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# The ASCA Pilot: Streamlining Conformity Assessment in Device Submissions

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Center for Devices and Radiological Health

May 20, 2021

# Agenda

- Accreditation Scheme for Conformity Assessment (ASCA) Pilot update
- Premarket submission preparation with ASCA testing
- Biocompatibility update
- Basic safety and essential performance update



# What is the ASCA Pilot?

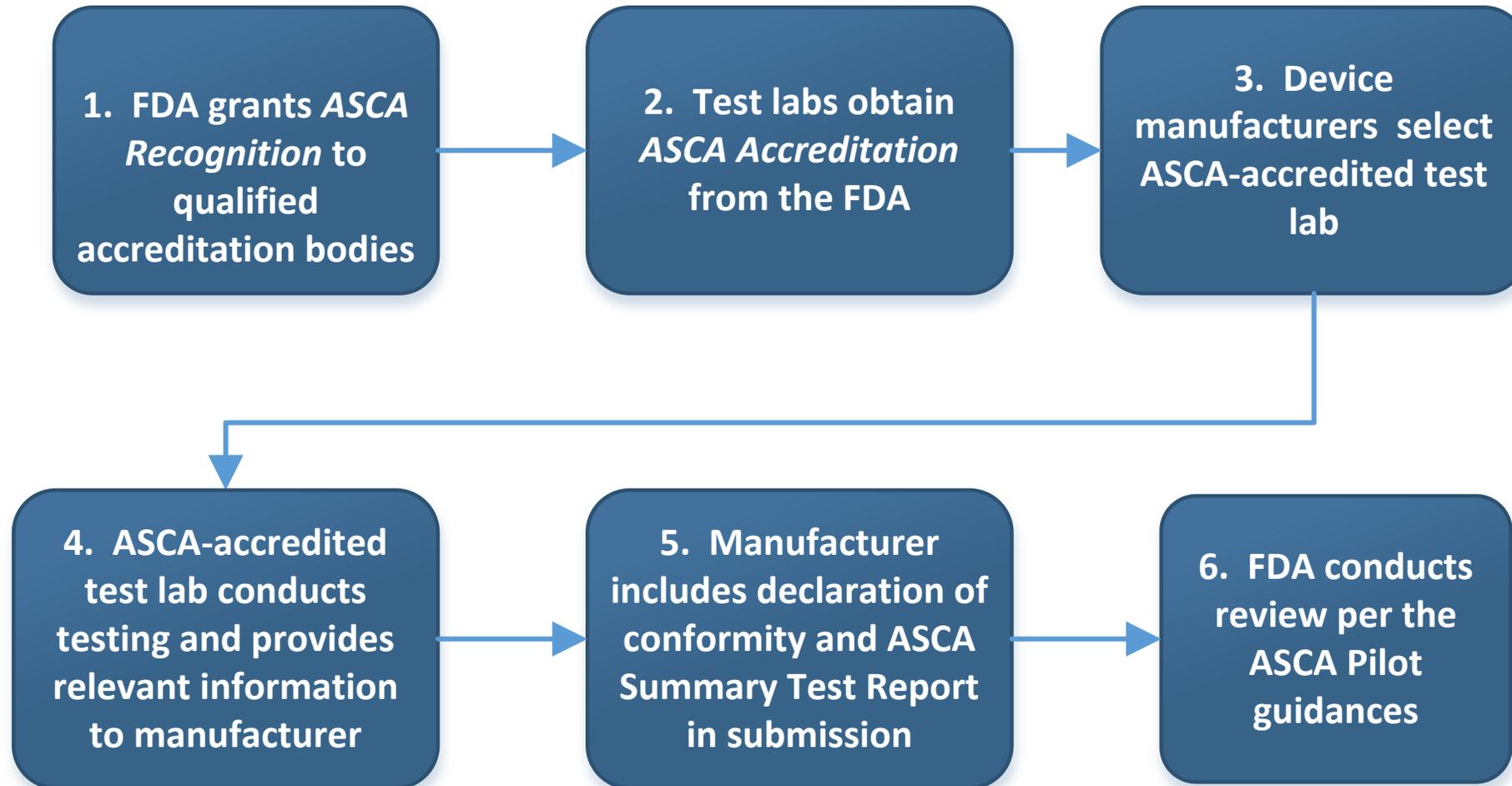
- Voluntary program
- Leverages a well-established international conformity assessment infrastructure
- Capitalizes on voluntary consensus standards in device development and review
- ‘Puts standards to work’ on both individual and international levels

# Why Use ASCA?

- Enhances the FDA's confidence in test methods and results
- Decreases need for additional information related to conformance with a standard
- Promotes consistency, predictability, and efficiency in medical device review
- Least burdensome approach to conformity assessment
- Patients have access to safe, effective, and high-quality medical devices

*ASCA Goal: Enhance the use of conformity assessment  
in premarket review*

# How ASCA Works



# ASCA Pilot Guidances



- **Program**
  - Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program
- **Standards-Specific**
  - Biocompatibility Testing of Medical Devices
  - Basic Safety and Essential Performance of Medical Electrical Equipment, Medical Electrical Systems, and Laboratory Medical Equipment

*Contains Nonbinding Recommendations*

**The Accreditation Scheme for Conformity Assessment (ASCA) Pilot Program**

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

Document issued on September 25, 2020.  
The draft of this document was issued on September 23, 2019.

For questions about this document regarding CDRH-regulated devices, contact the ASCA Pilot Program at [ASCA@fda.hhs.gov](mailto: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](mailto:ocod@fda.hhs.gov).

The OMB control number for this information collection is 0910-0889 (expires 06-30-2023).

*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**

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The OMB control number for this information collection is 0910-0889 (expires 06-30-2023).

# ASCA Progress

**Sept 2019: Draft  
guidance  
published**

**Sept 2020: Final  
guidances  
published**

**Nov 2020: Five  
accreditation  
bodies received  
*ASCA  
Recognition***

**Apr 2021: (53)  
test labs were  
granted *ASCA  
Accreditation*;  
manufacturers  
may engage**

# **Premarket Submission Preparation With ASCA Testing**

# Steps

1

Identify ASCA Pilot standards to be cited

2

Develop and agree on test plan with an ASCA-accredited test lab

3

Plan submission elements

4

Obtain results and Summary Test Report(s) from test lab

5

Prepare FDA submission

# 1. Identify ASCA Pilot Standards to be Cited

- Check ASCA web page on FDA.gov for ASCA standards
- Consult Recognized Consensus Standards database
  - Supplementary Information Sheet (SIS)
  - Standard's extent of recognition and edition

**\*\*\* When voluntary consensus standards are used, manufacturers are responsible for selecting and using FDA-recognized consensus standards and test methods appropriately \*\*\***

## 2. Develop and Agree on Test Plan with ASCA-accredited Test Lab

- Select an ASCA-accredited test lab
- Develop and agree on test plan
  - Note: Manufacturer is responsible for test plan(s)
  - Considerations:
    - Relevant FDA guidance documents
    - The FDA-recognized consensus standards
    - Testing outside a test lab's scope of *ASCA Accreditation*

# 3. Plan Submission Elements

## Cover Letter

- States that submission is for ASCA Pilot
- Name, location and IDs of test lab(s)
- The FDA-recognized consensus standard(s) and test methods used

## Declaration of Conformity (DOC)

- Manufacturer's responsibility
- *ASCA Accreditation* status for the test lab
- See suggested content in guidance

## ASCA Summary Test Report

- See standards-specific ASCA Pilot guidance documents for examples

**\*\*\* Device manufacturers are responsible for documenting how testing supports premarket authorization, even for ASCA Pilot submissions \*\*\***

# 3. Plan Submission Elements

## Cover Letter

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## ASCA Summary Test Report

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# Elements of a DOC

- Name and address of applicant/sponsor responsible for DOC
- Product/device identification
- Statement of conformity
- List of standards to which DOC applies
- The FDA recognition number for each standard

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and the FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

# Elements of a DOC, cont'd

- Date and place of issuance of DOC
- Signature, printed name, and function of applicant/sponsor responsible for DOC
- Any limitation on validity of DOC (for example, how long declaration is valid, what was tested, or concessions made about testing outcomes)
- Supplemental documentation

Please see ISO/IEC 17050-1:2004(en): *Conformity assessment-supplier's declaration of conformity-Part 1: General requirements* and the FDA's guidance: *Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*

# 3. Plan Submission Elements

## Cover Letter

- States that submission is for ASCA Pilot
- Name, location and IDs of test lab(s)
- The FDA-recognized consensus standard(s) and test methods used

## Declaration of Conformity (DOC)

- Manufacturer's responsibility
- *ASCA Accreditation* status for the test lab
- See suggested content in guidance

## ASCA Summary Test Report

- See standards-specific ASCA Pilot guidance documents for examples



# ASCA Summary Test Reports

- Supplemental documentation for ASCA submissions
- Developed by a panel of FDA knowledgeable staff
- Examples found in appendixes of the two ASCA standards-specific guidances

## 4. Obtain Results and Summary Test Report(s) from Test Lab

- Test lab
  - Conducts testing
  - Sends complete test reports and ASCA Summary Test Report(s) to manufacturer

## 5. Prepare FDA Submission

### Assemble the following:

- Cover letter with ASCA-specific information
- Declaration of conformity
- Summary Test Report
  - Generally don't need complete test reports
  - Manufacturer should not modify Summary Test Reports from testing laboratories
- All other submission requirements

# Using eSTAR

- Includes ASCA-specific information
- Voluntary, currently its own pilot for 510(k) submissions
- Benefits:
  - Fillable PDF
  - Will tell you if anything is missing
  - Includes ASCA option for eligible tests

# Using eSTAR

If you select the ASCA option, you will be prompted to include administrative information

**Cytotoxicity Testing**

What type of cytotoxicity testing was conducted?

Please summarize justifications, non-traditional test methods, or other relevant information:

- \* Direct Contact Method
- \* Extraction Method (MEM Elution)
- \* Another method (explained below)
- \* None (justified below)
- ASCA (MEM)**

Close Tab

Biocompatibility Reports and Documentation

**Accreditation Scheme for Conformity Assessment (ASCA) Information**

Date of Testing

Test Lab Name

ASCA Test Lab ID

Test Report Number

Was testing for the standard (and particular test method) in scope of ASCA accreditation for the testing laboratory?

ASCA Accreditation Status Suspension

Was the test article prepared per the ASCA Test Article Prep SOP?

Was testing conducted per the ASCA Test Method Protocol and 21 CFR 58?

Fluid Path Extractions Approach

Were there deviations in the testing?

# Summary

## The ASCA Pilot:

- Increases consistency and predictability in assessing conformance with the FDA-recognized standards
- Reduces regulatory burden by streamlining conformity assessment
- Ensures patient access to safe, effective devices

# Summary

## Five steps to prepare a submission with ASCA testing

1. Identify the standard(s)
2. Agree on test plan
3. Plan submission elements
4. Obtain results and ASCA Summary Test Reports
5. Prepare the FDA submission

## ASCA-specific elements of a device submission

1. Cover letter with ASCA-specific information
2. Declaration of conformity
3. Summary Test Reports

# The ASCA Pilot: Biocompatibility

**Shuliang Li, Ph.D.**

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Standards and Conformity Assessment Program  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# Topics

- ASCA Pilot biocompatibility testing
- Declarations of conformity (DOCs) for biocompatibility standards
- ASCA Pilot biocompatibility Summary Test Reports

# ASCA Pilot Standards: Biocompatibility



FDA Recognized Consensus Standard	Test Method(s)
ISO 10993-4	Complement Activation using a U.S. marketed ELISA kit
ISO 10993-4 and ASTM F756	Direct and Indirect Hemolysis
ISO 10993-5	MEM Elution Cytotoxicity
ISO 10993-10	Dermal Irritation, Intracutaneous Reactivity Irritation, and Closed Patch Sensitization
ISO 10993-10 and ASTM F720	Guinea Pig Maximization Sensitization
ISO 10993-11	Acute Systemic Toxicity
ISO 10993-11 and USP 151	Material-Mediated Pyrogenicity
ISO 10993-12	Sample preparation for all test types

**\*\*\* Please see the ASCA biocompatibility standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information \*\*\***

# Selection of Biocompatibility Testing and Testing Laboratory



- ASCA does not change the paradigm for the development of a biocompatibility evaluation: manufacturers work with testing laboratories to develop a testing plan
- To determine biocompatibility evaluation endpoints, refer to Attachment A of the general FDA biocompatibility guidance
  - *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*
- All biocompatibility testing under the ASCA Pilot should be conducted according to 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations

# Devices Excluded from ASCA Pilot



- Excluded from the ASCA Pilot biocompatibility scope:
  - Devices requiring customized sample preparation and/or testing methodologies
  - Absorbable devices
  - In situ polymerizing devices
  - Liquid devices
  - Creams, gels, hydrogel devices
  - Devices containing nanomaterials

# Declarations of Conformity for Biocompatibility Standards

# Example ASCA DOC for Biocompatibility

## **Appendix A: Example ASCA Declaration of Conformity (DOC) for Biological Evaluation of Medical Devices 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 may submit as part of its 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:<sup>18</sup>

1. Title of Standard: (e.g., ISO 10993-10 Third edition 2010-08-01 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization)-

- FDA Recognition #: (e.g., 2-174)
- Options Selected
  - Standard included no options
  - Standard included options



*List of options selected in standard (e.g., Clause 7.3 Guinea pig assays for detection of skin sensitization). No information is needed in this section if testing is from an ASCA-accredited test laboratory; 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)

# ASCA DOC for Biocompatibility Standards, page 1

## ISO 10993-10

- Clause 6.3 Primary skin irritation test
- Clause 6.4 Intracutaneous reactivity
- Clause 7.5 Guinea pig maximization test (GPMT)
- Clause 7.6 Closed-patch test (Buehler test)

## ASCA DOC for Biocompatibility Standards, page 2

- Testing Date(s): (e.g., Sep 1, 2020 – Sep 15, 2020)
- ASCA Accreditation Status on the Date(s) of Testing:
  - Standard (and particular test method) was not in testing laboratory's scope of ASCA Accreditation
  - Standard (and particular test method) 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, including date(s) of suspension.*

- Supplemental Documentation (*see 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 complete test report and the supplemental documentation: (e.g., Appendix A of this premarket submission)

<Repeat for each standard in DOC>

## Limitations on Validity of DOC

# ASCA DOC for Biocompatibility Standards, page 3

*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 laboratory, this should include, at a minimum:*

-  • *Information on how the test article compares with the device provided in this premarket submission<sup>19</sup> (including, selection of “representative” devices/portions) 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 lab 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)*
-  • *A statement that the device/test article does not require customized sample preparation and/or testing methodologies, or any absorbable or in situ polymerizing devices, liquid devices, creams, gels, hydrogel devices, and devices containing nanomaterials, as these types of materials are not eligible for biocompatibility testing under the ASCA Pilot*

### Signature

Printed name: \_\_\_\_\_  
Function within entity responsible for DOC: \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_

<sup>19</sup> Please see FDA’s guidance [Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"](#) for considerations regarding the use of medical devices in their final finished form or a representative test article for biocompatibility testing.

# ASCA Biocompatibility Summary Test Reports

# Biocompatibility ASCA Summary Test Report

- Test labs provide both complete test reports and ASCA Summary Test Reports to manufacturers
- The FDA generally will accept Summary Test Reports from ASCA-accredited test labs without the need to review complete test reports
- A complete test report may be needed when:
  - “Other” option is selected for test article preparation
  - Deviations/amendments
  - Changes in color/turbidity or particles in the test article and/or extract OR there was swelling/degradation of the test article
  - Results (including controls) are outside the range as specified in the ASCA guidance for biocompatibility testing

\*\*\* Note: review the footnotes in the example Summary Test Reports (Appendix B-J in the ASCA biocompatibility guidance) for more information \*\*\*

# Biocompatibility ASCA Summary Test Report

## Appendix C: Example ASCA Summary Test Report for Biocompatibility Testing of Medical Devices: Cytotoxicity – MEM Elution (ISO 10993-5)

ASCA Test Article Prep SOP#: [ASCATAPrep(date/version)]

- Test Article was prepared per the above protocol (no deviations/amendments); or
- Test Article was prepared per the above protocol, with the following deviations/amendments<sup>31</sup> (e.g., filtering, extract manipulation, pH adjustment):

*Description of deviations/amendments*

### Extraction Solvent:

- MEM with 5-10% animal serum
- Other:<sup>32</sup> [DESCRIBE]

<sup>31</sup> Since deviations/amendments were noted, the complete test report should be included with ASCA Summary Test Report during the ASCA Pilot (depending on the information provided, FDA may or may not request to review the complete test report). Test Laboratory/Manufacturer may also be requested to provide a rationale to support a regulatory decision.

<sup>32</sup> In this situation, the complete test report should be included with ASCA Summary Test Report during the ASCA Pilot (depending on the information provided, FDA may or may not request to review the complete test report). Test Laboratory/Manufacturer may also be requested to provide a rationale to support a regulatory decision.



Footnotes outline when a complete test report may be needed

# Summary

- Consult the FDA's general biocompatibility guidance to determine appropriate endpoints
- The manufacturer and ASCA-accredited test lab should collaborate to develop the test plan
- Comply with 21 CFR 58 GLP
- Submit the declaration of conformity with the ASCA Summary Test Report(s)
  - Be aware when a complete test report might be needed

# The ASCA Pilot: Basic Safety and Essential Performance

**Eric Franca, Ph.D.**

ASCA Testing Laboratory Lead, Basic Safety and Essential Performance

Standards and Conformity Assessment Program  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration

# Topics

- Recommendations for *ASCA Accreditation* applicants
- Test development and planning
- Summary Test Reports

# ASCA Pilot Standards: Basic Safety and Essential Performance



Standard	Standard Title
ANSI/AAMI 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (along with the FDA-recognized collateral and particular standards in the IEC/ISO 60601-80601 family)
IEC 61010-1	Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements (along with the FDA-recognized particular standards in the IEC 61010 family)

**\*\*\* Please see the ASCA basic safety and essential performance standards-specific guidance for a full listing of standards and test methods and visit the Recognized Consensus Standards database for more information \*\*\***

# Recommendations for ASCA *Accreditation Applicants*

# What to Do



- Test labs should:
  - Review and understand our guidance documents
  - Submit a **complete** application including:
    - Administrative information about the test lab site
    - A scope of accreditation from an ASCA-recognized accreditation body with accreditation to ISO/IEC 17025 **and** ASCA Pilot specifications
    - Signed agreement (see Appendix B of the ASCA Pilot program guidance)

Note: helpful information can be found in the *AAMI CR500:2019 Basic Introduction to the IEC 60601 Series* report at [www.aami.org](http://www.aami.org)

# What to Do

- Understand that the FDA reviews *ASCA Accreditation* applications as they are received
  - We intend to complete review within 60 days
  - The ASCA-accredited test lab list on our web page will be updated as new labs receive *ASCA Accreditation*
- Understand that the scope of *ASCA Accreditation* is limited to the relevant scope of accreditation from its accreditation body
  - Clauses and methods excluded in relevant standards on the scope of accreditation will also be excluded in the scope of *ASCA Accreditation*

# What to Avoid

- Test labs should avoid:
  - Sending an incomplete application
    - Include all the elements described in ASCA Pilot guidances
    - Ensure the scope of accreditation from your accreditation body includes assessment to ISO/IEC 17025 **and** the ASCA Pilot specifications
  - Requesting *ASCA Accreditation* for standards:
    - Not included in the ASCA Pilot
    - Not listed in the ASCA section of the scope of accreditation from your accreditation body
  - Submitting a separate application for a satellite lab – the satellite lab is included as part of the main lab
    - Do clarify in your submission that there is a satellite lab associated with the main test lab location, for our information

# If *ASCA Accreditation* is Granted

- If your test lab is granted *ASCA Accreditation*:
  - We will post your lab information on the ASCA web page
    - If you prefer generic lab contact information, please specify in your application
  - Though the listing on the ASCA web page does not include the versions/editions of standards, remember to only test to standards to which you have been accredited
  - Note any exclusions defined in the scope of accreditation from your accreditation body

# Test Plan Development

# Who is Responsible for the Test Plan?

- Manufacturers are responsible for the test plan and the appropriate selection and use of recognized consensus standards and test methods
- **However**, ASCA-accredited test labs often have expertise which exceeds manufacturers'
- Manufacturers and ASCA test labs should work together to develop a test plan

# What to Consider

- Consult the FDA's Recognized Consensus Standards database and Supplementary Information Sheets (SIS)
  - Some standards in the ASCA Pilot are only **partially recognized**
  - The SIS provides rationales and helpful references, including other relevant FDA guidances
- Review the ASCA Pilot Basic Safety and Essential Performance guidance and other relevant guidances
  - Examples of potentially relevant guidances (not an exhaustive list):
    - Information to Support a Claim of Electromagnetic Compatibility (EMC) of Electrically-Powered Medical Devices (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/information-support-claim-electromagnetic-compatibility-emc-electrically-powered-medical-devices>)
    - Design Considerations for Devices Intended for Home Use (<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/design-considerations-devices-intended-home-use>)
    - Laser Products - Conformance with IEC 60825-1 Ed. 3 and IEC 60601-2-22 Ed. 3.1 <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/laser-products-conformance-iec-60825-1-ed-3-and-iec-60601-2-22-ed-31-laser-notice-no-56>
    - Pulse Oximeters <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/pulse-oximeters-premarket-notification-submissions-510ks-guidance-industry-and-food-and-drug>



**Part B: Supplementary Information Sheet (SIS)**

**FR Recognition List Number** 050

**Date of Entry** 09/17/2018

**FR Recognition Number** 1-139

**Standard** (Included in [ASCA](#) pilot)



ISO 80601-2-61 Second edition 2017-12 (Corrected version 2018-02)  
Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment

**Scope/Abstract**

ISO 80601-2-61:2017 applies to the basic safety and essential performance of pulse oximeter equipment intended for use on humans, hereafter referred to as me equipment. This includes any part necessary for normal use, including the pulse oximeter monitor, pulse oximeter probe, and probe cable extender.

These requirements also apply to pulse oximeter equipment, including pulse oximeter monitors, pulse oximeter probes and probe cable extenders, which have been reprocessed.

The intended use of pulse oximeter equipment includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate of patients in professional healthcare institutions as well as patients in the home healthcare environment and the emergency medical services environment.

ISO 80601-2-61:2017 is not applicable to pulse oximeter equipment intended for use in laboratory research applications nor to oximeters that require a blood sample from the patient.

If a clause or subclause is specifically intended to be applicable to me equipment only, or to me systems only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to me equipment and to me systems, as relevant.



### Extent of Recognition

Partial recognition. The following part(s) of the standard is (are) not recognized:

Clause 201.12.1.101.1 SpO2 ACCURACY of PULSE OXIMETER EQUIPMENT, Specification is not recognized.

### Rationale for Recognition



This standard is relevant to medical devices and is recognized on its scientific and technical merit and/or because it supports existing regulatory policies.

This standard is recognized in part because "Clause 201.12.1.101.1 SpO2 ACCURACY of PULSE OXIMETER EQUIPMENT, Specification" is in conflict with an existing published final guidance. See Section 4.1 Accuracy of Pulse Oximeters, Table 3. Typical Arms Specification by Sensor Type, of the Guidance document cited below.

### Public Law, CFR Citation(s) and Procode(s)\*

Regulation Number	Device Name	Device Class	Product Code
<a href="#">§870.2700</a>	Oximeter	Class 2	<a href="#">DQA</a>



### Relevant FDA Guidance and/or Supportive Publications\*

AAMI CR500:2019 Basic Introduction to the IEC 60601 Series

Pulse Oximeters - Premarket Notification Submissions [510(k)s]: Guidance for Industry and Food and Drug Administration Staff, Issued March 2013.

### FDA Technical Contacts

**Sandy Weininger**  
 FDA/OC/CDRH/OSEL/DBP/  
 301-796-2582  
[sandy.weininger@fda.hhs.gov](mailto:sandy.weininger@fda.hhs.gov)

**Neel Patel**  
 FDA/OC/CDRH/OPEQ/OHTI/DHTIC/  
 301-796-6274  
[Neel.Patel@fda.hhs.gov](mailto:Neel.Patel@fda.hhs.gov)

### Standards Development Organization

ISO International Organization for Standardization

<https://www.iso.org/>

## What if the Test Lab has Concerns with a Manufacturer's Proposed Test Plan?

- ASCA-accredited test lab should exercise its independent judgment concerning the application of a standard and conduct of conformity assessment activities
- Test labs should communicate concerns with the test plan to the manufacturer in early interactions
- If concerns cannot be resolved with the manufacturer, test labs should detail the issues in the Summary Test Report

# Summary Test Reports

## 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
  - 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

*Include any relevant details regarding the specified use environment here.*

# Summary Test Report, page 1

**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) 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**

- 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

*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.*

# Summary Test Report, page 2

# Summary Test Report, page 3



### 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

# Summary

- For *ASCA Accreditation* applications:
  - Do
    - Review all relevant guidances, including the ASCA Pilot guidances
    - Submit complete applications
  - Don't
    - Include standards outside the ASCA Pilot in your requested scope
    - Submit an accreditation body certificate that does not reflect ASCA standards
  - Remember
    - Only test to standards in your ASCA scope of accreditation
    - Note any exclusions defined in your scope of accreditation from your accreditation body

# Summary

- **Test plan development**
  - Manufacturers are ultimately responsible
  - Test labs should use their expertise to help develop the test plan with manufacturers
  - Consider
    - The SIS for standards in the Pilot
    - Relevant FDA guidance
    - Any partial recognitions and references provided on the SIS
  - If concerns identified by the test lab can't be resolved, document that information in the Summary Test Report
- **Summary Test Reports**
  - Example format in the ASCA guidance is not mandatory
  - Please ensure all example content is included

**Questions?**



# Biocompatibility Resources

- 21 CFR 58 Good Laboratory Practices for Nonclinical Laboratory Studies regulations:  
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>
- General biocompatibility guidance:  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and>
- FDA Biocompatibility Assessment Resource Center:  
<https://www.fda.gov/medical-devices/premarket-submissions/biocompatibility-assessment-resource-center>

# Standards Resources

- **Standards & Conformity Assessment Program**  
[www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro](http://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/standards-and-conformity-assessment-program#intro)
- **FDA Recognized Consensus Standards Database**  
[www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm)
- **CDRH Learn: How to Study and Market Your Device: Standards**  
[www.fda.gov/training/cdrhlearn/default.htm](http://www.fda.gov/training/cdrhlearn/default.htm)

# Standards Resources

- ***Recognition and Withdrawal of Voluntary Consensus Standards*** guidance  
[www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recognition-and-withdrawal-voluntary-consensus-standards)
- ***Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices*** guidance  
[www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices)
- **AAMI CR500:2019 Basic Introduction to the IEC 60601 Series report**

# ASCA Resources



- **ASCA Pilot web page**  
[www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca](http://www.fda.gov/medical-devices/standards-and-conformity-assessment-program/accreditation-scheme-conformity-assessment-asca)
- **ASCA Pilot program guidance**  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/accreditation-scheme-conformity-assessment-asca-pilot-program>
- **ASCA Standards-specific guidances**
  - **Basic Safety and Essential Performance standards-specific guidance:**  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/basic-safety-and-essential-performance-medical-electrical-equipment-medical-electrical-systems-and>
  - **Biocompatibility standards-specific guidance:**  
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/biocompatibility-testing-medical-devices-standards-specific-information-accreditation-scheme>
- **Ask ASCA! ASCA@FDA.HHS.GOV**

# Additional Resources

Division of Industry and Consumer Education:

[DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)

Slide Presentation, Transcript and Webinar Recording will be available at:

<http://www.fda.gov/training/cdrhlearn>

Under Heading: How to Study and Market Your Device; Sub-heading: Standards

Please complete a short survey about your FDA CDRH webinar experience. The survey can be found [here](#) immediately following the conclusion of the live webinar