Accredited Standards Committee C63®

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

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

November 4, 2022; 7:00 AM – 8:30 AM - PT

Fall Meeting on WebEx

Webex Meeting Minutes

1. **Call to Order: Chair**
   - **1.1 Opening remarks and Announcements: Chair**
   - **1.2 Introductions: Secretary - roll call**
     Report any roster errors to the ASC-C63® Secretary (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
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

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
Berger, Stephen	X	Web	A	X	X	X	X	X
Case, David	X	Web	X	X	X	X		
DeLisi, Bob	X	X	A	X	X	X	X	X
Hare, Ed		X	X				X	
Hoolihan, Dan	X	X	X			X	X	X
Kuczynski, Victor	X	Web				X		
Liu, Steve			X	X	X	X	X	X
Schaefer, David						X	X	
Silberberg, Jeffrey L	X	X	X	X	X	X	X	X
Zimmerman, Dave	X	Web	A			X		X

AI: Chair to call John Becker regarding membership status.

After the meeting the chair called John. He is withdrawing his membership due to his recent job change and the demands on his time

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

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

4. Review of the patent slides

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.
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.

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. Two have completed their work. The draft is up to 0.6. Progress is hindered by lack of participation by electronic article surveillance (EAS) and metal detector manufacturers.

Jeff Silberberg reported that Howard Bassen, who is retired from the FDA, is doing a great job leading the Simulated Signals Task Group. He would like to be able to get into the FDA lab to make measurements, but FDA is currently not allowing volunteers and has become very strict regarding visitors.

Steve reported that the equipment of interest uses a wide range of field strengths and modulations. He suggested that the first version of the standard could focus on medical devices for which there continue to be reported problems. Maybe focus on neurostimulators.

Dan Hoolihan asked if we have active membership from the medical device industry and the status of the relationship with AdvaMed.

Steve Berger reported that there was participation but not enough. We had phone calls with AdvaMed and AAMI. Members of AdvaMed are participating in the Working Group. There is general consensus on how C63 could make a contribution and not be duplicative, by focusing on test methods and not specifying failure modes.

Jeff said that it was agreed that a test method is needed and to limit the work to that. Product committees could then set their own pass/fail criteria.

Steve reported that while there was no projected date to start a ballot, he would like to see a draft in six to nine months.

Jeff said that FDA has a subscription to ANSI standards, but Howard doesn't have access. Jeff asked about read-only access to C63 standards.

Bob DeLisi provided the following link:

https://app.box.com/s/tv8akgqrjncb3qwbbkdyobk6mgpiuwci

Steve Berger said that the Working Group might need to copy sections of C63 standards.

Dan Hoolihan said that this should be no problem.

Steve Liu asked if the Working Group has talked to the FCC about reported problems with neurostimulators.

Conclusions:

AI – Follow up on FCC involvement in the issue.

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.

Jeffrey Silberberg reported on recent incidents:
https://www.baxter.com/baxter-newsroom/baxter-issues-urgent-medical-device-correction-regarding-potential-radio-frequency

9.1 FDA Report

Jeff Silberberg verbally provided the following FDA report:

Jeff Silberberg reported on a recent EMC recall. The manufacturer's announcement can be found at the following link:

https://www.baxter.com/baxter-newsroom/baxter-issues-urgent-medical-device-correction-regarding-potential-radio-frequency

The electric hospital beds involved in the recall use an RFID system for detecting incontinence. There are four passive RFID chips in a pad on the bed and a reader that interrogates them. The power of the reader is 1 W with a 6 dBi antenna for a total ERP of 4 W. It was reported to interfere with both hospital and wearable infusion pumps, a fetal heart monitor, and telemetry equipment. As long as the bed is powered, the RFID system is active. The recall involves the company sending service engineers to disable the RFID reader. Jeff said that he planned to investigate which versions of IEC 60601-1-2 was used for clearance or approval of the devices that were affected.

Jeff reported that FDA is doing research on use of 5G in medical devices and also has a project with NIST [Jason Coder] to determine whether a 5G test signal is needed for immunity testing of medical devices, to be added to IEC 60601-1-2, and if so, to specify such a signal. Both FDA and NIST have in-house 5G base stations and user equipment. A Holter monitor (ambulatory ECG) was selected as a first test artifact and NIST is currently doing exploratory immunity testing.

Bob DeLisi asked if the results would be published. Jeff said yes.

Jeff reported that he had requested that a CDRH MDR analyst perform an analysis of EMI, ESD, and communication problem MDRs for the first half of CY2022. As in several recent past years, most of the reported problems were communications issues with Dexcom wireless glucose monitoring systems. The sensor typically worked OK with the dedicated wireless receiver provided by Dexcom but often failed to communicate with an app on a smartphone. There were over 7,000 EMI, ESD, and communication problem reports in total for this time period, most of which were reported to be malfunctions. The CDRH EMC experts decided to examine the death reports. There were 14, including one duplicate, for a total of 13. There was one reported to be due to ESD, one reported to be due to EMI, and the rest reported to be communication problems, including one due to a bad Ethernet cable. Examination of the narratives proved mostly inconclusive. Many said that the device had not been returned and/or the manufacturer

reported the information they had as of FDA's reporting deadline. Several promised a follow-up report. Jeff said that he was planning to look into accessing follow-up reports.

Steve Berger asked if the number of reported deaths was higher than in previous years. He showed a bar chart of his data for serious injury and death by year. Dexcom was the most frequent, but there were also increased number of reports over time with St Jude Medical, Medtronic, and Boston Scientific glucose monitoring systems. His data showed the number of reported deaths due to EMI, ESD, and communication problems in CY2021 to be 13.

Jeff said that there are a lot of Dexcom devices in use. However, in general, FDA does not have "denominator" data. The number of problem reports needs to be put in perspective to the number of devices in use.

Steve Berger remarked that most such wireless systems use Bluetooth LE. The band at 2.4 GHz is the most crowded. Difficult to "pull it out."

Jeff reported on FDA's activity on C63.33. He said that three FDA members and one retired FDA member have been working on the project.

He said that a colleague is applying for funding to do research regarding test methods, field strengths, and modulations for use in testing immunity of medical devices to wireless power transfer (WPT) systems.

Jeff said that it has become apparent that current ways of specifying immunity pass/fail criteria and dwell times for infusion pumps might not be adequate, especially when pumping at slow rates and during the IEC 61000-4-3 and IEC 61000-4-6 immunity tests. Flow rates are typically averaged over several hours, which would not reveal whether certain frequencies would affect the devices. He planned to study possible solutions with FDA colleagues.

Jeff mentioned the FDA Accreditation Scheme for Conformity Assessment, which included the IEC 60601 (Basic Safety and Essential Performance) and IEC 61010 series of standards. Testing by ASCA-accredited test labs is intended to expedite clearance/approval with regard to the associated FDA-recognized standards, and a summary test report could be provided instead of a full test report. Biocompatibility testing is also in the ASCA program. Jeff asked SC8 members to let him know if they're aware of anyone using ASCA for IEC 60601-1-2. At this time, his understanding is that not many manufacturers are using ASCA.

9.2 IEC Report

Jeff Silberberg verbally provided the following IEC report:

He reported that Amendment 1 of IEC 60601-1-2 is consolidated with Edition 4.0 to make Edition 4.1 (2020).

He said that IEC Subcommittee 62A Maintenance Team (MT23), the group that maintains 60601-1-2, had submitted two draft technical specifications (TSs) to the Secretary of 62A (Hae Cho of AAMI, the SC62A Secretary) for circulation to the National Committees of the IEC for ballot and comment, which was to occur after any needed editing.

The first draft TS is an update of IEC Technical Report (TR) 60601-4-2:2016, Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems. While the IEC 60601 series is all safety standards, 60601 4 2 is an actual EMC immunity standard. It has no emissions requirements. It requires that the device provide the INTENDED USE, i.e. the performance requirements can be more stringent than 60601 1 2, the immunity test levels are what MT23 considered "typical" and thus lower than those of 60601-1-2. The new draft TS was intended as an update to correspond to Edition 4.1 of 60601-1-2. For example, the Normative References have been updated. The new draft will be proposed as a technical specification due to a change in the IEC rules. IEC TR 60601-4-2:2016 was published as a technical report because at the time, technical specifications had to become a standard within three years or be withdrawn. However,

under the new rules, a technical report cannot make recommendations, whereas a technical specification can, and a technical specification no longer needs to become a standard within three years. There are approximately 110 recommendations in 60601-4-2. While Edition 4.1 of 60601-1-2 adds proximity magnetic fields immunity requirements at 30 kHz, 134.2 kHz, and 13.56 MHz, IEC TS 60601-4-2 does not. This is because when typical separation distances between magnetic field sources and the medical device were taken into consideration, the field strengths were negligible.

The second draft proposed TS is IEC TS 60601-4-XX, Medical electrical equipment - Part 4-XX: Guidance and interpretation – Voluntary guidance to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the possible effects of ELECTROMAGNETIC DISTURBANCES. It is similar to IEEE 1848-2020 and IEC 61000-1-2:2016. It recommends techniques and measures for mitigating the effects that can be caused by ELECTROMAGNETIC DISTURBANCES.

Jeff said that the “stability date” for IEC 60601-1-X standards is 2023. The next edition of IEC 60601-1-2 will be merged into IEC 60601-1, along with the rest of the IEC 60601-1-X standards. The next edition of 60601-1 will be in the form of a database and will not be written in MS Word. Authors will require training to use the new editing tools. The existing working groups will be dissolved and a call for experts will be circulated.

Jeff reported that IEC 60601-1-2 subclause 8.10 specifies immunity requirements in Table 9 for proximity RF fields from portable communication equipment but requires that if transmitters at other frequencies are in use, a risk analysis shall be performed to determine if immunity testing should be performed at the additional frequencies identified. MT23 members reported that some manufacturers appear to ignore the risk analysis requirement, while others are asking for recommendations regarding testing for immunity to 5G. He reported that German MT23 representatives had proposed some additional testing to be added to Table 9 for 5G. Also, an MT23 Co-Convenor is also a Co-Convenor of IEC 77B WG10, which (among other projects) is working on general broadband immunity test methods, including for 5G, which would become IEC 61000-4-41. The draft proposes white noise modulation. MT23 continues to monitor the progress of this draft.

Jeff reported that he had submitted comments on several IEC SC77B standards, including IEC 61000-4-2 (ESD immunity) and IEC 61000-4-6 (conducted RF immunity). He proposed (with permission) adding to 61000-4-2 material from C63.16, including testing of docking stations using charged peripherals. IEC SC77B MT12 contacted Jeff and the IEEE in September 2022 to obtain the necessary letter of permission, so it appears that some of the comments will be accepted.

Jeff submitted a comment on the “Evaluation of test results” clause of IEC 61000-4-6, which discusses “temporary loss of function or degradation”. Many manufacturers mistakenly misinterpret this to include when the test system moves to another frequency step. He asked the MT to add a Note to clarify this. He said that he was hoping to submit a similar comment to the next revision of IEC 61000-4-3 (radiated RF immunity).

9.3 Consultations on future of healthcare delivery

There were no items to discuss.

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	Chair to call John Becker regarding membership status.	S. Berger	Closed	11/8/22	John Becker has resigned his membership.
2	Follow up on FCC involvement in the	S. Berger	Open		

	EAS/MD interference issue.				

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	Chair to call John Becker regarding membership status.	S. Berger	Closed	11/8/22	John Becker has resigned his membership.
2	Follow up on FCC involvement in the EAS/MD interference issue.	S. Berger	Open		