



# Accredited Standards Committee C63®

## Electromagnetic Compatibility

### Subcommittee 8 - Medical Device EMC Test Methods

Chair: Stephen Berger

Vice Chair: John Becker

Secretary: Allen Crumm

September 18th, 2020; 2:30 PM – 3:30 PM - EDT

Spring Meeting on WebEx

### Meeting Agenda

1. **Call to Order: Chair** – The meeting was called to order at 2:30pm EDT.
  - 1.1 **Opening remarks and Announcements: Chair** – Stephen welcomed everyone and thanked them for attending.
  - 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 Berger, Allen Crumm, Boob Delisi, Dave Case, Jeffery Silberberg, Steve Liu Absent Don Heirman Guests: Dave Schaffer, Pao Thao

### Subcommittee 8 Membership Roster

Name	Role within SC	Affiliation
<a href="#">Becker, John</a>	Vice Chair	Hearing Industries Association
<a href="#">Berger, Stephen</a>	Chair	TEM Consulting
<a href="#">Case, David</a>	Member	Cisco Systems
<a href="#">DeLisi, Bob</a>	Member	UL, LLC
<a href="#">Hare, Ed</a>	Member	ARRL
<a href="#">Heirman, Don</a>	Member	Don HEIRMAN Consultants
<a href="#">Hoolihan, Dan</a>	Member	Hoolihan EMC Consulting
<a href="#">Kuczynski, Victor</a>	Member	Vican Electronics
<a href="#">Liu, Steve</a>	Member	PCTEST Engineering Laboratory LLC
<a href="#">Silberberg, Jeffrey L</a>	Member	FDA Center for Devices & Radiological Health
<a href="#">Zimmerman, Dave</a>	Member	Spectrum EMC, LLC

Guests and Observers: (n

- 1.3 **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?** **(No)** 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 Dave Case Motioned, Jeffery Silberberg 2<sup>nd</sup>.**  
Approved.

- 2.1 **Approval of the previous Minutes – Done by email**

{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 Send Victor an email.**

**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	11/8/17	5/2/18	11/28/18	5/24/19	11/20/19	06/17/20	09/18/20
<a href="#">Becker, John</a>	X	X	Web	X		X	
<a href="#">Berger, Stephen</a>	X	X	Web	X	Web	A	X
<a href="#">Case, David</a>	Web	X	Web	X	Web	X	X
<a href="#">DeLisi, Bob</a>	X	X	Web	X	X	A	X
<a href="#">Hare, Ed</a>					X	X	
<a href="#">Heirman, Don</a>	X	X	Web	X	Web	A	A
<a href="#">Hoolihan, Dan</a>	X	X	Web	X	X	X	
<a href="#">Kuczynski, Victor</a>		X	Web	X	Web		
<a href="#">Liu, Steve</a>	X	X	Web			X	X
<a href="#">Silberberg, Jeffrey L</a>	Web	X	Web	X	X	X	X
<a href="#">Zimmerman, Dave</a>	X	X	Web	X	Web	A	

**Any members at risk?** Send Victor an email.

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

**3.3 Approval of Membership (Spring meeting only)**

**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 <a href="#">Learn more</a>	On-Site Medical Radiated RF Immunity testing	SC 8	<a href="#">Silberberg, Jeffrey</a>	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.

#### 5.2 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.

#### 6. Old Business: Chair

**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 – Appointed Dave Schaffer as chair.**

**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**

**8. [C63.org](http://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 on 6/17/2020.**

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

**10. Time and place of next meeting: December 4<sup>th</sup>, 2020 2:00pm EST.**

**11. Closing remarks and Adjournment: Chair EDT.**

\*\*\*\*\* 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	:	
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This form may be submitted via E-mail to [mweldon@ansi.org](mailto: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*.

<b>1. Designation of Proposed Standard:</b>	ANSI C63.32	
<b>2. Title of Standard:</b>	<div style="border: 1px solid black; height: 20px; width: 100%;"></div> American National Standard for Evaluating Immunity of Portable Electronic Medical Devices to Electronic Article Surveillance (EAS) Systems and Metal Detectors	
<b>3. Project Intent:</b> (Check the applicable box below)		
Create new American National Standard (ANS)	<input checked="" type="checkbox"/>	
*Adopt identical ISO or IEC standard	<input type="checkbox"/>	
*Adopt modified ISO or IEC standard	<input type="checkbox"/>	
<b>*AND</b> this adoption revises this current ANS	<input type="checkbox"/>	
Revise current ANS	<input type="checkbox"/>	
Revise and Redesignate current ANS	<input type="checkbox"/>	
Revise, Redesignate and Consolidate current ANS	<input type="checkbox"/>	
Revise and Partition current ANS	<input type="checkbox"/>	
Reaffirm current ANS	<input type="checkbox"/>	
Reaffirm and Redesignate current ANS	<input type="checkbox"/>	
Addenda to a current ANS under Continuous Maintenance: (this document relates to/updates the following base document that is registered under Continuous Maintenance)	<input type="checkbox"/>	
Supplement to current ANS	<input type="checkbox"/>	
Withdraw current ANS	<input type="checkbox"/>	
Maintain ANS under stabilized maintenance	<input type="checkbox"/>	
<b>4. This standard contains excerpted text from an ISO or IEC standard, but is not an ISO or IEC adoption.</b>	<input type="checkbox"/> 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.	
<b>5. Provide a brief explanation of the need for the project</b> (see 2.5 of the <i>ANSI Essential Requirements</i> ):	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	
<b>6. Identify the stakeholders</b> (e.g., telecom, consumer, medical, environmental, etc.) <b>likely to be directly impacted by the standard</b> (see 2.5 of the <i>ANSI Essential Requirements</i> ):	EAS system manufacturers Metal detector manufacturers Medical device manufacturers Test labs, Regulators	
<b>7. Unit of Measure: Non Applicable, US, Metric, or Both</b>		

<b>8. This PINS revises a previous PINS submittal</b> (see 2.5 of the <i>ANSI Essential Requirements</i> ):	Note: A revised PINS is only required if the previously identified stakeholders have changed substantively (see item 6 on this form.).
<b>9. Description of Contents of Standard:</b> (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.
<b>10. Request an Announcement in Standards Action to Solicit New Consensus Body Members</b> (Note that participants from diverse interest categories shall be sought with the objective of achieving balance. See 1.3 and 2.3 of the <i>ANSI Essential Requirements</i> .)	Check here to request the publication in Standards Action of a call for membership on the relevant consensus body.
<b>11. Consumer Product or Service:</b>	Check here if standard covers Consumer Product or Service
<b>12. Accredited Standards Developer Acronym:</b>	
<b>13. Submitter:</b> (Specify Accredited Standards Developer submitter's name and complete contact information, address, phone, email, etc.)	Name: David Schaefer
	Title: EMC Operations Manager
	Organization: Element Materials Technology
	Address: 9349 W. Broadway Ave
	City, ST, Zip: Brooklyn Park, MN 55445
	Phone: 612-638-5136
	Fax:
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