



Accredited Standards Committee C63[®]

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

Chair: Stephen Berger

Vice Chair: John Becker

May 17, 2022; 8:00 AM – 9:30 AM - EDT

Spring Meeting on WebEx

Webex Meeting Minutes

1. Call to Order: Chair

1.1 Opening remarks and Announcements: Chair

1.2 Introductions: roll call (record attending members with their affiliations and guests separately below) Report any roster errors to the ASC-C63[®] Secretary (insert [SC8 membership roster](#) from the website as shown below)

2. Subcommittee 8 Membership Roster

Name	Role within SC	Affiliation
Becker, John	Vice Chair	Hearing Industries Association
Berger, Stephen	Chair	TEM Consulting
Case, David	Member	Consultant
DeLisi, Bob	Member	UL, LLC
Hare, Ed	Member	ARRL
Hoolihan, Dan	Member	Hoolihan EMC Consulting
Kuczynski, Victor	Member	Vican Electronics
Liu, Steve	Member	PCTEST Engineering Laboratory, LLC
Schaefer, David	Member	Element Laboratories
Silberberg, Jeffrey L	Member	FDA Center for Devices & Radiological Health
Zimmerman, Dave	Member	Spectrum EMC, LLC

2.1 Guests and Observers: (non-voting)

Members

- Stephen Berger
- Bob DeLisi
- Dan Hoolihan
- Ed Hare
- Steve Liu
- David Schaefer
- Jeff Silberberg

Guests

- Nicholas Abbondante,
- Ramona Saar
- Jeremiah Darden
- Paul Tau
- Ken Gjerde

- Janet O'Neil
- Steve Friersen
- John Kanter
- John Norgaard
- Harry Hodes

2.2 Quorum

NOTE: Quorum will be assumed unless a quorum count is requested, per Robert's Rules.

3. Approval of the Agenda: Chair

A motion to approve the agenda was made by Jeff Silberberg, seconded by Bob DeLisi and approved unanimously

4. Approval of the previous Minutes - [Minutes of the previous meeting](#)

No prior minutes were presented for approval at the meeting. After the meeting an E-Mail ballot was held to approve the minutes of the March 10, 2021 and May 17, 2022 meetings. The E-Mail ballot closed on May 31, 2022 and approved both sets of minutes.

5. Review of the [patent slides](#)

The patent slides were presented.

6. Review of [Subcommittee Membership](#)

6.1 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.

6.2 Member Attendance Log:

Name	5/24/19	11/20/19	06/17/20	09/18/20	12/04/20	3/10/21	5/17/22	
Becker, John	X		X		X			
Berger, Stephen	X	Web	A	X	X	X	X	
Case, David	X	Web	X	X	X	X		
DeLisi, Bob	X	X	A	X	X	X	X	
Hare, Ed		X	X				X	
Hoolihan, Dan	X	X	X			X	X	
Kuczynski, Victor	X	Web				X		
Liu, Steve			X	X	X	X	X	
Schaefer, David						X	X	
Silberberg, Jeffrey L	X	X	X	X	X	X	X	
Zimmerman, Dave	X	Web	A			X		

Any members at risk? These members are at risk:

6.3 Consideration of new members [Application for C63® Subcommittee Membership](#)

A call was given by the chair, asking if anyone cared to apply for membership. Nobody expressed an interest in joining the SC.

6.4 Approval of Membership (Spring meeting only)

A motion was made to approve the membership as shown above by Bob Delisi, seconded by Dan Hoolihan. The motion was approved unanimously.

7. Approval of Scope & Duties: (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®.

A motion to approve the current scope was made by Jeff Silberberg, seconded by Dan Hoolihan and approved unanimously.

A motion to approve the current duties was made by Ed Hare, seconded by Dan Hoolihan and approved unanimously.

7.1 Election of Officers (as required)

A motion to reelect Stephen Berger to chair SC8 was made by Dan Hoolihan, seconded by David Schaefer and approved unanimously.

8. **Working Group reports - Chair** - [More information about each standard](#) is available on the Standards Status Matrix page of the [C63@ web site](#). This information will be reviewed for accuracy at each Subcommittee meeting.

8.1 C63.18: C63.18: On Site Medical Device Immunity Testing

C63.18-2014 Learn more	On-Site Medical Radiated RF Immunity testing	SC 8	Silberberg, Jeffrey	No active PINS	Current. No plans for further maintenance at this time.
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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.

8.2 C63.19: Hearing Aid Compatibility - [Stephen Berger](#)

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.

8.3 C63.33: David Schaefer

It was announced that David Schaefer is stepping down as WG chair.

AI – Stephen Berger took an action item to find a new chair and vice-chair for the C63.33 WG.

It was also announced that a letter has been received by AdvaMed expressing a set of concerns with the C63.33 standard as currently being pursued.

Significant discussion follows that included potential leadership for the C63.33 WG and the how this project fits into existing standards, particularly IEC 60601-1-2 Amendment 1.

Important points discussed were:

- The IEC 60601-1-2 standard has a different approach to risk management than that in ANSI C63.27. The approach used in ANSI C63.33 has yet to be determined.
- It was noted that IEC 60601-1-2 Amendment 1, was passed in 2020, covers down to 134.2 kHz and claims to cover EAS (Electronic Article Surveillance) devices.

- It was also noted that while those involved with C63.33 thought that the PINS received no comments, in fact there were comments. The explanation is that comments were misrouted and did not become known to ANSI C63 until recently.
- It was also reported that all IEC 60601-1's are being integrated into IEC 60601-1 and all part 2's are being revised to reflect the changes in the part 1's. A result of this is that none of the part 1's will be changed until after the process is complete.

Stephen Berger reported on his efforts to open a dialogue with AdvaMed. After discussion he was given the following **Action Items**:

- **Arrange for a telecon with AdvaMed to discuss their concerns with C63.33.**
- **Issue new calls for participation in C63.33, particularly targeting test laboratories and medical device manufacturers and to include the accreditation bodies.**

9. Old Business: Chair

9.1 Written reports – No written reports were submitted

10. New Business: Chair

10.1 FDA Report

Jeff Silberberg gave a verbal report on recent FDA activities.

10.2 IEC Report

Jeff Silberberg gave a verbal report on recent IEC activities.

He noted that the IEC is interested in testing for immunity to 5G devices. This effort focuses on subclause 8.1 table 9, immunity to portable radio equipment.

10.3 Consultations on future of healthcare delivery

11. Review of the Action Items: Secretary

11.1 Review of Action Items from this meeting:

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

11.2 Review of Action Items from previous meeting:

(insert consolidated Action Item table from the previous meeting Minutes as shown below)

Consolidated Action Items from previous Meeting of SC8

Action Item #	Subject	Responsible Person(s)	Status	Delivery Date	Comments

12. Time and place of next meeting: Chair

The next C63 series of meetings will be held in Santa Rosa, CA November 7-11.

The chair announced that the next SC8 meeting will be by Webex in that timeframe.

13. Closing remarks and Adjournment: Chair

The meeting was adjourned by the chair.

***** End of Meeting *****

Consolidated Action Items from today's Meeting of SC8

Action Item #	Subject	Responsible Person(s)	Status	Delivery Date	Comments
1	Have a conference call with AdvaMed regarding the development of ANSI C63.33	S. Berger			
2	Issue a new call for participation in C63.33.	S. Berger			
3	Recruit replacement chair and vice- chair for C63.33.	S. Berger			