# Accredited Standards Committee C63<sup>®</sup> Electromagnetic Compatibility

Accredited by the American National Standards Institute, Inc. Secretariat: Institute of Electrical and Electronic Engineers, Inc.

C63<sup>®</sup> SC8 - Medical Device EMC Test Methods APPROVED MINUTES of the May 2, 2018 meeting IEEE Headquarters Piscataway, NJ

Chairman: Stephen Berger, <a href="mailto:stephen.berger@jeee.org">stephen.berger@jeee.org</a>
Vice-Chair: Steve Whitesell, <a href="mailto:swhitesell@jeee.org">swhitesell@jeee.org</a>
Secretary: Allen Crumm, <a href="mailto:acrumm1@outlook.com">acrumm1@outlook.com</a>

#### Attendance:

| Member's Name   | Member's Role on SC8  | Present                         | Absent |
|---|---|---------------------------------|--------|
| Becker, John  | Member  | Х                               |        |
| Berger, Stephen   | Chair   | Х                               |        |
| Case, David   | Member  | Х                               |        |
| DeLisi, Bob   | Member  | Х                               |        |
| Hare, Ed  | Member  | Х                               |        |
| Heirman, Don  | Member  | Х                               |        |
| Hoolihan, Dan   | Member  | Х                               |        |
| Kuczynski, Victor   | Member  | Х                               |        |
| Liu, Steve  | Member  | Х                               |        |
| Moongilan, Dheena   | Member  | Х                               |        |
| Silberberg, Jeffrey L   | Member  | Х                               |        |
| Whitesell, Steve  | Vice-Chair  | Х                               |        |
| Zimmerman, Dave   | Member  |                                 | Х      |
|   |   |                                 |        |
| Names   | Observers only below this line.   |                                 |        |
| Jerry Ramie   | Observer  | Х                               |        |
| JC Chen   | Observer  | Х                               |        |
| 00011011  | 00001101  |                                 |        |
| Randy Long  | Observer  | Х                               |        |
|   |   |                                 |        |
| Randy Long  | Observer  | Х                               |        |
| Randy Long<br>Henry Benitez   | Observer Observer   | X<br>X<br>X                     |        |
| Randy Long Henry Benitez Bill Hurst   | Observer Observer - Webex   | X<br>X<br>X                     |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff  | Observer Observer - Webex Observer  | X<br>X<br>X<br>X<br>X           |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff Doug Kramer  | Observer Observer - Webex Observer Observer   | X<br>X<br>X<br>X<br>X           |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff Doug Kramer Harry Hodes  | Observer Observer - Webex Observer Observer Observer Observer   | X<br>X<br>X<br>X<br>X<br>X      |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff Doug Kramer Harry Hodes Ross Carlton                             | Observer Observer - Webex Observer Observer Observer Observer Observer Observer                             | X<br>X<br>X<br>X<br>X           |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff Doug Kramer Harry Hodes Ross Carlton Keith Skoglund              | Observer                   | X<br>X<br>X<br>X<br>X<br>X      |        |
| Randy Long Henry Benitez Bill Hurst Bill Graff Doug Kramer Harry Hodes Ross Carlton Keith Skoglund John Norgard | Observer | X<br>X<br>X<br>X<br>X<br>X<br>X |        |

- 1. Call to Order: Chair, Stephen Berger called the meeting to order.
  - 1.1 **Opening remarks and announcements:** Chair, Stephen Berger, welcomed those in attendance and set up the web meeting.
  - 1.2 **Introductions:** The chair asked for introductions. Everyone around the table introduced themselves and their affiliation. A sign-in sheet was sentaround the room.
- **2. Approval of the Agenda:** Chair, Stephen Berger, reviewed the agenda. A motion was made to adopt the agenda. A vote was taken, and the motion passed.
- **3. Presentation of** <u>patent slides</u>: Chair, Stephen Berger, showed the slides regarding IEEE patent policy. Chair, Stephen Berger, went over the content of the slides and an opportunity was given to the subcommittee members to identify/disclose patents.
- **4. Approval of minutes of previous meeting:** The minutes were reviewed. David Case made a motion to approve the minutes as amended, and Jerry Ramie seconded the motion. The minutes were approved by consent, hearing no objection.
- **5. Meeting attendance & Membership:** Chair, Stephen Berger, announced that two members, Poul Anderson and Andy Griffith, have been removed due to inactivity. John Becker has joined the SC since the last meeting.
- 6. Working Group reports:
  - **6.1 C63.18:** Currently suspended.
  - **6.2** C63.19: Steve Berger gave a verbal report regarding a good meeting that was held on C63.19. More information about each standard is available on the Standards Status section of the C63<sup>®</sup> web page.
- 7. Old Business: There was no old business discussed.
- **8.** New Business: Chair, Stephen Berger, asked if there was any new business.
  - **8.1 Medical device manufacturers:** A task group was appointed to solicit participation by medical device manufacturers.
  - **8.2 FDA EMC Activities Report:** Jeff Silberberg gave a report.
  - **8.3 IEC SC62A MT23 Liaison Report:** Jeff Silberberg gave a report.

**9. Action Items:** The open action items from the previous meeting are shown below.

| Action | Subject  | Responsible     | Status | Deliverable     | Comments |
|--------|--|-----------------|--------|-----------------|----------|
| Item#  |  | Person          |        | Date            |          |
| AI-1:  | Review and send updates on the website to Jerry Ramie with the most current information. | David Zimmerman | Closed | 1 January 2018  |          |
| AI-2:  | Send e-mail to at risk members, Poul<br>Andersen, Andy Griffin, and Ed Hare.             | David Zimmerman | Closed | 1 December 2017 |          |
| AI-3:  | Put Stephen Berger in touch with Curt Sponberg.  | Jeff Silberberg | Closed | 1 January 2018  |          |
| AI-4:  | Update the reflectors for SC8 and C63.19 on the website.                                 | Stephen Berger  | Closed | 1 January 2018  |          |

- **10. Time and place of next meeting:** The proposed date of the next SC8 meeting is during the dates of November 26-30, 2018 prior to the main committee meeting. The next meeting will be held in Boulder, CO.
- 11. Closing remarks and Adjournment: Chair, Stephen Berger adjourned the meeting.

### **Current SC8 Membership**

| #  | Name                  | Role within Subcommittee 8 | Affiliation / Financial Support              |
|----|-----------------------|----------------------------|--|
| 1  | Becker, John          | Member                     | HIA  |
| 2  | Berger, Stephen       | Chair                      | TEM Consulting                               |
| 3  | Case, David           | Member                     | CISCO  |
| 4  | DeLisi, Bob           | Member                     | UL, LLC                                      |
| 5  | Hare, Ed              | Member                     | ARRL   |
| 6  | Heirman, Don          | Member                     | Don HEIRMAN Consultants                      |
| 7  | <u>Hoolihan, Dan</u>  | Member                     | Hoolihan EMC Consulting                      |
| 8  | Kuczynski, Victor     | Member                     | Vican Electronics                            |
| 9  | Liu, Steve            | Member                     | PCTEST Engineering Laboratory, Inc.          |
| 10 | Moongilan, Dheena     | Member                     | Nokia  |
| 11 | Silberberg, Jeffrey L | Member                     | FDA Center for Devices & Radiological Health |
| 12 | Whitesell, Steve      | Vice Chair                 | Whitesell Consulting, LLC                    |
| 13 | Zimmerman, Dave       | Secretary                  | Spectrum EMC, LLC                            |

The members highlighted in red have been removed from the membership roster. The members highlighted in yellow are at risk.

# C63®

### **Accredited Standards Committee C63®**

#### **Electromagnetic Compatibility**

**Subcommittee 8 - Medical Device EMC Test Methods** 

Chair: Stephen Berger Vice Chair: Steve Whitesell Secretary: Allen Crumm

May 02, 2018; 10:00 AM - 12:00 PM - EDT

IEEE Headquarters Piscataway, NJ

#### **Meeting Agenda**

1. Call to Order: Chair

1.1 Opening remarks and Announcements: Chair

1.2 Meeting logistics announcements: Host

1.3 Introductions: Secretary - roll call (record attending members with their affiliations and guests separately below) Report any roster errors to the ASC-C63<sup>®</sup> Secretary (insert <u>SC8 membership roster</u> from the website as shown below)

#### Subcommittee 8 Membership Roster

| #  | Name                  | SC Role    | Affiliation                                  |
|----|-----------------------|------------|--|
|    | Andersen, Poul        | Member     | SAE - Alternate                              |
| 1  | Becker, John          | Member     | Starkey                                      |
| 2  | Berger, Stephen       | Chair      | TEM Consulting                               |
| 3  | Case, David           | Member     | Cisco Systems                                |
| 4  | DeLisi, Bob           | Member     | UL, LLC                                      |
|    | Griffin, Andy         | Member     | CISCO Systems                                |
| 5  | Hare, Ed              | Member     | ARRL   |
| 6  | Heirman, Don          | Member     | Don HEIRMAN Consultants                      |
| 7  | Hoolihan, Dan         | Member     | Hoolihan EMC Consulting                      |
| 8  | Kuczynski, Victor     | Member     | Vican Electronics                            |
| 9  | Liu, Steve            | Member     | PCTEST Engineering Laboratory, Inc.          |
| 10 | Moongilan, Dheena     | Member     | Nokia  |
| 11 | Silberberg, Jeffrey L | Member     | FDA Center for Devices & Radiological Health |
| 12 | Whitesell, Steve      | Vice Chair | Whitesell Consulting LLC                     |
| 13 | Zimmerman, Dave       | Member     | Spectrum EMC, LLC                            |

- 2. Approval of the Agenda
- 3. Review of the patent slides
- 4. Results of Pre-Meeting E-Mail Ballot

#### 4.1 Approval of the previous Minutes - Minutes of the previous meeting

**Review of Subcommittee Membership** 

Report any errors to the ASC-C63<sup>®</sup> Secretary

#### 4.2 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                  | 11/10/16 | 5/10/17 | 11/8/17 | 5/2/18 |
|-----------------------|----------|---------|---------|--------|
| Andersen, Poul        |          |         |         |        |
| Becker, John          |          |         | X       |        |
| Berger, Stephen       | Х        | Х       | Х       |        |
| Case, David           |          |         | Web     |        |
| DeLisi, Bob           |          | X       | Χ       |        |
| Griffin, Andy         |          |         |         |        |
| Hare, Ed              |          |         |         |        |
| Heirman, Don          | Х        |         | Х       |        |
| Hoolihan, Dan         | Х        | X       | X       |        |
| Kuczynski, Victor     | Х        | X       |         |        |
| Liu, Steve            |          |         | Х       |        |
| Moongilan, Dheena     |          | Х       | X       |        |
| Silberberg, Jeffrey L | Х        | Х       | Web     |        |
| Whitesell, Steve      |          |         | Web     |        |
| Zimmerman, Dave       | X        | X       | X       |        |

#### **4.3 Consideration of new members** Application for C63® Subcommittee Membership

### **4.4 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®.

## 5. Working Group reports - Chair - More information about each standard is available on the Standards Status Matrix page of the C63® web site.

#### 3.1 C63.18: On Site Medical Device Immunity Testing – No active work.

| C63.18- | On-Site Medical  | <u>SC 8</u> | Silberberg,    | No     | Current. No plans for  |
|---------|------------------|-------------|----------------|--------|------------------------|
| 2014    | Radiated RF      |             | <u>Jeffrey</u> | active | further maintenance at |
| Learn   | Immunity testing |             |                | PINS   | this time.             |
| more    |                  |             |                |        |                        |

### 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:** <u>IEEE Store</u>. 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.

#### 3.2 C63.19: Hearing Aid Compatibility maintenance - Stephen Berger

| C63.19-     | EMC for Hearing | <u>SC 8</u> | Berger, | C63.19 | Current. New revision |
|-------------|-----------------|-------------|---------|--------|-----------------------|
| 2011        | Aids,           |             | Stephen | PINS   | being developed.      |
| Learn       |                 |             | -       |        |                       |
| <u>more</u> |                 |             |         |        |                       |

### 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. Other 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 the <u>PowerPoint template</u>. Prior to the Main Committee meeting, the <u>SC report</u> and <u>approved previous meeting minutes</u> 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<sup>®</sup> <u>Newsletter editor</u>.
- **6.2** 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.
- **6.3** 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
- 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 Report of Action Items from previous meeting
- 10. Time and place of next meeting: Chair
- 11. Closing remarks and Adjournment: Chair