Effective September 19, 2023, the FDA is converting the Accreditation Scheme for Conformity Assessment program from a pilot to a permanent program. This transition is authorized by the Medical Device User Fee Amendments of 2022 (MDUFA V). This guidance was developed and issued prior to the enactment of MDUFA V. FDA is assessing how to revise this guidance to represent our current thinking on this topic, including the incorporation of best practices gained from the pilot phase of the Accreditation Scheme for Conformity Assessment program. For more information, please contact the ASCA Program at ASCA@fda.hhs.gov.

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Contains Nonbinding Recommendations

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

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

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For questions about this document regarding CDRH-regulated devices, contact the ASCA Pilot 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.

U.S. FOOD & DRUG ADMINISTRATION

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 VI of this guidance.

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Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration 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 FDA-2019-D-3805. Comments may not be acted upon by the Agency until the document is next revised or updated.

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 20011 and 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., WO71, Room 3128, Silver Spring, MD 20903, 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.

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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) Pilot Program

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

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

I. Introduction

This guidance provides information regarding how the basic safety and essential performance standards are incorporated into the Pilot Accreditation Scheme for Conformity Assessment Program (hereafter referred to as the ASCA Pilot). The ASCA Pilot is described in FDA's guidance The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.[1]

[1] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program

For the edition of the FDA-recognized consensus standard(s) included in the ASCA Pilot, see the FDA Recognized Consensus Standards Database.[2] For more information regarding use of consensus standards in regulatory submissions, please refer to FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices[3] and Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research.[4]

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:

- A list of the FDA-recognized consensus standards included in the ASCA Pilot for basic safety and essential performance;
- The program specifications for the FDA-recognized consensus standards in the ASCA Pilot for basic safety and essential performance; and
- The recommended premarket submission contents specific to FDA-recognized consensus standards 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) Pilot Program describes how accreditation bodies, testing laboratories, device manufacturers, and FDA staff participate in the ASCA Pilot as well as how FDA-recognized consensus standards and test methods are selected and how program specifications are developed.

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

[2] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm
[3] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices
[4] Available at Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation andhttps://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation Research

Evaluation of safety is critical for electrically powered medical devices. The IEC 60601/80601[5] series of standards applies to devices used in patient care settings, while the IEC 61010-1 series applies to devices used in laboratory settings. These standards are used in the majority of premarket submissions for electrically powered medical devices to support device safety. 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 eligible for inclusion in the ASCA Pilot for basic safety and essential performance of medical devices and laboratory equipment are listed below. 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 Pilot. The extent of FDA recognition (complete or partial) is provided in the Supplemental Information Sheet (SIS) for each standard listed in the FDA Recognized Consensus Standards Database.[6] 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.

- ANSI/AAMI ES60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.*
- IEC 61010-1 *Safety requirements for electrical equipment for measurement control and laboratory use - Part 1: General requirements.*
- IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.*
- IEC 60601-1-3 *Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment.*
- IEC 60601-1-6 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.*
- IEC 60601-1-8 *Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*

[5] 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, and the IEC or ISO 80601-2-xx particulars.
[6] Available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

- IEC 60601-1-10 *Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers.*
- IEC 60601-1-11 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*
- ANSI/AAMI HA60601-1-11 *Medical Electrical Equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical equipment and medical electrical systems used in the home healthcare environment.*
- IEC 60601-1-12 *Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment.*
- IEC 60601-2-1 *Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV.*
- IEC 60601-2-2 *Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.*
- IEC 60601-2-5 *Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment.*
- IEC 60601-2-6 *Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment.*
- IEC 60601-2-8 *Medical electrical equipment - Part 2-8: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV.*
- IEC 60601-2-10 *Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators.*
- IEC 60601-2-11 *Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment.*
- IEC 60601-2-16 *Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis haemodiafiltration and haemonfiltration equipment.*
- IEC 60601-2-17 *Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy after loading equipment.*
- IEC 60601-2-18 *Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment.*

- IEC 60601-2-19 *Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators.*
- IEC 60601-2-20 *Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators.*
- IEC 60601-2-21 *Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers.*
- IEC 60601-2-22 *Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical cosmetic therapeutic and diagnostic laser equipment.*
- IEC 60601-2-23 *Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment.*
- IEC 60601-2-25 *Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs.*
- IEC 60601-2-27 *Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.*
- IEC 60601-2-28 *Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis.*
- IEC 60601-2-29 *Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators.*
- IEC 60601-2-31 *Medical electrical equipment Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source.*
- IEC 60601-2-33 *Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis.*
- IEC 60601-2-34 *Medical electrical equipment - Part 2-34: Particular requirements for the basic safety including essential performance of invasive blood pressure monitoring equipment.*
- IEC 60601-2-36 *Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy.*
- IEC 60601-2-37 *Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.*
- IEC 60601-2-43 *Medical electrical equipment - Part 2-43: Particular requirements for the safety and essential performance of X-ray equipment for interventional procedures.*

- IEC 60601-2-44 *Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of x-ray equipment for computed tomography.*
- IEC 60601-2-45 *Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices.*
- IEC 60601-2-47 *Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.*
- IEC 60601-2-50 *Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment.*
- IEC 60601-2-52 *Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds.*
- IEC 60601-2-54 *Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy.*
- IEC 60601-2-57 *Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic diagnostic monitoring and cosmetic/aesthetic use.*
- IEC 60601-2-62 *Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment.*
- IEC 60601-2-63 *Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment.*
- IEC 60601-2-64 *Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment.*
- IEC 60601-2-65 *Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral-X-ray equipment.*
- IEC 60601-2-68 *Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators light ion beam therapy equipment and radionuclide beam therapy equipment.*
- IEC/TR IEC 60601-4-2 *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems.*
- ISO 80601-2-12 *Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators.*

- ISO 80601-2-13 *Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation.*
- IEC 80601-2-30 *Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.*
- IEC 80601-2-35 *Medical electrical equipment-Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets pads or mattresses and intended for heating in medical use.*
- ISO 80601-2-55 *Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.*
- ISO 80601-2-56 *Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.*
- IEC 80601-2-59 *Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening.*
- IEC 80601-2-60 *Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment.*
- ISO 80601-2-61 *Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment.*
- ISO 80601-2-69 *Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment.*
- ISO 80601-2-70 *Medical Electrical Equipment - Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnoea Breathing Therapy Equipment.*
- ISO 80601-2-72 *Medical electrical equipment - Part 2-72: Particular requirements for basic safely and essential performance of home healthcare environment ventilators for ventilator-dependent patients.*
- ISO 80601-2-74 *Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment.*
- IEC 80601-2-77 *Medical electrical equipment - Part 2-77: Particular requirements for the BASIC SAFETY and essential performance of ROBOTICALLY ASSISTED SURGICAL EQUIPMENT.*
- ISO 80601-2-79 *Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment.*
- ISO 80601-2-80 *Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency.*

IV. Accreditation and Assessment of Testing Laboratories by ASCA- Recognized Accreditation Bodies

A. Scope of Assessments

Section 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.[7] There are no additional expectations for assessments under the ASCA Pilot for basic safety and essential performance standards. That is, in the ASCA Pilot, ASCA-recognized accreditation bodies may assess a sample of the basic safety and essential performance standards in order 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 Pilot. 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 the ASCA program specifications identified in this section. 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")[8] below correspond to the numbering and nomenclature of clauses/subclauses in ISO/IEC 17025.

ISO/IEC 17025 Section 4 "General requirements"

For the purposes of the ASCA Pilot, testing laboratories inspect the 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 manufacturer's risk management process. Nor do they make judgments concerning the acceptability of risk or the adequacy of the manufacturer's decisions concerning risk. Each time a clause of IEC 60601/80601 or IEC 61010 calls for inspection of the risk management policy, plan, or records (i.e., the risk management file), it is to check to see if a related IEC 60601/80601 or IEC 61010 expectation has been complied with.

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

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

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 agrees to have policy 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 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 Section 5 "Structural requirements"

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

ISO/IEC 17025 Section 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 agrees to maintain technical personnel who are qualified and competent to:
   - Establish and carry out the appropriate test methods required for the standard.
   - Understand and apply the specifications and underlying rationale (including concepts of 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 agrees to:
   - 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 defined 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 job descriptions 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 agrees to ensure that all equipment used for testing and evaluating devices is available and in proper working order for requested scope of accreditation.

b) The testing laboratory agrees to 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 agrees to 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 agrees to 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 Section 7 "Process requirements"

7.1 Review of requests, tenders and contracts

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

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

e) The testing laboratory agrees to 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 Pilot as long as details of the 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.[9]

f) The testing laboratory agrees to 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 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 agrees to 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 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 manufacturer's stated intended use and essential performance claims monitored during testing, reporting of the operational state(s) of the equipment during each test, as well as, if needed, any

[9] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

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) undertaken;
- 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 applicant agrees to 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 agrees to convey in writing to the customer 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.
   - Concerns regarding any other aspect of conformity to the standard.

d) The testing laboratory agrees to 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 as specified in this guidance will be submitted to the client at the end of testing activities.

f) The testing laboratory agrees to convey in writing to the customer 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 which, 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 Section 8 "Management system requirements"

8.1 Options
Regardless of the option selected (i.e., ISO/IEC 17025 Option A or Option B), the testing laboratory agrees to maintain an index of standard operating procedures (SOPs) and any relevant ASCA test-related documents (e.g., SOPs, test methods, work instructions, master protocols, test-specific protocols, data collection worksheets, training information) applicable to any of the standards included in the ASCA Pilot for basic safety and essential performance of medical devices and laboratory equipment program specifications in this Appendix.

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

FDA recommends that the following be included in any regulatory submission that contains 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 guidance The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.

B. Declaration of Conformity

Section IV.A. of FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices[10] recommends contents for a DOC to an FDA-recognized consensus standard. For basic safety and essential performance testing from an ASCA-accredited testing laboratory, FDA recommends the device manufacturer include the following additional items in a 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 not subject to any temporary labeling constraints as a result of a suspension of *ASCA Accreditation* at the time testing was conducted. If the relevant standard was impacted by a suspension of *ASCA Accreditation*, the DOC should include an explanation of how this suspension may or may not affect the testing results.
- Limitations on the validity of the DOC:
  - How the test article compares with the device provided in this premarket submission (including any modifications made during testing)
  - How any concerns communicated by the test laboratory were resolved
  - How any observations and/or degradations during testing were resolved

An example DOC is provided in Appendix A of this guidance. This example provides one approach to how a single DOC might contain testing to FDA-recognized consensus standards included and not included in a testing laboratory's scope of *ASCA Accreditation*.

C. Supplemental Documentation

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

An ASCA summary test report is recommended for all testing conducted under the ASCA Pilot.[11] 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 DOC in a premarket submission to FDA.

During the ASCA Pilot, FDA generally will accept determinations from ASCA-accredited testing laboratories (i.e., test results) when the standard and test methods are within the testing laboratory's scope of *ASCA Accreditation* at the time of testing. Circumstances where FDA may 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 guidance titled The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program.

The ASCA Pilot processes and policies enhance confidence in testing results only when specific test methods and acceptance criteria are used. In cases where the standard permits modifications or additions to individual clauses to ensure basic safety and essential performance, FDA recommends that the premarket submission include the test plan and procedure, acceptance criteria, and results justifying the safety claim. In such cases, FDA recommends that the ASCA summary test report include relevant information about the testing that was performed. The following examples illustrate a few situations where this additional documentation is appropriate.

- Where a test method specified in a clause of the standard was modified based on specific characteristics and/or intended use of the device or its operating conditions.
- Where the acceptance criteria specified in a clause was modified based on the manufacturer's risk management.
- Where clauses in the IEC 60601/80601 and IEC 61010 series do not provide specific test methods and acceptance criteria. For example, a clause might indicate "compliance is checked by inspection of the risk management file and functional tests if necessary." In other cases, a clause may provide for revision of the specific test methods and acceptance criteria based on risk management.

VI. 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).

[11] 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 available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket

The time required to complete this information collection is estimated[12] 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).

[12] Rounded to the nearest whole number.

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

Note: This example is intended to illustrate elements of the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices *that the device manufacturer submits as part of their premarket submission.*

Responsible Party
Name of entity responsible for DOC: _____
Address of entity responsible for DOC: _____

Product/Device Identification

All identifying information for the product/device including (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[13]:

- Title of Standard: *(e.g., ANSI/AAMI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.)*
- FDA Recognition #: *(e.g., 19-4)*
- Options Selected
  - ☐ Standard included no options
  - ☐ Standard included options

List of options selected in standard (e.g., clause 5.3 permits modified test conditions if ambient temperature cannot be maintained). No information is needed in this section if testing is from an ASCA-accredited test lab; instead, 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 (as applicable): *(e.g., ASCA001)*
- Testing Location(s): *(e.g., 1234 Example Road, Silver Spring, MD 20993)*
- Testing Date(s): *(e.g., Sep 1, 2020 – Sep 15, 2020)*
- *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*;

[13] 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.

☐ *ASCA Accreditation* was not suspended
☐ *ASCA Accreditation* was suspended

Description of reasons for suspension and their impact on testing results, including date(s) of suspension.

- Supplemental Documentation *(Refer to Section V.C. of this guidance for specific recommendations)*:
  ☐ Supplementary documentation is not included
  ☐ Supplementary 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., Appendix A of this premarket submission)*

<Repeat for each standard in DOC>

Limitations on Validity of DOC

Description of any limitation on the validity of the DOC (e.g., how long the declaration is valid, what was tested, or concessions made about the testing outcomes). 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 can be found at the following location in this premarket submission: (e.g., Section V, pages 45-50)*
- *Information on how any concerns communicated by the test laboratory were resolved can be found at the following location in this premarket submission: (e.g., Appendix D of this premarket submission)*
- *Information on how any observations and/or degradations during testing were resolved can be found at the following location in this premarket submission: (e.g., Appendix D of this premarket submission)*
- *Information about how conformity was assessed for clauses 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: (e.g., identification, marking and documents (clauses 7.1-7.9) were evaluated by the manufacturer and are described in section X. of this premarket submission; all aspects of these clauses have been adequately addressed to support conformance to the standard)*
- *Information on how the labeling requirements of the standard are met can be found at the following location(s) in this premarket submission: (e.g., Section X. of this premarket submission)*

Signature

Printed name: _____
Function within entity responsible for DOC: _____

_____
Signature Date

GRZAN

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

Note: This example is intended to illustrate the supplemental documentation that should accompany the Declaration of Conformity per FDA's guidance Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices. *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. *ASCA Accreditation* Status on the Date(s) of Testing:
   - ☐ Standard was *NOT* in testing laboratory's scope of *ASCA Accreditation*[14]
   - ☐ Standard was in testing laboratory's scope of *ASCA Accreditation*
     - ☐ *ASCA Accreditation* was not suspended
     - ☐ *ASCA Accreditation* was suspended

Description of reasons for suspension and their impact on testing results.

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 which 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.

Use Environment

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

[14] 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*.

Include any relevant details regarding the specified use environment here.

Clauses Tested

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

List of and rationale for any clauses identified as not applicable

2. Clauses Tested
   - ☐ All clauses were tested
   - ☐ The following clauses were not tested

List of any clauses not tested.

3. Clauses with Failing Results
   - ☐ No clauses had failing results
   - ☐ The following clauses had failing results

List of any clauses with failing results. Descriptions of any failures.

Modification(s)[15] 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 test plan and procedure, acceptance criteria that were applied, and the test results.

Additional Testing Performed to Demonstrate Conformity with the Standard[16]

- ☐ No additional testing was performed other than that specified in the standard
- ☐ Additional testing was performed as specified by the manufacturer to address a hazardous situation not specifically addressed by the standard

[15] 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.

[16] For example, clause 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. Example include:

- *Instances of device showing unexpected behaviors (e.g., display of incorrect values, display of error messages, device or components need to be restarted, if the device or components restart unexpectedly).*
- *Instances of device or components being unexpectedly damaged and need replacement or other intervention to return to normal operation.*

This list should capture 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 would 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.

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