

ASC C63[®] SC 8: Medical Devices

Minutes for Wednesday, October 27, 2010

SAE Headquarters, Troy, Michigan

The following individuals (* indicates a member of SC8) were present:

Bob DeLisi*, Chair
Dan Hoolihan*, Acting Secretary
Steve Whitesell*
Bill Hurst*
Don Heirman*
Jeff Silberberg*
Stephen Berger*
David Dzumba*
Victor Kuczynski*
Ralph Showers*
H. R. (Bob) Hofmann*
Ed Hare*
Dheena Moongilan*
James Turner*
Dennis Camell
Ken Joyner
Masud Attayi
Janet O'Neil
Jerry Ramie

1 Call to order

The meeting was called to order at 1515 hours by Bob DeLisi, SC8 Chair. Mr. Hoolihan agreed to be acting secretary for the meeting. The meeting logistics were explained by Chairman DeLisi. Self-Introductions were done; nineteen individuals were present at the meeting including 14 members of SC8.

2 Approval of the Agenda

At the request of various members, the following item was added to the draft agenda previously circulated to the subcommittee by email:

- IEC SC62A MT23 activities – Silberberg

A Motion was made by Mr. Hare to adopt the revised Agenda. The Motion was seconded and unanimously approved.

3 Presentation of patent slides

The Patent Slides were reviewed for the attendees by Mr. DeLisi. No questions or comments were raised by the attendees of the meeting.

4 Presentation of meeting attendance fee slides

The meeting fees for the C63 meetings and membership were reviewed by Mr. DeLisi.

5 Approval of minutes of previous meeting

The Minutes of the previous meeting were reviewed. At the request of Mr. Silberberg, several typographical errors in the draft minutes of April, 2010 were corrected. On a motion by Mr. Hare, seconded by Mr. Hoolihan, the modified draft minutes were approved.

6 Review of Subcommittee membership

No new members were announced or proposed.

7 Working group reports

- 7.1 C63.18: Mr. Silberberg gave a verbal report on the status of C63.18. Mr. Silberberg reported that a third recirculation will take place shortly. Response to comments were completed on 10/27/10. Revisions to the latest DRAFT were completed on 10/26/10.
- 7.2 C63.19: Mr. Berger provided a verbal report on C63.19. He presented a PINS-C for approval. See attached. Ed Hare Moved to approve the PINS-C, seconded by Hofmann. Motion was approved on a voice vote. Mr. Dzumba moved to Amend the Motion to remove the words "emerging technologies." Seconded by Mr. Turner. After some discussion, Hoolihan moved to table the Motion to Amend the PINS-C. Motion was seconded; the hand-vote was 7 in favor and 5 opposed. Motion passed. The Chair of SC8 the appointed an editing committee of Mr. Berger, Mr. Turner, and Mr. Dzumba, The editing committee met for approximately 15 minutes and, with the help of Mr. Hurst from the FCC, arrived at a reworded PINS-C, especially in section 5. Mr. Hoolihan then moved to place the Motion to Amend back on the table. The Motion was seconded and unanimously approved. The Chair of SC8 then asked for discussion on the Motion to Amend the PINS-C. Hearing no requests for additional discussion, the Chair asked for a vote. The Motion to Amend the PINS-C (see amended PINS-C) was unanimously approved.

8 Other old business

No "Other Old Business" was reported by Chairman DeLisi.

9 New business

- 9.1 Vice Chair position: The Chair announced that he had appointed Steve Berger as Vice-Chair of the Subcommittee.
- 9.2 Working Group officers: The Chair requested volunteers for open officer positions in the Working Groups of SC8.
- 9.3 AAMI liaison to SC8: Mr. Heirman presented a report on the AAMI/SC8 liaison. He also reported that the recently published AAMI TIR 18 references C63.18 numerous times.
- 9.4 FDA: Mr. Silberberg presented the FDA report. See the attached documentation for the entire report. Mr. Silberberg did stress a new relationship with the University of Oklahoma in Tulsa; they and the FDA will be developing a strategy on wireless coexistence. Specifically, "they will be providing assistance in developing a wireless coexistence test method for medical devices."
- 9.5 IEC SC62A MT23: Mr. Silberberg also presented a status report on Maintenance Team 23 of the IEC SC 62A. As a result of the last negative ballot on 60601-1-2, the MT developed a questionnaire (62A/700/Q) which was distributed to the National Committee members of the IEC. The results were compiled in 62A/722/RQ; 217 comments were received. The next goal is to circulate CD2 of 60601-1-2 in early 2011. Jeff asked for help from C63 on validating some of the present and proposed test methods in 60601-1-2.

9.6 New work proposal: Mr. Silberberg expressed an interest in exploring whether C63® SC8 might be interested in working on a recommended practice for the wireless coexistence testing that was discussed under 9.4.

10 C63.org website use and updates

The web site was discussed. Thanks and compliments were given to Ed Hare for his improvements on the web page.

11 Review of the action items from previous meetings

There were no Action Items to review.

12 Time and place of next meeting

The next meeting will be held in ETS- Lindgren's facility in Texas. The date is May 4, 2011.

13 Closing remarks and adjournment

The Chair thanked all the attendees for their participation and closed the meeting.