

WELCOME to the ASCA PUBLIC WORKSHOP

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



Download the Workshop App:

Desktop version: <https://crowd.cc/fda-asca2018>

Mobile device version: <https://crowd.cc/s/1zzsM>

**Event Name in the App Directory - "Public Workshop
- Accreditation Scheme for Conformity Assessment"**

**Please also take the survey on your plan for
breakout sessions**

Webcast Information

May 22, 2018:

- **9:00 am - 5:00 pm** - (Section B&C) - **Plenary Session, Breakout Session I:** “Technical Requirements for ASCA Pilot”, Breakout Session II: 60601 Basic Safety and Essential Performance/ EMC/Alarms:
<https://collaboration.fda.gov/ascaplenarybreakout/>
- **1:00 pm - 5:00 pm** - (Section A) - **Breakout Session:** “Biocompatibility”:
<https://collaboration.fda.gov/ascabreakout/>

May 23, 2018:

- **9:00 am - 4:30 pm** - (Section B&C) - **Breakout Session II:** 60601 Basic Safety and Essential Performance/ EMC/Alarms, **Plenary Sessions:** Breakout session Summaries and ASCA Pilot Performance Metrics:
<https://collaboration.fda.gov/ascaplenarybreakout/>
- **9:00 am - 11:00 am** - (Section A) - **Breakout Session:** “Biocompatibility”:
<https://collaboration.fda.gov/ascabreakout/>



Webcast and WebEx Info for Breakout Session II: Tuesday 2:45pm-4:30pm

60601 Basic Safety and Essential Performance/EMC/Alarms (multiple breakout sessions)

- **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 BY WEBEX MEETING
<https://fda1.webex.com/fda1/j.php?MTID=m06d5d05798fe708cbec9b4c2c041ccad>
Meeting number (access code): 905 556 959
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 BY WEBEX MEETING
<https://fda1.webex.com/fda1/j.php?MTID=mfcfde9e7ccff26be56853a55f0f5aa34>
Meeting number (access code): 906 206 764
Meeting password: ASCAb6060118
JOIN BY PHONE
+1-210-795-0506 US Toll / +1-877-465-7975 US Toll Free



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



ASCA

A voluntary pilot program that will authorize FDA-qualified Accreditation Bodies (ABs) to accredit testing laboratories (TLs) to ASCA program requirements.

ASCA

It will enhance FDA's confidence in TLs' competence to conduct tests and generate results according to specified standards.

Reviewers will be able to accept manufacturers' Declarations of Conformity based upon the test report without further review of test protocols and detailed results.



ASCA

The expected result: increased consistency and predictability in the way FDA determines conformance to standards in product review

Why ASCA?

ASCA capitalizes upon the increasingly prominent role that standards play in regulatory science and practice.



ASCA

ASCA brings the expertise of the whole conformity assessment community together to advance regulatory science.

Why ASCA?

The collective expertise of Accreditation Bodies, testing labs, standards developers, regulators and manufacturers will ensure program success, as well as identify efficiencies as yet not considered.

Why ASCA?

Regulatory burdens on manufacturers should be reduced once reviewers' need for additional information and consults diminishes.

Why ASCA?

Accreditation Bodies will benefit from participating in and contributing to conformity assessment schemes.



Why ASCA?

Testing labs will enjoy an enhanced partnership with clients and regulators through ASCA.

Why ASCA?

Standards Developing Organizations will receive valuable feedback on standards' utility for conformity assessment and will see greater application of standards in the future.

Why ASCA?

Reviewers should receive better structured submissions, which will free up time and resources where they are needed most: innovative new technologies and collaborations with stakeholders.



Why ASCA?

Patients are our top priority.

ASCA means they will have access to safe and effective life-saving devices sooner.