



Welcome to the Accreditation Scheme for Conformity Assessment (ASCA) Workshop – Day 2

**For all workshop-related documents and information
please visit:**

<https://go.usa.gov/xQE7s>

Webcast and WebEx Info for Breakout Session II: Wednesday 09:00am-11:00am

60601 Basic Safety and Essential Performance, EMC, Alarms

(Continue in breakout sessions or meet as a combined 60601 group)

- **ANSI/AAMI ES 60601-1: Great Room B&C**

JOIN DISCUSSION BY WEBCAST: <https://collaboration.fda.gov/ascaplenarybreakout/>

- **IEC 60601-1-2: Room 1504**

JOIN WEBEX MEETING:

<https://fda1.webex.com/fda1/j.php?MTID=m7d7339fac6e87f3c9f47365a9196edea>

Meeting number (access code): 902 673 739

Meeting password: Asca6060112

JOIN BY PHONE

+1-210-795-0506 US Toll / +1-877-465-7975 US Toll Free

- **IEC 60601-1-8: Room 1408**

JOIN WEBEX MEETING:

<https://fda1.webex.com/fda1/j.php?MTID=me9b85a3c7a9be3316ac4e028c218b21c>

Meeting number (access code): 900 503 272

Meeting password: ASCAb6060118

JOIN BY PHONE

+1-210-795-0506 US Toll / +1-877-465-7975 US Toll Free

Breakout Session II: ANSI/AAMI ES 60601-1 (Continued): Great Room B&C

Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Goals of the Breakout Sessions:

1. Find the Value ASCA Provides to Stakeholders
2. Gather Issues, Concerns and Suggestions from Stakeholders for Implementation of the Accreditation Scheme
3. Identify Suitable Candidate Standards and Scope for Pilot Program
4. Identify Criteria for Determining Competency of ASCA Testing Laboratories for Testing of the Standards in accordance with the ASCA Scheme based upon ISO/IEC 17025



Break

11:00-11:15am

Next Session: 11:15am-12:15pm

**Plenary Session: Summary of Breakouts on the
ASCA Scheme to the Standards
Outlined in the Pilot, Q&A Session
Great Room B/C**



Plenary Session

Great Room B/C

Summary of Breakouts on the ASCA Scheme
to the Standards Outlined in the Pilot

Question and Answer Session



Breakout Session I: Biocompatibility Summary Slides

ASCA Public Workshop

May 22-23, 2018



Breakout I: Biocompatibility Wrap-Up

- Topic 1: Proposed ASCA Biocomp Tests
 - Proposed tests seem appropriate
 - ADD: 10993-12 (Sample Prep0
 - Consider adding:
 - Additional cytotoxicity assays
 - ocular irritation



Breakout I: Biocompatibility Wrap-Up

- Topic 2: Proposed Roles – Key Stakeholders
 - Test Labs: more dialogue welcome (e.g., electronic records, substantial changes, level of info needed on documentation)
 - AB: consistency across ABs/technical assessors; depth of assessments can impact costs
 - Use of NAI/VAI findings by site: consistency across inspectors could help



Breakout I: Biocompatibility Wrap-Up

- Topic 3: ASCA Biocomp Scheme Discussion
 - Agree to start with GLP studies for Pilot
 - Test Labs: agreed to propose list of substantial vs. non-substantial modification (Thor Rollins/Nelson will help coordinate)
 - Proficiency testing: cannot state specific numbers of animals/duration of experience (may be harder for smaller labs): test lab specific approaches needed for proficiency – FDA can learn with pilot



Breakout I: Biocompatibility Wrap-Up

- Topic 4: Proposed ASCA Biocomp Test Summary
 - General agreement on:
 - Proposed summary information
 - Pilot exclusions: hydrogels/absorbables/nanomaterials/in situ-polymerizing (due to difficult sample prep issues)
 - Clarify form so that users understand form */** (whether or not manufacturers need to submit the detailed test report for FDA)
 - Some FDA training on the form may be needed
 - Signatures:
 - let TL/manufacturers decide who will sign
 - TL use electronic systems – may impact implementation

Breakout I: Biocompatibility Wrap-Up

- Round Table Discussion:
 - FDA described most of the critical elements
 - In vivo: animal identification is important
 - Acute systemic tox: balance calibration is key
 - Rabbit colony selection/maintenance issues
 - Standardize complement activation
 - Training/documentation: technician specific
 - Proficiency assessments/requalifications are needed (annual vs. quarterly – may be lab/test dependent)
 - Community of Practice to continue more detailed discussions
 - Further work on sample preparation/extraction selection consistency in approaches may be helpful for some complex devices



Thank You

Panel and active audience participation was amazing

FURTHER COMMENTS/QUESTIONS?

- Please email: standards@cdrh.fda.gov



Breakout Session II: IEC 60601-1-8 – Alarms

Goals of the Breakout Sessions:

1. Find the Value ASCA Provides to Stakeholders
 - Improve consistency
 - Improve transparency
 - Collaboration towards standards development
2. Gather Issues, Concerns and Suggestions from Stakeholders for Implementation of the Accreditation Scheme
 - Are there enough test labs currently performing 60601-1-8 testing?
 - How to handle labeling / risk management requirements?
 - Will testing under an ASCA-scheme be usable for global marketing?



Breakout Session II: IEC 60601-1-8 – Alarms

Goals of the Breakout Sessions:

3. Identify Suitable Candidate Standards and Scope for Pilot Program

- Some portions of standard not well defined (Intelligent / distributed alarm systems)
- Overlap with particular standards
- Amendment to standard being drafted that is expected to improve testing, how will ASCA handle revisions and updates to standards?

4. Identify Criteria for Determining Competency of ASCA Testing Laboratories for Testing of the Standards in accordance with the ASCA Scheme based upon ISO/IEC 17025

- Training
- Equipment
- Physical setup for audible alarm testing
- Test procedures



Lunch Break
12:15-1:00pm

Next Session:

**Plenary Session: ASCA Pilot Performance Metrics, 1:00-2:30pm,
Great Room B/C**



Plenary Session: ASCA Pilot Performance Metrics

- What does success look like for all stakeholders?
- What are the key performance indicators?
- What areas can be improved in testing, standards development and in regulatory science platforms where standards are used from the ASCA Pilot?



Break 2:30-2:45pm

Next Session

Open Public Session: 2:45-3:30pm

Great Room B/C



Open Public Session



Workshop Summary and Next Steps



Workshop Adjournment

Thank You!