

ANSI ACCREDITED STANDARDS COMMITTEE C63
ELECTROMAGNETIC COMPATIBILITY
SUBCOMMITTEE 8 – MEDICAL DEVICES AND EMC

FINAL Minutes

27 April 2005 –IEEE Operations Center – Piscataway, New Jersey
Includes corrections from September – 2005 meeting

1 Opening and Self-Introductions

People Present at the meeting - *designates members

Dan Hoolihan*	Hoolihan EMC Consulting
Don Heirman*	Don Heirman Consultants
Jeff Silberberg*	FDA
Victor Kuczynski*	Vican Electronics
Jon Casamento*	FDA
Ed Hare	ARRL
Stephen Berger*	TEM Consulting
Mike Windler*	UL
George Hirvela	Cingular
Al Wiczorek*	Motorola
Dheena Moongilan*	Lucent
Dennis Camell	NIST
Robert Wegner*	Panasonic
Werner Schaefer*	Cisco
Joe Morrissey*	Motorola
Bob DeLisi*	UL
Bill Stumpf*	ACIL

2 Review and Adoption of Agenda

The DRAFT Agenda was reviewed and adopted. See Attachment 1.

3 Review and Adoption of Minutes of Previous Meeting

It was moved by Don Heirman to approve the minutes of the previous meeting; the Motion was seconded and approved by the subcommittee.

4 Review of Subcommittee Membership

The Subcommittee Membership was reviewed and approved for 2005. See Attachment 2.

5 Working Group Reports

5.1 WG#1 – Jeff Silberberg - C63.18

Working Group 1 is developing the Second Edition of C63.18. A Working Group meeting was held on April 26th at the IEEE. The Second Edition will use a field-strength meter as the principal instrument for measuring fields from cellular sources. Dave Baron, from ETS-Lindgren, has agreed to help specify the field-strength meters.

Action Item – Steve Berger – Talk to Dave Baron and report back to Jeff Silberberg and Joe Morrissey on discussions relative to peak and average power measurements with field strength meters.

Al Wieczorek referenced an Australian report for additional information on cell phones and field strength levels from cell phones. The reference was “Interference to Hearing Aids by the Digital Mobile Telephone System Global System for Mobile Communications, NAL Report No. 131, May – 1995, National Acoustic Labs.

5.2 WG#2 – Howard Bassen – C63.21

Howard Bassen has resigned as chair of this working group. The subcommittee chair has asked Bob DeLisi from UL to take over the project; Bob is requesting support and approval from his management chain before accepting the position.

5.3 WG#3 – Steve Berger – C63.19

Steven Berger reported on the latest status of the revision of C63.19. The revision has been completed after a third recirculation to the ANSI C63 balloting group. It is out for ANSI public review; a 45-day process which will be concluded in early June.

Jeff Silberberg had some comments on the third recirculation; some of the comments were inadvertently left off the final copy of the standard. Steve Berger considered the comments to be editorial and they could be implemented before the standard is released.

It was noted that a Public Notice from the FCC (DA 05-1134) had been released on April 25, 2005 clarifying the use of the Revised Wireless Phone and Hearing Aid Compatibility Standard.

Specifically, the Office of Engineering and Technology has determined that applicants for hearing aid compatibility certification may rely on either the 2001 or draft 2005 version of ANSI C63.19. See Attachment 3.

6 New Business

6.1 PINS-C for C63.19 – Steve Berger

Steve Berger introduced a PINS-C to revise the C63.19 standard. A PINS-C is a more informal Project Initiation that is not advertised in the ANSI Standards Action. The PINS-C is approved by the main C63 committee and the work is done at or below the main committee level. Issues to be addressed include the Articulation Weighting Factor, increasing the frequency of the source (cordless phones) up to 6 GHz, Wireless-Fidelity phones, and other topics. See Attachment 4.

6.2 PINS for C63.19 – Al Wieczorek

Al Wieczorek from Motorola introduced a PINS form to revise the C63.19 document. The PINS had much of the same information as the PINS-C but it would publicize the proposed changes in a public venue. See Attachment 5.

After some discussion, a compromise Motion was proposed and approved. The Motion states “Adopt the Berger PINS-C with a mandated report to Subcommittee 8 by July 15, 2005 to “go” or to “not go” forward with a formal PINS.”

7 Liaison Reports

7.1 IEC SC62A Maintenance Team 23

Mr. Silberberg reported on the activities of the Maintenance Team for IEC 60601-1-2. The Maintenance Team had met in Williamsburg, Virginia from April 12-15. The MT has made comments on the latest Draft of 61000-2-5. Concerns were raised about test labs testing products for compliance to IEC 60601-1-2 but not checking for label requirements. Some organizations will help manufacturers with labels but EMC test labs do not inspect for label compliance in their normal testing. Battery operated products were discussed relative to 61000-3-2 and 61000-3-3. The international trend for electrical medical devices is to separate EMC requirements for functional safety (where a safe failure may be acceptable) and EMC requirements for performance into separate standards.

A more complete report on the MT 23 activities can be found in Attachment 6.

7.2 AAMI/EMC Committee Report

Jeff Silberberg reported that AAMI's TIR 18 is being revised. It is being expanded beyond radiated immunity into other EMC areas. They are probably one year away from having a Draft edition for voting.

The next meeting of the AAMI/EMC Committee will be held May 13-17 – 2005 in Tampa, Florida.

7.3 FDA Report

Jon Casamento reported on FDA activities. The FDA is still actively working on security systems and their potential interference to implanted medical devices. The FDA is developing a magnetic coil for simulating the variety of impulse waveforms on the market in various security devices. Field strengths on the order of 200 A/m up to 10 kHz are being considered.

7.4 IEEE 1073/ISO TC 215 Working Group on Wireless in Health Care

This working group has published the first edition of ISO/TR 21730 – Health Informatics – Use of Mobile Wireless Communication and Computing Technology in Healthcare Facilities – Recommendations for the Management of Unintentional Electromagnetic Interference with Medical Devices.” As the title states, this is intended for management personnel in healthcare facilities.

8 Next Meeting

September 28th - 2005 – Location to be determined

Attachments:

- 1 – Agenda
- 2 – Membership for 2005
- 3 – FCC Public Notice
- 4 – PINS-C for C63.19 (Berger)
- 5 – PINS for C63.19 (Wieczorek)
- 6 – Reports from MT 23 (Silberberg)