ASC C63 SC 8: Medical Device EMC
Minutes for Wednesday, October 7, 2008; 8:00 AM
Piscataway NJ

The following SC8 members were present:

Joe Morrissey, SC-8 Chairman	**Motorola**	
Bob DeLisi, SC8 Vice Chair	**UL**	**Robert.v.delisi@us.ul.com**
Steve Berger, WG3 chairman	**Ind Consultant**	**stephen.berger@ieee.org**
Victor Kuczynski	**Vican Elecronics**	**vican@on.aibv.com**
Mike Windler	**UL**	**michael.j.windler@us.ul.com**
Linda Kozma-Spytec	**Gallaudette**	**Linda.kozma@tap.gallaudet.edu**
Jeff Silberberg	**FDA**	**jeffrey.silberberg@fda.hhs.gov**
Jim Turner	**ATIS**	**jturner@atis.org**
David Case	**Cisco**	**davecase@cisco.com**
George Hirvela	**ATT**	**george.hirvela@att.com**
Daoud Attayi	**RIM**	**dattayi@rim.com**
Steve Coston	**SonyEricsson**	**steve.coston@sonyericsson.com**
Steve Whitesell	**TIA**	**swhitesell@vtech.ca**
Ralph Showers	**Ind Consultant**	**showers@seas.upenn.edu**
Don Witters	**FDA**	**donald.witters@fda.hhs.gov**
Poul Andersen	**SAE**	**anderpoul@comcast.net**
Colin Brench	**SWRI**	**colin.brench@ieee.org**
Dennis Camell	**NIST**	**camell@nist.gov**
Steve Julstrom	**Etymotic**	**sjulstrom@comcast.net**
Dave Preves	**Starkey**	**dpreves@aol.com**
Bob Hofmann	**Ind Consultant**	**hrhofmann@att.net**
Tom Knipple	**Motorola**	**tom.knipple@motorola.com**

The following members were absent:

Don Heirman, ANSI ASC C63® Chair	Ind Consultant	d.heirman@ieee.org

Dan Hoolihan	Ind Consultant	danhoolihanemc@aol.com
Ed Hare	AARL	w1rfi@arrl.org
Herb Mertel	Ind Consultant	hmertel@sbcglobal.net
Jag Nadakuduti	Motorola	EJN026@motorola.com
Dheena Moongilan	Alcatel / Lucent	moongilan@lucent.com
Werner Schaefer	Cisco	wsemc@cisco.com
Paul Cardinal	RIM	pcardinal@rim.com
Harry Levitt	NYU	harrylevitt@earthlink.net
Mike Violette	ACIL	mikev@wll.com
Richard Worley		
Bill Hurst	FCC	william.hurst@fcc.gov
Matt Bakke	Gallaudett	matthew.bakke@gallaudet.edu
Daniel Ahlers	Nokia	danield.ahlers@nokia.org
Bill Stumpf	DLS Elect Syst	bstumpf@dlsemc.com
Masud Attayi	RIM	mattayi@rim.com
Bob Jenkins	Welch Allyn	bjenkins@monitoring.welchallyn.com
Tom Victorian	Starkey	tom_victorian@starkey.com
Kendra Green	Samsung	kgreen@sta.samsung.com
David Zimmerman	TUV America	dzimmerman@tuvam.com

The following guests observed the meeting:

The following IEEE staff were present:

Meeting Minutes:

1. was called to order at 8:00 AM by the Subcommittee 8 Chairman
2. The agenda and minutes from the last meeting were approved

3. Patent and membership fees were presented
4.
5. WG-1 report
    a. Jeff Silberberg reported on an EMI test using RFID readers on medical devices performed by TNO in the Netherlands using the current edition of C63.18. Comments on the study were made by the RFID industry in a letter to be sent to JAMA. JS reported some concern regarding their description of ANSI C63.18.
    b. Action Item – Jeff Silberberg, Joe Morrissey, and Steve Berger will form a task group and craft language to present to the steering committee to decide whether an E-mail should be sent to the RFID industry (task group to identify the correct RFID group that would receive the letter).

6. WG-3 report was made by Steve Berger (WG# meeting held the prior day)
    a. WG#3 meeting minutes will be posted on ASC C63® website. NOTE: These should be included as an attachment to the SC8 meeting minutes for members of SC8 who are not part of WG3.
    b. WG3 identified a Task group to develop new chapter in the standard (ANSI C63.19) on interference potential of new technologies. Motion from WG3: "**Move to develop a new chapter for the standard to address the interference potential of new technologies and not require testing of products that do not have a significant potential for interference**". Motion passed unanimously. Task group members are Dave Case, Joe Morrissey, Dave Preves, Stephen Berger, Steve Julstrom
    c. WG3 also identified a Task group to develop a generalized test method. Motion from WG3: "**Move to develop a test procedure in Clause 4 to implement a generalized test method, but leave the current method unchanged in the document. The new method would apply to new RF technologies, not presently included in the current AWF table**." Motion passed. Task group members are Joe Morrissey, Dave Preves, Scott Isabelle, Steve Julstrom, Stephen Berger
    d.
7. A discussion on polling / consensus procedures for the subcommittee was held with no agreed procedure. The SC8 chair closed the discussion and took an Action Item to present this to the main committee and suggest that polling / consensus procedures should be developed as recommendations for all subcommittees and their WGs.
8. A motion to form a balloting group in the main committee was made by Steve Berger for the next revision to C63.19 (to allow inclusion of the members of the balloting group for data distribution to keep them informed of data and studies). The motion was defeated 4 to 6. George Hirvela asked for his negative vote to be recorded.
9. Presentations:

a. HIA presentation – Dave Preves describe a study comparing GTEM vs dipole testing of hearing aid immunity to confirm prior data from Delta Labs and validate correlations between the two methods
b. NIDRR / Gallaudet / FDA presentation - S. Julstrom and L. Kozma-Spytek gave an update on their research comparing GTEM and dipole measurements of HA immunity. They will also examine cochlear implant wearers using subjective responses in the presence of noise recorded from wireless devices illuminating a certain hearing aid.
c. HEI research update - Joe Morrissey provided an update on the study at the House Ear Institute. Data has been generated but not released by the funder (wireless industry). It will hopefully be released and presented by the next conference call
d. ATIS AISP.4 update was given by Jim Turner and included the recent filing with the FCC.

10. Liaison reports:
    a. Jeff Silberberg gave a report on IEC SC62A Maintenance Team 23 – Medical device standards will address safety with regard to electromagnetic disturbances and performance (EMC) in separate subclauses of the same document. The 4th Edition of IEC 60601-1-2 will point to the safety related aspects only. A near field test method is being proposed in the next edition in addition to standard accepted tests. Looking to have a CD by March 2009.
    b. Don Heirman provided a report on AAMI EMC Committee Report – Managing RF in healthcare environments ballot document is almost ready for circulation.
    c. Jeff Silberberg also reported on the activities of the FDA – There is a lot of focus on RFID at the time with related fields being drug authentication. The CDRH is cautioning about the use of high power readers in the medical environment. FDA has a recall going on of a blood pump due to EMC related effects due to electrosurgical units. FDA issued a public health advisory - X-ray photons from CT machines are creating photoelectrons in pacemakers/external infusion pumps. If a CT dwells over the implant it can cause issues to the implant creating a hazard. FDA issued guidance for wireless medical devices for public comment. Public comments are still being addressed prior to release of the revised formal document. FDA is working on recognizing AAMI 60601-1 (safety standard). Guidance document has been generated but not released. The FDA only plans to recognize the AAMI version since there are US national deviations. Webinar scheduled for December 4 will address 3rd and 4th editions of 60601-1-2.

d. SC3 – Poul Andersen gave an update on International standards harmonization - Six documents were identified. C63.18 and C63.19 are part of the list of standards that are to be looked at to be harmonized or to be adopted by international organizations.
e. No FCC representative present – Dan Hoolihan sent in a report on the presentation the FCC provided at the TCBC meeting (presented by S. Berger to the SC).

11. Meeting adjourned at 12 noon. Next meeting in Piscataway NJ.