Accredited Standards Committee C63®

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

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

May 9, 2022; 2:00 AM – 3:00 AM - CT

Spring Meeting on WebEx

Webex Meeting Minutes

1. **Call to Order: Chair**
   - **1.1 Opening remarks and Announcements: Chair**
   - **1.2 Introductions: roll call**
     Report any roster changes (insert SC8 membership roster from the website as shown below)
   - **1.3 Subcommittee 8 Membership Roster**
     - **1.3.1 Review of** Subcommittee Membership
       - **1.3.1.1 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.

1.3.1.2 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.

Name	Role within SC	Affiliation
Berger, Stephen	Chair	TEM Consulting
Case, David	Member	Consultant
DeLisi, Bob	Member	UL, LLC
Hoolihan, Dan	Member	Hoolihan EMC Consulting
Kuczynski, Victor	Member	Vican Electronics
Liu, Steve	Member	Consultant
Schaefer, David	Member	Element Laboratories
Silberberg, Jeffrey L	Member	FDA Center for Devices & Radiological Health
Zimmerman, Dave	Member	Spectrum EMC, LLC

1.3.2 Guests and Observers: (non-voting)

1.3.3 Quorum

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

1.3.4 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	11/4/22	5/9/23
Berger, Stephen	X	Web	A	X	X	X	X	X	X
Case, David	X	Web	X	X	X	X			
DeLisi, Bob	X	X	A	X	X	X	X	X	
Hoolihan, Dan	X	X	X			X	X	X	
Kuczynski, Victor	X	Web				X			
Liu, Steve			X	X	X	X	X	X	X
Schaefer, David						X	X		
Silberberg, Jeffrey L	X	X	X	X	X	X	X	X	X
Zimmerman, Dave	X	Web	A			X		X	X

Any members at risk? These members are at risk:

1.3.5 Consideration of new members Application for C63® Subcommittee Membership

1.3.6 Approval of Membership (Spring meeting only)

2. Approval of the Agenda: Chair

Dan Hoolihan moved to accept agenda. Motion was seconded by Jeff Silberberg and unanimously approved.

3. Approval of the previous Minutes - Minutes of the previous meeting

November 2022 minutes were previously approved

4. Review of the patent slides

http://www.c63.org/documents/misc/patents/C63_Patent_Call_slideset_final_1.pdf

The patent slides were reviewed.

5. 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®.

6. Election of Officers (as required)

7. 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.

7.1 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.

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.

7.2 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.

Stephen Berger & Steve Liu reported on recent FCC action relevant to HAC and ANSI C63.19.

7.3 C63.33: Stephen Berger

Stephen Berger reported that the C63.33 Working Group is moving ahead actively, meeting every other week. There are three task groups.

Read only copy of standards on Box:
https://app.box.com/s/tv8akgqrjncb3qwbbkdyobk6mgpiuwci

8. Old Business: Chair

8.1 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. New Business: Chair

Jeff Silberberg verbally reported on FDA and IEC activities.

FDA is working with Jason Coder of NIST on test signals for 5G.

MT23 is meeting the week of May 22.

9.1 FDA Report

Jeff Silberberg verbally provided the following FDA report:

FDA and NIST have been working to develop a test signal that can be used to test for immunity to 5G signals. Most of the work had been done by Susanna Mosleh. She had characterized waveforms using a variety of 5G parameters.

Steve Liu said that he had worked with 5G while at Element. He offered to help with the project.

Jeff said he would pass the message along to the investigators.

9.2 IEC Report

Jeff Silberberg verbally provided the following IEC report:

IEC SC62A MT23 (EMC)

Jeff reported that IEC SC62A MT23 would be meeting the week of May 22 in Waupaca, WI to review and respond to the International comments on proposals for two draft technical specifications:

- IEC TS 60601-4-2, Electromagnetic immunity: Performance of medical electrical equipment and medical electrical systems

The purpose of this draft is to convert 60601-4-2:2016 from a technical report to a technical specification and bring it up to date with IEC 60601-1-2:2020.

- IEC TS 60601-4-XX, Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

The purpose of this draft is to provide recommendations for the techniques and measures used in the design, VERIFICATION, and validation of systems, hardware, and software (firmware) used in ME EQUIPMENT or ME SYSTEMS to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the ELECTROMAGNETIC DISTURBANCES that could occur throughout the EXPECTED SERVICE LIFE.

IEC SC77B (High frequency phenomena)

Jeff said that the immunity standards under the jurisdiction of SC77B (e.g., IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-6) are very important to medical devices. He said that in 2023, NEMA resigned as US Technical Advisor to SC77B. This meant that the US EMC experts not on a SC77B working group would not be able to provide US National Comments or ballot recommendations on SC77B standards. He said that fortunately ANSI assumed the Secretariat, John Maas volunteered to be US Technical Advisor for SC77B, and the Technical Advisory Group approved his nomination.

John Maas recently circulated two significant SC77B documents:

- A committee draft (CD) (at which stage comments are invited) of IEC 61000-4-41, Testing and measurement techniques - Broadband radiated immunity test

The draft relates to radiated disturbances posed by broadband signals, for example, due to communication devices or services. It's intended to test for immunity to 4G and 5G and uses pulsed waveforms with white noise modulation.

- An FDIS (the stage just prior to publication) of Edition 5 of IEC 61000-4-6, Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields

Jeff reported on two particular changes made to the standard based on his comments:

o Many medical device manufacturers have misunderstood the phrase "temporary loss of function or degradation of performance" in the Evaluation of the test results clause. They have thought that if a device degrades at some frequencies but not at others while the frequency is being stepped from 150 kHz to 80 MHz, that is a "pass". FDA would then explain the difference between transient phenomena and continuous phenomena and appropriate performance criteria for each type, that any frequency in the range could persist periodically or continuously in the environment. The SC77B working group added a requirement to the standard that "The test results shall be evaluated during the dwell time". This makes the situation clearer and will help with reviews of future medical device submissions. Jeff said that he hoped that a similar requirement could be added to IEC 61000-4-3 the next time it's revised.

o There was a discrepancy in the standard regarding the minimum length of equipment with cables that are subject to the test, and the "start frequency" for e.g., battery-powered equipment. The minimum length based on Figure B.1 has been shown as λ/10, whereas the text specified λ/4 (for a minimum of 1 m). Also, the length of a cable between two pieces of equipment for which they were specified to be one

equipment (such that the cable between them was not tested) was 1 m (based on λ/4). The FDIS now harmonizes each of these specifications with Figure B.1 and λ/10.

10. Review of the Action Items:

10.1 Review of Action Items from this meeting:

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

Action Item #	Subject	Responsible Person(s)	Status	Delivery Date	Comments
1					
2					

10.2 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

11. Time and place of next meeting: Chair

To be announced after dates and time of next C63 meeting is decided.

12. 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
1					
2					