASCA Program guidance document, FDA recommends device manufacturers consult with ASCA-accredited testing laboratories when developing a comprehensive test plan for their device. FDA encourages a collaborative relationship between the device manufacturer and testing laboratory wherever possible. Such collaboration may help to ensure the appropriate selection and use of FDA-recognized consensus standards and test methods.

If the testing laboratory has questions or concerns associated with the device manufacturer's proposed test plan (e.g., essential performance(s), unclear acceptance criteria), they should discuss such concerns/questions with the device manufacturer, preferentially in advance of finalization of the test plan. If those concerns or questions remain unresolved, the testing laboratory should consider detailing the potential issues in the ASCA Summary Test Report (e.g., in the Concerns Identified section in the example provided in Appendix B of this guidance).

(1) Essential Performance

FDA recommends the device manufacturer specifies the essential performance(s) of their device. Additionally, testing laboratories should have expertise in the terminology, evaluation, and performance of the FDA-recognized consensus standards to assist a device manufacturer in understanding the concept of essential performance and how it might relate to their device, as appropriate.

We recommend that testing laboratories and device manufacturers consider the content of the AAMI consensus report CR500:2019, Basic Introduction to the IEC 60601 Series, which includes clarifications to help device manufacturers understand "essential performance."[5]

If a device manufacturer is unsure what constitutes the essential performance(s) of their device, FDA recommends submitting a Q-submission[6] prior to initiating testing to request formal feedback from the appropriate CDRH Office of Health Technology (OHT) or CBER Review Office for their future premarket submission. For information on presubmissions, please see the FDA guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

(2) Electromagnetic Compatibility (EMC)

For test plans that intend to use the current, FDA-recognized version of the IEC 60601-1-2 collateral standard, we recommend that device manufacturers and testing laboratories consider the FDA guidance entitled "Electromagnetic Compatibility (EMC) of Medical Devices." This guidance provides recommendations that might impact test plans including current, FDA-recognized versions of IEC 60601-1-2.

[5] For additional information about a regulatory perspective on "essential performance," we recommend the AAMI consensus report entitled CR500:2019 Basic Introduction to the IEC 60601 Series.

[6] For more information, please see the FDA guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program."

B. Testing laboratory subcontracting within the Basic Safety and Essential Performance standards of the ASCA Program

ASCA-accredited testing laboratories may subcontract testing, as allowed in ISO/IEC 17025 and the ASCA specifications listed above, as long as that the outscourcedtesting is included in the ASCA-accredited testing laboratory's scope of *ASCA Accreditation* (i.e., the testing laboratory issuing the ASCA Summary Test Report). Ultimately, the ASCA-accredited testing laboratory is responsible for the data, testing methodology, and results presented in the test reports provided to the device manufacturer.

C. ASCA Summary Test Reports

Appendix B of this guidance contains an example ASCA Summary Test Report that includes the information needed to support premarket review.

Testing laboratories participating in the ASCA Program may devise their own ASCA Summary Test Report formats; however, the requested information outlined in each section of Appendix B should be addressed.

FDA recommends device manufacturers review the example in Appendix B to familiarize themselves with the content of an ASCA Summary Test Report.

(1) Concerns Identified by the Testing Laboratory

If the testing laboratory identifies any concerns with the evaluation of the device, they should communicate these concerns to the device manufacturer and work to resolve them prior to the issuance of the ASCA Summary Test Report. In situations where concerns remain unresolved, the testing laboratory should detail the concerns in the ASCA Summary Test Report. For example, by using the "Concerns Identified" section included in the example ASCA Summary Test Report (*Refer to* Appendix B of this guidance).

Examples of potential concerns that the testing laboratory may identify include, but are not limited to, concerns with the:

- test plan (e.g., unclear pass/fail criteria or essential performance(s),
- risk analysis (e.g., underestimation of risk level, unidentified risks related to the device) based on the test lab's experience with specific device types, or
- presence of unique device features or characteristics that may raise safety concerns which may not be sufficiently assessed via the device manufacturer's test plan.

FDA recommends device manufacturers address any concerns identified in the ASCA Summary Test Report in their declaration of conformity for the ASCA Program (ASCA DOC) and reference relevant sections of their premarket submission containing supporting documentation which may further mitigate any concerns identified by the testing laboratory.

D. Devices intended to record, display, and/or analyze physiological data

Devices that are intended to record, display, and/or analyze physiological data (e.g., electrocardiographs) have inherent clinical components/performances/uses that cannot be directly evaluated by a testing laboratory. In testing these types of devices to FDA-recognized consensus standards, the performance of the device is typically monitored and evaluated for any observations or degradations which impact the intended performance (e.g., assessment of the performance of devices exposed to electromagnetic disturbances).[7]

If observations or degradations related to the recording, display and/or analysis of data are noted for these device types, the test report should include a description of the observations or degradations alongside representative data demonstrating the observed behavior in the Observations and Degradations During Testing section of the ASCA Summary Test Report or as an attachment to the report.

VI. Premarket Submission Contents for FDA-Recognized Consensus Standards in the ASCA Program for Basic Safety and Essential Performance

FDA recommends that the following be included in any regulatory submission that reports basic safety and essential performance testing conducted by an ASCA-accredited testing laboratory.

A. Cover Letter

FDA recommendations for a cover letter for a premarket submission containing testing results from an ASCA-accredited testing laboratory are provided in FDA's draft guidance The Accreditation Scheme for Conformity Assessment (ASCA) Program.

B. ASCA Declaration of Conformity

Section IV.A. of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices recommends contents for a DOC to an FDA-recognized consensus standard. For basic safety and essential performance testing from an ASCA-accredited testing laboratory, the device manufacturers should include the following additional items in an ASCA DOC:

- Date(s) the testing was conducted.
- Location(s) where the testing was conducted.
- Confirmation that the FDA-recognized consensus standards used during testing were within the laboratory's scope of *ASCA Accreditation* and that such standards were not

[7] For more information, please see the FDA guidance entitled "Electromagnetic Compatibility (EMC) of Medical Devices" (https://www.fda.gov/regulatory-information/search-fda-guidance-documents/electromagnetic-compatibility-emc-medical-devices) and IEC TR 60601-4-2.

suspended from the scope of *ASCA Accreditation* at the time testing was conducted. If the relevant standard was impacted by a suspension of *ASCA Accreditation*, the ASCA DOC should include an explanation of how this suspension may or may not affect the testing results.

- Limitations on the validity of the ASCA DOC:
  - How the test article compares with the device provided in the premarket submission, including any modifications made during testing. If modifications were made during testing, it is helpful if the ASCA DOC states whether or not these modifications are included in the final finished device. FDA also recommends that the ASCA DOC include a rationale for why it was deemed appropriate to leverage any testing conducted before the modifications were made.
  - Details about how any concerns communicated by the test laboratory have been mitigated (see Section V.C.1. above).
  - Details about how any observations and/or degradations during testing were resolved.
  - If there is additional data or documentation that support any of the limitations on the validity of the ASCA DOC, FDA recommends that a reference identifying where to find this information be provided in the ASCA DOC.

An example ASCA DOC is provided in Appendix A of this guidance.

C. Supplemental Documentation

In lieu of submitting the full test report, FDA recommends that testing performed under the ASCA program be submitted using the recommended ASCA Summary Test Report format.[8] An example ASCA Summary Test Report is provided in Appendix B of this guidance. Note that the ASCA-accredited testing laboratory provides the ASCA Summary Test Report to the device manufacturer who then includes it with its own ASCA DOC in a premarket submission to FDA.

Under the ASCA Program, FDA generally will accept test results from ASCA-accredited testing laboratories when the standard and test methods are within the testing laboratory's scope of *ASCA Accreditation* at the time of testing. Examples of circumstances where FDA might request and review additional information relating to testing from an ASCA-accredited testing laboratory are described in the bulleted points of Section XIII.A of the ASCA Program guidance.

The ASCA Program processes and policies enhance confidence in testing results only when specific test methods and acceptance criteria are used. In cases where the standard permits

[8] An ASCA Summary Test Report is different from the test report summary described in FDA's guidance Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions.

539 modifications or additions to individual clauses or subclauses to ensure basic safety and
540 essential performance, FDA recommends the submitter include the test plan and procedure,
541 acceptance criteria, and results justifying the safety claim in its premarket submission. In
542 such cases, FDA recommends that the ASCA Summary Test Report include relevant
543 information about the testing that was performed. The following examples illustrate a few
544 situations where this additional documentation is appropriate:
545
546 • Where a test method specified in a clause or subclause of the standard was modified
547 based on specific characteristics and/or intended use of the device or its operating
548 conditions.
549 • Where the acceptance criteria specified in a clause or subclause was modified based
550 on the device manufacturer's risk management.
551 • Where clauses or subclauses in the IEC 60601/80601 and IEC 61010 series do not
552 provide specific test methods and acceptance criteria. For example, a clause or
553 subclause might indicate "compliance is checked by inspection of the risk
554 management file and functional tests, if necessary." In other cases, a clause or
555 subclause might provide for revision of the specific test methods and acceptance
556 criteria based on risk management.

VII. 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[9] 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).

[9] Rounded to the nearest whole number.

Appendix A: Example ASCA Declaration of Conformity (ASCA DOC) for Basic Safety and Essential Performance Standards in the ASCA Program

Note: This example is intended to illustrate elements expected in an ASCA DOC. The content of an ASCA DOC expands on the content of a DOC described in FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices.[10] *Submitters should include an ASCA DOC as part of their premarket submission when including ASCA testing (i.e., an ASCA Summary Test Report).*

Responsible Party

Name of entity responsible for DOC: _____

Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device (e.g., product code(s), device marketing name(s), model number(s), etc.).

Statement of Conformity

☐ The test results demonstrate that the device is in conformity with the standard(s) listed below[11]:

- Title of Standard(s):[12] *(e.g., ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.)*_____
- FDA Recognition #(s): *(e.g., 19-46)*
- Options Selected
  - ☐ Standard(s) included no options
  - ☐ Standard(s) included options

List of options selected in related standard(s) (e.g., subclause 5.3 permits modified test conditions if ambient temperature cannot be maintained). This section may reference the ASCA Summary Test Report provided as supplementary documentation.

- Testing Laboratory Name: *(e.g., Testing Laboratory ABC)*
- ASCA Testing Laboratory Identification Number(s): *(e.g., TL-01)*

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

[11] See section 514(c)(3)(A)(i) of the FD&C Act, cited in Section IV.A.(3)(f) of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Device.

[12] A device manufacturer may declare conformity to multiple standards evaluated by a test lab within the ASCA Program.

- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2023 – Sep 15, 2023)*
- *ASCA Accreditation* Status on the Date(s) of Testing:
  - ☐ Standard was not in testing laboratory's scope of *ASCA Accreditation*
  - ☐ Standard was in testing laboratory's scope of *ASCA Accreditation*;
    - ☐ *ASCA Accreditation* was not suspended
    - ☐ *ASCA Accreditation* was suspended

> *If ASCA Accreditation was suspended during the testing date(s), a description of reasons for suspension and their impact on testing results should be provided. 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.*
>
> ***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.*

- Supplemental Documentation *(Refer to Section VI.C. of this guidance for specific recommendations)*:
  - ☐ Supplemental documentation is not included
  - ☐ Supplemental documentation is included at the following location within the submission, and I have checked that there are no differences regarding protocol and data between the testing conducted and the supplemental documentation: *(e.g., IEC 60601-1-2 ASCA Summary Test Report located in Appendix A of this premarket submission)*_____

Limitations on Validity of DOC

Description of any limitation on the validity of the ASCA DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes) including a reference to the relevant locations of such information in the premarket submission. For testing from an ASCA-accredited test lab, this should include:

- *Information on how the test article compares with the device provided in this premarket submission including, any modifications made during testing for basic safety and essential performance and whether the modifications are included in the final, finished device.*
- *Information on how any concerns communicated by the test laboratory were resolved.*
- *Information on how any observations and/or degradations during testing were resolved.*
- *Information about how conformity was assessed for clauses or subclauses of the relevant standard(s) that were not evaluated by an ASCA-accredited testing laboratory, including detailed information about who performed such testing, the test methods used, and the test results*
- *Information on how the labeling requirements of the standard are met (e.g., reference to relevant section/pages of the user manual).*

Signature

Printed name: _____

Function within entity responsible for DOC: _____

_____

Signature Date

Appendix B: Example ASCA Summary Test Report for Basic Safety and Essential Performance Standards in the ASCA Program

Note: This example is intended to illustrate the supplemental documentation that should accompany the ASCA DOC as described in Appendix A. The ASCA Summary Test Report is provided by the testing laboratory to the device manufacturer.

Administrative Information

1. Testing Laboratory Name:
2. ASCA Testing Laboratory Identification Number:
3. Testing Location(s):
4. Testing Date(s):
5. Standard(s) evaluated:

FDA Recognition Number	Standard Designation Number	Tested conducted under the ASCA Program (Y/N)
e.g., 19-4	*e.g., ANSI AAMI ES60601-1*	*Y*
...	...	...

6. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☐ Standard was *NOT* in testing laboratory's scope of *ASCA Accreditation*[13]
   - ☐ Standard was in testing laboratory's scope of *ASCA Accreditation*
     - ☐ *ASCA Accreditation* was not suspended
     - ☐ *ASCA Accreditation* was suspended

If ASCA Accreditation was suspended during the Date(s) of testing, a description of reasons for suspension and their impact on testing results should be provided.

***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

[13] See FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices for information regarding supplemental documentation necessary to support FDA-recognized consensus standards that are not in a testing laboratory's scope of *ASCA Accreditation*.

Device Essential Performance Characteristics

Description of the device essential performance characteristics supplied by the device manufacturer to the testing laboratory (including reference to any relevant particular standards with essential performance specified) and that were included in the testing. List any differences (if any identified) between the essential performance identified by the standard and the essential performance considered during the test. For multiple standards and/or multiple tests, include the essential performance characteristics used for each.

Device Pass/Fail Criteria

Description of any Pass/Fail criteria specific to the device beyond the requirements specified in the standard(s) being evaluated. This should include a brief description for how these criteria were identified and monitored during the testing.

Pass/Fail criteria specific to the device should be clear and verifiable. Pass/Fail criteria might include device-specific criteria for clinical functions unrelated to identified essential performance.

Use Environment

- ☐ Home Healthcare Environment [IEC 60601-1-11]
- ☐ Professional Healthcare Facility Environment
- ☐ Magnetic Resonance (MR) Environment
- ☐ Commercial Aircraft Environment
- ☐ Emergency Medical Services Environment [IEC 60601-1-12]
- ☐ Special / Other Environment

Include any relevant details regarding the specified use environment here.

Clauses/Subclauses Tested

1. Clauses/Subclauses Deemed Applicable
   - ☐ All clauses/subclauses were deemed applicable.
   - ☐ The following clauses/subclauses were deemed not applicable.

List of all clauses and subclauses identified as not applicable (N/A) with a rationale for ***every*** *clause/subclause identified as N/A. This may be provided as an attachment to the Summary Test Report.*

If specific clauses/subclauses are excluded on the testing laboratory's scope of accreditation, they should be listed either as N/A in this section, if appropriate, or in the next section as a clause or subclause that was not tested.

2. Clauses/Subclauses Tested

☐ All applicable clauses/subclauses were tested

For clauses or subclauses allowing multiple test methods, list the specific clause or subclause and test method used with a brief rationale for the choice.

☐ The following applicable clauses/subclauses were not tested.

List of any applicable clauses or subclauses not tested. Rationales should also be provided to clarify why applicable clauses/subclauses were not tested.

If specific clauses or subclauses are determined to be applicable but are not within the testing laboratory's scope of accreditation (i.e., excluded in the scope of accreditation), then those clauses/subclauses should be listed here with a corresponding explanation.

3. Clauses/Subclauses with Failing Results

☐ No clauses or subclauses had failing results

☐ The following clauses/subclauses had failing results

List of any clauses and subclauses with failing results and a description of the failures.

Modification(s)[14] to Test Methods and/or Acceptance Criteria

☐ No test methods specified in the standard were modified

☐ No acceptance criteria specified in the standard were modified

☐ One or more test methods or acceptance criteria were modified

List of test methods and/or acceptance criteria that were modified. Appropriate supporting documents should be attached to this ASCA Summary Test Report including the rationale for the modification, test plan and procedure, acceptance criteria that were applied, scientific rationale for the acceptance criteria, and the test results.

Additional Testing Performed to Demonstrate Conformity with the Standard[15]

☐ No additional testing was performed other than that specified in the standard

☐ Additional testing was performed as specified by the device manufacturer to address a hazardous situation not specifically addressed by the standard

[14] Modification(s) include special test conditions and additions or modifications to test methods and/or acceptance criteria as permitted by IEC 60601-1 subclauses 4.2.3.2 and 4.5 and ISO/IEC 17025 subclause 7.2.1.4.

[15] For example, subclause 4.2 of ANSI/AAMI ES60601 indicates that hazards not specifically addressed in the ANSI/AAMI ES60601-1 are to be addressed in the risk management process.

Description of additional testing performed to address a hazardous situation not specifically addressed by the standard. Appropriate supporting documents are attached to this ASCA Summary Test Report including the test plan and procedure, acceptance criteria that were applied, and the test results.

Device Configuration(s) and Mode(s) of Operation

Description of how device was configured including modes of operation used during testing.

Observations and Degradations During Testing

☐ Observations and degradations were NOT found during testing

☐ Observations and degradations were found, but deemed acceptable based on the pass/fail criteria identified by the device manufacturer

Description of observations and degradations of concern to the testing laboratory but deemed acceptable. Examples include:

- *Instances of device showing unexpected behaviors (e.g., display of incorrect values, display of error messages, device or components needing to be restarted, if the device or components restart unexpectedly).*
    - *Representative bench data should be provided to visualize the unexpected behaviors observed affecting devices intended to record, display, and/or analyze physiological data*
- *Instances of device or components being unexpectedly damaged and needing replacement or other intervention to return to normal operation.*

This list should capture any unexpected events. As an example, an error message would be unexpected (and therefore would be listed) during EMC testing when a valid input is present; conversely, the same error message would be expected (and therefore would not be listed) during a test that feeds an out-of-range input to verify the function of input errors. Any unexpected behavior is reported even if acceptable per the pass/fail criteria. If the unexpected behavior is listed as possible in the labeling (e.g., "the device may restart unexpectedly"), it should still be reported here.

Modifications to Test Article(s) During Testing

☐ No modifications were made to the test articles during testing

☐ Modifications were made to the test articles during testing. Description of modification including their impact on prior test outcome(s) are provided below.

Description of modifications made to test articles during testing. Description of prior tests that were repeated based on modifications made or justification for not repeating prior tests.

Concerns Identified

☐ No concerns were identified.

☐ Concerns were communicated to the device manufacturer; see list below.

List and description of concerns communicated to the device manufacturer. *Concerns may include aspects that do not constitute a failure for the specific test conducted, but might have an impact on the safety and potential effectiveness of the device subject to the testing. Examples include, but are not limited to, concerns regarding the test plan (e.g., unclear pass/fail criteria or essential performance(s), disagreements regarding the evaluation of certain clauses or subclauses), inconsistencies in risk analysis (e.g., underestimation of risk level, unidentified risks related to the device) based on the test laboratory's experience with specific device types, presence of unique features/characteristics which may raise safety questions not addressed via the test plan.*

I confirm that:

☐ The above summary information includes all original and any retest data

☐ The above summary information is an accurate representation of the testing conducted

_____

Name: [TYPED NAME POSITION] Date