Accredited Standards Committee C63®

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

Chair: Stephen Berger **Vice Chair: John Becker**

March 10th , 2021; 9:30 AM – 11:30 AM – EDT

Meeting by WebEx

Meeting Minutes

1. **Call to Order: Chair**
   - **1.1 Opening remarks and Announcements: Chair**
   - **1.2 Introductions: Secretary - 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		Element Materials Technology
Silberberg, Jeffrey L	Member	FDA Center for Devices & Radiological Health
Zimmerman, Dave	Member	Spectrum EMC, LLC

Guests and Observers: (non-voting)

- **2.1 Quorum: (50% of roster + 1) constitutes a quorum.** (rounding down) (**Example**: 11 roster members / 2 = 5.5 + 1 = 6.5 (therefore 6 people are required for a quorum) **Was quorum achieved? (Yes)** If not, any actions taken are subject to confirmation by electronic ballot or at a future meeting. (Quorum is not required for Working Group meetings)

3. **Approval of the Agenda:**

4. **Approval of the previous Minutes –** Minutes of the Dec. 4, 2020 meeting.

5. Review of the patent slides – No issues.

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	5/2/18	11/28/18	5/24/19	11/20/19	09/18/20	12/04/20	3/10/21
Becker, John	X	Web	X			X	
Berger, Stephen	X	Web	X	Web	X	X	X
Case, David	X	Web	X	Web	X	X	X
DeLisi, Bob	X	Web	X	X	X	X	X
Hare, Ed				X			
Hoolihan, Dan	X	Web	X	X			X
Kuczynski, Victor	X	Web	X	Web			X
Liu, Steve	X	Web			X	X	X
Schaefer, David							X
Silberberg, Jeffrey L	X	Web	X	X	X	X	X
Zimmerman, Dave	X	Web	X	Web			X

Any members at risk? These members are at risk:

6.3 Consideration of new members Application for C63® Subcommittee Membership

6.4 Approval of Membership (Spring meeting only)

The membership application of Dave Schafer was unanimously approved.

7. Approval of Scope: (Spring meeting only)

(Report approval or any changes to the Main Committee)

7.1 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 was made and seconded to approve the current scope and duties of SC8 for the next year. The motion passed unanimously.

7.2 Election of Officers (as required)

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 – Jeff Siblerberg

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.

A/I Check and correct summary. Reaffirmed in 2019.

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 maintenance - 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.

On February 16, 2021, the FCC adopted a Report and Order (R&O) in WT Docket No. 20-3 for FCC adoption of ANSI C63.19-2019. There is a two-year transition period. Both the 2011 and 2019 versions of ANSI C63.19 may be used until February 2023. In 2023 the 2019 version of ANSI C63.19 becomes the exclusive standard for evaluating HAC under the FCC rules.

ISED issued RSS-HAC Issue 1 in March 2019, which became effective on publication. The document makes the 2011 version of ANSI C63.19 mandatory on January 1, 2024.

8.3 C63.32: Immunity to EAS Systems - David Schaefer

Dave Schaefer reported that after the PINS for C63.32 was approved a call for volunteers was issued. Approximately 12 people have volunteered to join the working group. However, no EAS manufacturers are represented on the WG and there is a need for more representation of medical device manufacturers.

Dave gave a preliminary estimate that the standard would be ready for ballot in Q32023.

9. Old Business: Chair

9.1 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 either the C63_ PowerPoint template or the C63_PowerPoint_template_wide. Prior to the Main Committee meeting, the SC report and approved previous SC 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® Newsletter editor.

9.2 Status of PINS for C63.32

9.3 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.

9.4 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.

10. New Business: Chair

10.1 FDA Report

The FDA has Issued Draft Guidance on Electromagnetic Compatibility of Medical Devices:

https://content.govdelivery.com/accounts/USFDA/bulletins/2ac323c

The comment period has closed but comments will still be accepted.

10.2 IEC Report

10.3 Consultations on future of healthcare delivery

11. C63.org website use and updates: Secretary - We normally post documents to the SC8 protected area. If any SC or WG needs help with this posting, a Technical Secretary is available to assist.

12. Review of the Action Items: Secretary

12.1 Review of Action Items from this meeting:

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

12.2 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

13. Time and place of next meeting:

The next meeting of the subcommittee will be focused on an exploration of the future of healthcare and healthcare delivery. The chair will explore the possibility of a joint meeting with another relevant committee for this topic, with the meeting time and date to be determined by the chair.

14. Closing remarks and Adjournment: Chair

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

Consolidated Action Items from today's Meeting of SC8

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