

# Accredited Standards Committee C63<sup>®</sup> Electromagnetic Compatibility

Accredited by the American National Standards Institute, Inc.  
Secretariat: Institute of Electrical and Electronic Engineers, Inc.

## C63<sup>®</sup> SC8 - Medical Device EMC Test Methods DRAFT MINUTES of the November 28, 2018 meeting NIST Boulder, CO

**Chairman: Stephen Berger**  
**Vice-Chair: John Becker**  
**Secretary: open**

**Attendance:**

Member's Name	Member's Role on SC8	Present	Absent
Becker, John	Vice-Chair	X - Web	
Berger, Stephen	Chair	X	
Case, David	Member	X - Web	
DeLisi, Bob	Member	X	
Hare, Ed	Member	X	
Heirman, Don	Member	X	
Hoolihan, Dan	Member	X	
Kuczynski, Victor	Member	X	
Liu, Steve	Member	X	
Moongilan, Dheena	Member	X	
Silberberg, Jeffrey L	Member	X	
Zimmerman, Dave	Member		X
<b>Names</b>	<b>Observers only below this line.</b>		
Antola, Mike	Observer	X	
Benitez, Henry	Observer	X	
Briggs, Mark	Observer	X	
Chamberlain, David	Observer	X	
Chen, JC	Observer	X	
Coder, Jason	Observer	X	
Crumm, Allen	Observer	X	
Detts, Nate	Observer	X	
Elliott, William (Mac)	Observer	X	
Gjerde, Ken	Observer	X	
Graff, Bill	Observer	X	
Khian, Ho Sze	Observer	X	
Kramer, Doug	Observer	X	
Lee, Edmund	Observer	X	
Long, Randy	Observer	X	
Nixon, Jason	Observer	X	
Norgard, John	Observer	X	
Ramie, Jerry	Observer	X	
Sigouin, Dan	Observer	X	
Zakharia, Deanna	Observer	X	

1. **Call to Order:** Chair, Stephen Berger, called the meeting to order.
  - 1.1 **Opening remarks and announcements:** Chair, Stephen Berger, welcomed those in attendance and set up the web meeting.
  - 1.2 **Introductions:** The Chair asked for introductions. Everyone around the table introduced themselves and their affiliation. A sign-in sheet was sent around the room.
2. **Approval of the Agenda:** Chair, Stephen Berger, reviewed the agenda. A motion was made to adopt the agenda. A vote was taken and the motion passed.
3. **Presentation of [patent slides](#):** Chair, Stephen Berger, showed the slides regarding IEEE patent policy. Chair, Stephen Berger went over the content of the slides and an opportunity was given to the subcommittee members to identify/disclose patents.
4. **Meeting attendance & Membership:** Chair, Stephen Berger, announced, with sadness, that Steve Whitesell, SC8's vice-chair and very active member, had passed away.
5. **Working Group reports:**
  - 5.1 **C63.18:** Currently suspended.
  - 5.2 **C63.19:** Stephen Berger gave a verbal report regarding C63.19. SC8 held an email ballot before the meeting, which passed, resulting in a recommendation to the parent committee that the current draft be balloted. As a result of that recommendation, the parent committee had held an email ballot and approved the current draft to go to ballot. The C63 Secretariat accordingly sent an invitation to join the ballot group for C63.19, with a Dec. 3, 2018 closing date.  
  
[More information about each standard](#) is available on the Standards Status section of the [C63® web page](#).
6. **Old Business:** There was no old business discussed.
7. **New Business:** Chair, Stephen Berger, asked if there was any new business.
  - 7.1 **FDA EMC Activities Report:** Jeff Silberberg gave a report.
  - 7.2 **IEC SC62A MT23 Liaison Report:** Jeff Silberberg gave a report.
  - 7.3 A discussion was held of possible new projects for SC8. The following possibilities were discussed:
    - 7.3.1 Alarms – What safeguards are expected when alarms are transmitted wirelessly? What actions are expected when an alarm fails to reach its intended destination?
    - 7.3.2 Logging – What information related to wireless performance, e.g. failed packets, failed attempts to communicate, is recorded? When and where is this information reported?
    - 7.3.3 Usefulness of PIM/PISM/PSM model for SC8 work – The Object Management Group has developed a detailed system to organize their standards to define performance while allowing companies technical freedom. The system includes:
      - 7.3.3.1 PIM - platform-independent model
      - 7.3.3.2 PISM - platform-independent simulation model
      - 7.3.3.3 PSM – platform specific model
    - 7.3.4 Life-Cycle Considerations – How are equipment aging issues incorporated into device evaluation and more broadly to the risk assessment process for devices?
    - 7.3.5 Risk Assessment – What are the characteristics of a good or deficient risk assessment? Is more specific guidance needed on the testing risk category level?
    - 7.3.6 GNURadio and SDR Technology. Is more tutorial and guidance needed for using spectrum record and playback for medical device testing? More broadly is the potential of software-defined RF instrumentation being adequately applied to medical device evaluation?
    - 7.3.7 Bluetooth connectivity issues.
    - 7.3.8 Equivalence of the effects of 50% square-wave modulation with actual RFID waveforms.
    - 7.3.9 Alarm fatigue, cognitive issues & application to wireless alarms.

8. **Time and place of next meeting:** The proposed date of the next SC8 meeting is during the dates of April 29 – May 3, 2019 at UL in Research Triangle Park, NC.
9. **Closing remarks and Adjournment:** Chair, Stephen Berger adjourned the meeting.

## Current SC8 Membership

#	Name	Role within Subcommittee 8	Affiliation / Financial Support
1	<a href="#">Becker, John</a>	Vice-Chair	HIA
2	<a href="#">Berger, Stephen</a>	Chair	TEM Consulting
3	<a href="#">Case, David</a>	Member	CISCO
4	<a href="#">DeLisi, Bob</a>	Member	UL, LLC
5	<a href="#">Hare, Ed</a>	Member	ARRL
6	<a href="#">Heirman, Don</a>	Member	Don HEIRMAN Consultants
7	<a href="#">Hoolihan, Dan</a>	Member	Hoolihan EMC Consulting
8	<a href="#">Kuczynski, Victor</a>	Member	Vican Electronics
9	<a href="#">Liu, Steve</a>	Member	PCTEST Engineering Laboratory, Inc.
10	<a href="#">Moongilan, Dheena</a>	Member	Nokia
11	<a href="#">Silberberg, Jeffrey L</a>	Member	FDA Center for Devices & Radiological Health
12	<a href="#">Zimmerman, Dave</a>	Member	Spectrum EMC, LLC

The members highlighted in red have been removed from the membership roster.  
The members highlighted in yellow are at risk.

Chair: Stephen Berger

Vice Chair: John Becker

Secretary: *open*

November 28, 2018; 10:00 AM – 12:00 PM - MDT

NIST  
Boulder, CO  
**Generic Meeting Agenda**

**10. Call to Order: Chair**

**10.1 Opening remarks and Announcements: Chair**

**1.3 Introductions: Roll Call** (record attending members with their affiliations and guests separately below)  
Report any roster errors to the ASC-C63<sup>®</sup> Secretary (insert [SC8 membership roster](#) from the website as shown below)

### Subcommittee 8 Membership Roster

#	Name	SC Role	Affiliation
1	<a href="#">Becker, John</a>	Member	HIA
2	<a href="#">Berger, Stephen</a>	Chair	TEM Consulting
3	<a href="#">Case, David</a>	Member	Cisco Systems
4	<a href="#">DeLisi, Bob</a>	Member	UL, LLC
5	<a href="#">Hare, Ed</a>	Member	ARRL
6	<a href="#">Heirman, Don</a>	Member	Don HEIRMAN Consultants
7	<a href="#">Hoolihan, Dan</a>	Member	Hoolihan EMC Consulting
8	<a href="#">Kuczynski, Victor</a>	Member	Vican Electronics
9	<a href="#">Liu, Steve</a>	Member	PCTEST Engineering Laboratory, Inc.
10	<a href="#">Moongilan, Dheena</a>	Member	Nokia
11	<a href="#">Silberberg, Jeffrey L</a>	Member	FDA Center for Devices & Radiological Health
13	<a href="#">Zimmerman, Dave</a>	Member	Spectrum EMC, LLC

**11. Approval of the Agenda**

**12. Working Group reports - Chair - More information about each standard is available on the Standards Status Matrix page of the [C63® web site](#).**

**3.1 C63.18: On Site Medical Device Immunity Testing – No active work.**

C63.18-2014 <a href="#">Learn</a>	On-Site Medical Radiated RF Immunity testing	SC 8	<a href="#">Silberberg, Jeffrey</a>	No active PINS	Current. No plans for further maintenance at this time.
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<a href="#">more</a>					
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**C63.18: C63.18-2014 On-site, Ad-Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio Frequency Transmitters**

**Contact:** [Silberberg, Jeffrey L](#) (Working Group Chair)

**Scope:** This recommended practice is a guide to evaluating the electromagnetic immunity of medical devices to radiated radio-frequency (RF) emissions from common RF transmitters (e.g., two-way radios; walkie-talkies; mobile phones; wireless-enabled tablets, e-readers, laptop computers, and similar devices; radio-frequency identification (RFID) readers; networked mp3 players; two-way pagers; and wireless personal digital assistants [PDAs]).

**Status:** Current. No plans for further maintenance at this time.

**Purchase:** [IEEE Store](#). To purchase individual standards, go to the IEEE store and search on the standard number. Withdrawn standards can still be purchased. Draft revisions are not yet available for sale.

**3.2 C63.19: Hearing Aid Compatibility maintenance - [Stephen Berger](#)**

C63.19-2011 <a href="#">Learn more</a>	EMC for Hearing Aids,	<a href="#">SC 8</a>	<a href="#">Berger, Stephen</a>	<a href="#">C63.19 PINS</a>	Current. New revision being developed.
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**C63.19: C63.19-2011 American National Standard for Methods of Measurement of Compatibility between Wireless Communications Devices and Hearing Aids**

**Contact:** [Berger, Stephen](#) (Working Group Chair)

**Scope:** Uniform methods of measurement for compatibility between hearing aids and wireless communications devices are set forth.

**Status:** Current. New revision being developed. An explanation or interpretation is [available](#).

**Purchase:** [IEEE Store](#). To purchase individual standards, go to the IEEE store and search on the standard number. Draft revisions are not yet available for sale

**4. Other Old Business: Chair**

**4.1 Written reports** - Written reports of this Subcommittee meeting shall be presented by the Subcommittee Chair at the Main Committee meeting. These reports shall be made using the [PowerPoint template](#). Prior to the Main Committee meeting, the [SC report](#) and [approved previous meeting minutes](#) shall be provided to the projectionist for showing on the screen at the Main meeting. The Presentation and any written report shall also be sent by the Subcommittee Chair to the ASC-C63<sup>®</sup> [Newsletter editor](#).

**4.2 Coordination with SC2 for definitions** - Before any Working Group draft can be submitted to the Subcommittee for approval, the document must be provided to the SC2 Chair for evaluation and coordination of the definitions used.

**4.3 Coordination with SC3 for harmonization** - Before any Working Group draft can be submitted to the Subcommittee for approval, the document must be provided to the SC3 Chair for evaluation and coordination of any harmonization effort.

**5. New Business: Chair**

**6. Review of the patent slides**

**7. Results of Pre-Meeting E-Mail Ballot**

## 7.1 Approval of the previous Minutes - Minutes of the previous meeting

### Review of [Subcommittee Membership](#)

Report any errors to the ASC-C63® Secretary

## 7.2 Review of Membership Guidelines

### Subcommittees:

For an individual to remain a voting member of a Subcommittee, active participation in Subcommittee meetings and regular responses to Subcommittee email votes is required. Should a member fail to attend at least one of three consecutive scheduled meetings (in person or remotely via web conference (when used)) or respond to at least one of every two consecutive Subcommittee email votes, their membership in that Subcommittee may be at risk.

Note: Abstentions shall be treated the same as a “yes” or “no” vote regarding the requirement to respond to email votes.

### Working Groups:

For an individual to remain a member of a Working Group, active participation is required. Should a member fail to attend at least one of three consecutive scheduled meetings (in person or via web conference (when used)), their membership in that Working Group may be at risk. Individual Working Groups may establish additional participation criteria and/or modify this requirement.

### Member Attendance Log:

Name	11/10/16	5/10/17	11/8/17	5/2/18	11/28/18
<a href="#">Becker, John</a>			X	X	Web
<a href="#">Berger, Stephen</a>	X	X	X	X	X
<a href="#">Case, David</a>			Web	X	Web
<a href="#">DeLisi, Bob</a>		X	X	X	X
<a href="#">Hare, Ed</a>				X	X
<a href="#">Heirman, Don</a>	X		X	X	X
<a href="#">Hoolihan, Dan</a>	X	X	X	X	X
<a href="#">Kuczynski, Victor</a>	X	X		X	X
<a href="#">Liu, Steve</a>			X	X	X
<a href="#">Moongilan, Dheena</a>		X	X	X	X
<a href="#">Silberberg, Jeffrey L</a>	X	X	Web	X	X
<a href="#">Zimmerman, Dave</a>	X	X	X		

## 7.3 Consideration of new members Application for C63® Subcommittee Membership

### 7.4 Approval of Scope: (Spring meeting only) (Report approval or any changes to the Main Committee)

### Scope

Subcommittee 8 is responsible for writing and maintaining existing and proposed C63® standards for medical devices, as assigned by the Main Committee ASC 63®.

## 9. Review of the Action Items: Secretary

### 9.1 Review of Action Items from this meeting:

(read Action Items to Members, who must agree that they understand their meaning)

**9.2 Report of Action Items from previous meeting**

**10. Time and place of next meeting: Chair**

**11. Closing remarks and Adjournment: Chair**