Accredited Standards Committee C63®

Electromagnetic Compatibility

Subcommittee 8 - Medical Device EMC Test Methods

Chair: Stephen Berger **Vice Chair: John Becker** **Secretary: Allen Crumm**

December 4th, 2020; 2:00 PM – 4:00 PM - EDT

Spring Meeting on WebEx

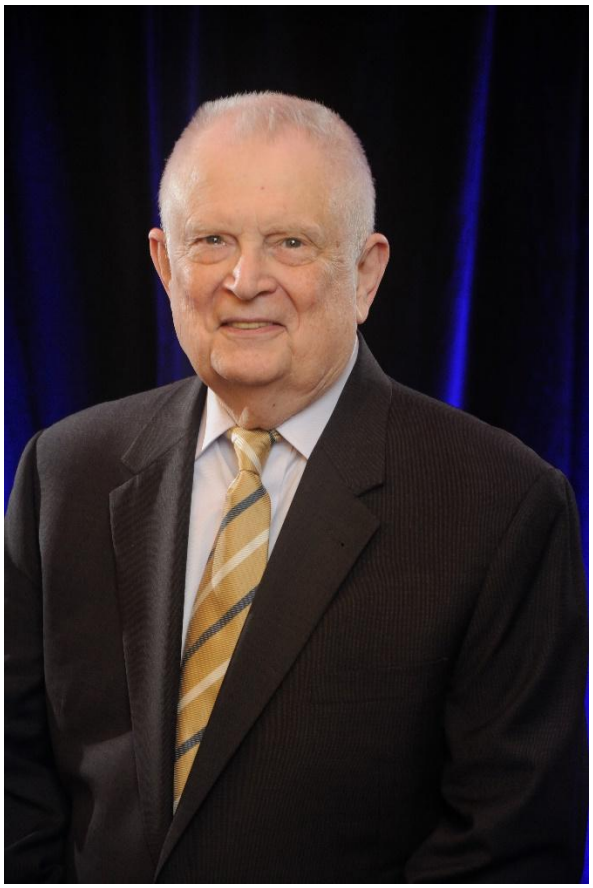
Meeting Minutes

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) Stephen Burger, John Becker, Allen Crumm, Steve Liu, Dan Hoolihan. Dave Case, Jeffrey Silberberg,

1.3 Moment of silence for Don Heirman.



Subcommittee 8 Membership Roster

Name	Role within SC	Affiliation
Becker, John	Vice Chair	Hearing Industries Association
Berger, Stephen	Chair	TEM Consulting
Case, David	Member	Cisco Systems
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, Inc.
Silberberg, Jeffrey L	Member	FDA Center for Devices & Radiological Health
Zimmerman, Dave	Member	Spectrum EMC, LLC

Guests and Observers: (non-voting)

1.4 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)

2. Approval of the Agenda: Chair Steve Liu Motioned, Dave Case 2nd, Approved

2.1 Approval of the previous Minutes - Minutes of the previous meeting (3 missing sets) Jeff Silberberg, Dan H. Approved.

{No minutes need approval at this meeting.}

2.2 Review of the patent slides – No issues.

3. Review of Subcommittee Membership - Secretary – Report any errors to the ASC-C63® Secretary

3.1 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.

Member Attendance Log:

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

Any members at risk? These members are at risk:

3.2 Consideration of new members Application for C63® Subcommittee Membership
3.3 Approval of Membership (Spring meeting only)
A/I – Query Dave Schafer as to status of his application.

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®.

4.1 Election of Officers (as required)

5. 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.

5.1 C63.18: C63.18: On Site Medical Device Immunity Testing – Currently Suspended

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.

5.2 C63.19: Hearing Aid Compatibility maintenance - Stephen Berger

A/I – Stephen to submit New revision of C63.19 to FCC for adoption.

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.

6. Old Business: Chair

Lets add C63.32 above in section 5.

6.1 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.

6.2 Status of PINS for C63.32

6.3 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.

6.4 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.

7. New Business: Chair

Jeffrey gave a verbal report 60601 amendment 1 had been published. New EMC guidance document out for comment. Add URL here. Don Witters is retiring.

8. 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.

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 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

10. Time and place of next meeting: Friday March 12th 2021 - 9:30 AM EST.

After the meeting, a conflict arose with the March 12 date originally set for this meeting. The meeting was moved to March 10.

11. 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

An online version of this form is available at http://psawebforms.ansi.org.

Date:	

This form may be submitted via E-mail to mweldon@ansi.org

PINS: PROJECT INITIATION NOTIFICATION SYSTEM FORM *(Effective 01.01.08)*

*NOTE: Adoptions of an ISO or IEC standards require compliance with the *ANSI Policy Regarding Rights to Nationally Adopt IEC and ISO Standards or Otherwise Use IEC and ISO Material* and with the *ANSI Procedures for the Adoption of ISO and IEC Standards as American National Standards.*

1. Designation of Proposed Standard:	ANSI C63.32	
2. Title of Standard:	American National Standard for Evaluating Immunity of Portable Electronic Medical Devices to Electronic Article Surveillance (EAS) Systems and Metal Detectors	
3. Project Intent: (Check the applicable box below)		
Create new American National Standard (ANS)	X	
*Adopt identical ISO or IEC standard		
*Adopt modified ISO or IEC standard		
***AND** this adoption revises this current ANS		
Revise current ANS		
Revise and Redesignate current ANS		
Revise, Redesignate and Consolidate current ANS		
Revise and Partition current ANS		
Reaffirm current ANS		
Reaffirm and Redesignate current ANS		
Addenda to a current ANS under Continuous Maintenance: (this document relates to/updates the following base document that is registered under Continuous Maintenance)		
Supplement to current ANS		
Withdraw current ANS		
Maintain ANS under stabilized maintenance		
4. This standard contains excerpted text from an ISO or IEC standard, but is not an ISO or IEC adoption.		Check here if this standard includes excerpted text from an ISO or IEC standard but is not an identical or modified adoption of an ISO or IEC standard.
5. Provide a brief explanation of the need for the project *(see 2.5 of the ANSI Essential Requirements)*:	The proliferation of portable electronic medical devices and their potential proximity to electronic article surveillance systems in retail environments and metal detectors in security applications creates the need to evaluate the performance of medical devices when exposed to these electromagnetic fields	
6. Identify the stakeholders (e.g., telecom, consumer, medical, environmental, etc.) **likely to be directly impacted by the standard** *(see 2.5 of the ANSI Essential Requirements)*:	EAS system manufacturers Metal detector manufacturers Medical device manufacturers Test labs, Regulators	
7. Unit of Measure: Non Applicable, US, Metric, or Both		

8. This PINS revises a previous PINS submittal *(see 2.5 of the ANSI Essential Requirements)*:		Note: A revised PINS is only required if the previously identified stakeholders have changed substantively (see item 6 on this form.).
9. Description of Contents of Standard: (Provide a one paragraph description, not to exceed 500 characters. Please note in the scope if this standard is intended to be submitted for consideration as an ISO or ISO/IEC JTC-1 standard.)		Test methods and immunity test levels for testing immunity of portable electronic medical devices to EAS systems and metal detectors, using actual EAS systems and metal detectors or simulated signals. Information on incorporation of results into risk management.
10. Request an Announcement in Standards Action to Solicit New Consensus Body Members (Note that participants from diverse interest categories shall be sought with the objective of achieving balance. See 1.3 and 2.3 of the *ANSI Essential Requirements*.)		Check here to request the publication in Standards Action of a call for membership on the relevant consensus body.
11. Consumer Product or Service:		Check here if standard covers Consumer Product or Service
12. Accredited Standards Developer Acronym:		
13. Submitter: (Specify Accredited Standards Developer submitter's name and complete contact information, address, phone, email, etc.)	Name:	David Schaefer
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