ICES

International Committee on Electromagnetic Safety

Approved Minutes

IEEE/ICES TC95 Subcommittee 3

Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0 Hz - 3 kHz

and

IEEE/ICES TC95 Subcommittee 4

Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

FDA Campus (White Oak), Silver Spring, Maryland
WO-Bldg 02, Room 2031
13 January 2010 (Wednesday)
0900 – 1530 h

1. **Call to Order**

   Co-chairman Ziskin called the meeting to order at 0930 h.

2. **Introduction of those Present**

   Each of the attendees introduced her/himself. (See Attachment 1 for list of attendees.)

3. **Approval of Agenda**

   Following a motion by D'Andrea and a second by Cotton the agenda was approved without change (see Attachment 2).

4. **Approval of the Minutes (June 2009 Meeting)**

   Following a motion by Bushberg and a second by Chou, the minutes of the June 2009 meeting were approved as presented.

5. **Secretary's Report**

   Petersen reported on the status of PC95.1a (amendment to include ceiling values on induced and contact current) and PC95.3.1 (low frequency measurements and computations). He reported that both documents were approved by the sponsor balloting group with 100% affirmative votes after recirculation. Specifically, balloting PC95.1a closed 22 October 2009 and the draft is on the 18 January SASB Review Committee (RevCom) early consideration agenda. If approved by RevCom, n letter ballot will be carried out for SASB approval. Balloting on PC95.3.1 closed 31 December and the draft will be on the March RevCom agenda. Petersen explained that a more detailed report on these and other items will be presented during the secretary's report at the TC95 meeting on Friday.

6. Chairmen's Report

a) Recent ICNIRP reviews – RF bio-effects and mobile phones & tumor risks

Co-chairman Ziskin provided an update on the recent ICNIRP review "Exposure to high frequency electromagnetic fields, biological effects and health consequences (100 kHz-300 GHz)" and statement on the "Guidelines for limiting exposure to time-varying electric, magnetic, and electromagnetic fields (up to 300 GHz)." He briefly summarized the conclusions regarding the mobile phone/cancer risk issue by pointing out that there is considerable data available, most of which indicates a low risk. Many of the studies suffer from various biases including recall bias. The conclusions of the recent ICNIRP reviews conclude that there is weak evidence of a slight increase in glioma associated with the use of mobile telephones but these studies suffer from issues regarding exposure duration, recall bias, etc. and there are no clear explanations regarding a mechanism. He noted that the concept of causation versus association may be an issue in epidemiology. Bailey cautioned against making claims of possible associations from a single study unless the evidence is striking. Typically, weaker results should be followed by *in vitro* and animal studies before any associations can be made. Bowman agreed and added that epidemiology has limits. For example some of the studies in the Interphone Study suffered from recall and selection bias, unknowns such as output power during calls, the environment – urban/suburban – etc. Many of these issues are being examined during the evaluation of Interphone studies.

Morrissey reminded everyone that the Interphone Study resulted from public concern/pressure and was not initiated from a pure research point of view. He noted that when first proposed, the Interphone study was touted as being the beginning and end of all mobile telephone studies and he hopes this just another study and not the "final" study. In response to a comment from Bodemann regarding the Hardell studies, Martin noted that there have been a number of reviews of the Hardell studies but no consensus conclusion has been reached.

b) ICES comments to ICNIRP draft ELF guidelines

Bodemann reported that ICES was invited to submit comments in the ICNIRP Draft "Guidelines for limiting exposure to time-varying electric and magnetic fields (1 to 100 kHz)." Most of the detailed comments were submitted by Reilly who explained that the major issues related to inadequate description of the rationale for the reference levels and the basic restrictions. He said the ICNIRP rationale is getting closer to that of ICES but is explained poorly. In his comments he urged ICNIRP to take a close look at the ICES rationale and consider adopting it instead of the rationale found in the 1998 guidelines. Reilly explained that there was considerable discussion at the Umea meeting regarding difficulties in trying to implement the ICNIRP low frequency requirements in the workplace. He said there was some pushback by ICNIRP regarding expending a dialog with ICES but ICES was well-represented and well-received by the attendees. Reilly noted that a German proposal was submitted at the Umea meeting as a possible alternative to ICNIRP and ICES. Bodemann said that he was familiar with the document and that was concerned that none of the authors could be considered stakeholders. Bodemann explained that the reference levels and basic restrictions are closer to the corresponding ICES values than to those of ICNIRP – the document has been submitted to the working party responsible for addressing limits in the workplace. He said that if the EU recognizes the document, it will be evidence of ICES influence.

Bowman said that he is familiar with the German proposal and it should simplify dealing with multi-frequency and pulsed-fields. For example, the German proposal requires fewer Fourier components in the summation, i.e., only the strongest components are included. Reilly explained that he has not yet studied the German proposal in detail cautioned about how Fourier components are considered, e.g., linear versus non-linear responses. Chou said that he thought the Umea meeting was very successful. His and Reilly's presentations on the C95 standards including differences between the ICNIRP and IEEE processes, e.g., open versus closed, were well accepted. One issue that might be impeding acceptance of the IEEE standards is that of freely available (ICNIRP) versus available by purchase (IEEE).

c) ICNIRP and ICES harmonization

Klauenberg briefly reviewed the history of efforts to set up a process for collaboration//harmonization between ICES and ICNIRP. Several meetings were held between ICNIRP members and ICES members—the first was held during the BEMS meeting in Munich in 2000, another was held in San Antonio a year later but no agreement on a dialog evolved and all attempts at harmonization failed. We are still looking for a credible system for addressing the harmonization issue. He stressed that collaboration and harmonization is becoming even more important now in light of the EU Worker's Directive and issues with the ICNIRP low frequency limits. It is important that ICES and ICNIRP get together to try to resolve the issue since 24 of the 28 NATO members will have to follow the Worker's Directive, which may have different limits than those in the IEEE NATO STANAG replacement standard now under development by TC95/SC3/SC4. He explained how ICES presentations at meetings in Europe, e.g., Umea Sweden, have heightened recognition of ICES and the open IEEE process. One obstacle for further acceptance is the fact that IEEE standards are not publicly available, i.e., they must be purchased. In response to a question from Needy about publishing a summary of the normative sections in a journal that would permit downloading without charge, similar to the arrangements between ICNIRP and *Health Physics*, Petersen said that depending on how detailed the summary is we probably could obtain IEEE permission. Bailey pointed out that the page charges to the authors in journals that allow downloading without charge are usually high.

ACTION ITEM 1

Bodemann agreed to try to determine the arrangements between *Health Physics* and ICNIRP that permit downloading pdf files of published ICNIRP papers at no charge.

It was decided that it would be useful to move forward and establish a drafting group to summarize the relevant normative sections of C95.1-2005 with the goal of publishing the document such that it would be freely available.

ACTION ITEM 2

Chou will lead an ad hoc group comprised of Bodemann, Cotton, D'Andrea Erdreich, Klauenberg and Morrissey that will develop a document summarizing the salient points of the normative sections of C95.1-2005 for publication.

Martin cautioned that the issue of compliance with a summary document, and not the standard, may be problematic. Reilly agreed—the entire standard is needed. He said that he doesn't quite understand why cost is an issue with companies, agencies, etc.

Klauenberg explained that if NATO is expected to adopt the standard, it has to be freely available to all the members and organizations within NATO. Considerable discussion followed that included suggestions that to lower costs the standard could be published as two standards—one normative, the other informative. In response to a question from Tell, Klauenberg explained that the DoD annual license fee to access IEEE C95 standards is approximately $180 k. It was agreed that preparing a summary papers is a good first step in moving forward.

d) Status of Australian ELF standard

Martin discussed the revised Australian ELF exposure limits. He noted that the draft is complete, the limits have been changed, and a cost benefit analysis is now in progress—the issue of costs relation to a precautionary approach may be more important than costs relating to compliance. He noted that the limits at low frequencies are similar to those in the C95 standards. He expects final approval in a few weeks.

7. Issues on Merging of C95.1 and C95.6

a) Literature surveillance and review/evaluation

To open the discussion on literature review and evaluation, Morrissey briefly reviewed the September 15, 2009 US Congressional Hearing "Expert Conference on Cell Phones and Health: Science and Public Policy Questions," chaired by Senator Specter. (See Attachment 3.) Morrissey explained that the goal of the hearing was to address a "serious question that deserves a serious answer" and was not meant to be "inflammatory" or to make "stark statements." He then went on to note that close to 30 in-depth reviews of the of the RF bioeffect literature have been carried out during the past few years by expert panels of scientists throughout the world. He said that conclusions of these reviews are much in line with those of C95.1-2005. While some suggest precaution, none claim that there is sufficient evidence to assume that adverse effects are established.

Morrissey went on to describe the SC3/SC4 literature surveillance/evaluation process and the database. He noted a slight increase in the number or relevant studies published in 2009, compared with the number published in 2008 (see Attachment 3). He mentioned some important ongoing studies, e.g., IIT, and explained that it is important to maintain a 5-year review cycle because of the increase in the number of studies being published, particularly with glioma as the end point. The increase is partly due to increased publications from organizations in countries such as Korea that have had limited contributions in the past. He then discussed the various anatomical models that are being used for numerical analyses. In addition to the established families of models, work is ongoing to develop models of pregnant women and the fetus.

Morrissey explained that he has an invitation to publish literature review/evaluations in the *International Journal of Hyperthermia*. Martin pointed out that this may appear as a bias, i.e., we have made up our mind that the mechanism is solely related to tissue heating. In response to a question from Ziskin regarding the percentage of papers that address low frequencies, Morrissey explained that at this point, only RF papers are being considered; Erdreich noted that a mechanism is rarely included in the epidemiology papers, i.e., there is no underlying assumption regarding mechanism. Bailey suggested publication in *Health Physics* as an alternate choice. Regarding a format for the summaries, Bushberg suggested summarizing the studies by organ type. In response to a question from Bowman regarding how the weight of evidence is considered between *in vitro* versus *in vivo* versus epidemiology studies, and how study design, quality etc. are considered in the evaluations, Morrissey explained that there is some subjectivity but generally animal studies are weighted more heavily than *in vitro* studies, for example. Bowman asked if animal studies, for example, are good studies for glioma—he said that we should be concerned that we may just be adding positive and negative results for the various endpoints. Morrissey explained that each study is evaluated on its own merits; Ziskin explained that each study is evaluated individually and weighted accordingly. Bassen said that he supports Martin's concern about publishing in the *International Journal of Hyperthermia*, e.g., it would seem inappropriate for cancer studies. There was general consensus that depending on the outcome of the literature evaluations, an appropriate journal or journals should be decided at that time.

b) Report from Editorial Working Group – status of the merging work

Chou reviewed progress of the Editorial WG toward merging C96.1-2002 and C95.1-2005 into a single document, i.e., a single document that would cover the frequency range of 0 Hz to 300 GHz. This new standard would be numbered C95.1, but would have a broader scope. The normative clauses of this revision would also be the normative clauses of PC95.1-2345—the replacement of NATO STANAG 2345. He reported that the PAR for PC95.1-2345 was approved by the IEEE SA Standards Board (SASB) at their Sept meeting; a PAR for the revision of C95.1-2005 will be submitted early spring. Chou explained that a major task will be to address the frequency range where effects associated with electrostimulation and effects associated with tissue heating overlap, i.e., between approximately 100 kHz and 5 MHz—Reilly is the key person to address the rationale, definitions, MPEs and basic restrictions in this region. Chou noted that WG meetings were held in July and September—the September meeting was held at the FDA White Oak Campus and was followed by an Inter-Agency Working Group meeting.

c) Numerical computations at ELF

Reilly reviewed the present low frequency MPEs and basic restrictions and the induction models that were used to relate the exposure fields to the internal fields and basic restrictions (see Attachment 4). He pointed out that differences between the ICNIRP circular induction model and the ICES ellipsoidal model result in approximately a factor of two difference in the MPEs—the C95.6 values being higher. He explained that this is one of several issues that must be resolved for the revision of C95—other issues include large differences in FDTD results compared with results for the ellipsoid, differences among reported FDTD results for similar models, resolution of interface E-field peaks, and appropriate models including adult models for B-field exposure and child model for E-field exposure. The intent is to use anatomically correct models, similar to those being developed by Hirata—defining exactly what work has to be done in this area is ongoing.

Reilly introduced Dr Hirata who gave a presentation "Inter-comparison of induced fields in Japanese male model TARO due to magnetic field exposures" (see Attachment 5). He reviewed some of the factors that influence computational results, many of which appear to be artifactual and possibly can be addressed post-computation. He concluded by reviewing the intercomparison study program in which six institutes participated. He focused on the calculated induced electric fields and current densities, which were in reasonable agreement between the participating institutes. Bassen pointed out that PC95.3.1 includes a number of numerical anatomical models, called the virtual family, which includes child models. Kainz explained that the resolution of these CAD models is about $1 \times 1 \times 1$ mm but different resolutions are available for different regions of the body. Bassen discussed numerical techniques other than the FDTD method, e.g., the finite element method, the impedance method, all of which, including the FDTD method are discussed in PC95.3.1. Bodemann suggested establishing a workshop to discuss the various numerical methods, some of which are being applied in MRI research. Ziskin said that he was not certain that an in-depth workshop would be of interest to many SC3/SC4 members; Bassen pointed out that some members of SC1 and, perhaps, a few members of SC3 and SC4 may find it of interest.

d) NATO standards

Klauenberg presented a briefing on the status and background of NATO STANAG 2345 (see Attachment 6). He pointed out that STANAG 2345 is based on the C95.1 limits; it was last revised in 2003, and the triennial review to revise, reaffirm or cancel is stalled because of the EU Workers Directive that mandates use of the ICNIRP limits in the workplace. He described a survey of NATO nations that showed concerns about the operational impacts on mission safety of a reduction of the Action Level for contact currents to 40 mA. If implemented this would become a de facto limit. He pointed out that the issue has been resolved via the amendment to C95.1-2005 that provides ceiling values for induced and contact currents of 500 mA for workplace exposures. In response to a question from Tell, Klauenberg explained that the rights to IEEE STD C95.1-2345 will be owned by IEEE—not by NATO.

8. Other New Business

Morrissey presented a review of the Thermal Aspects of Radio Frequency Exposure Workshop held earlier in the week (11 – 12 January). (See Attachment 7.) He reported that the workshop was well-attended with over 100 attendees and a good representation of experts from the hyperthermia community, and included members of ICNIRP. There was also a good representation of the government public health agencies. The presentations were well-received. The goal of the workshop was to try to provide answers to the following questions: What are the most appropriate health endpoints for a given tissue / system? What are the most appropriate time periods for acute and chronic exposure? Are there any well established time-temperature thresholds? What is the cost effective and targeted research to better define time-temperature thresholds in support of human exposure standards? Morrissey said that he was not convinced of some of the conclusions of individual speakers, e.g., Miller's conclusion that thermal effects related to spontaneous abortion and teratogenesis obey a non-threshold, linear hypothesis. Chou noted that with respect to RF safety standards, there was general agreement that behavioural disruption is an appropriate endpoint for establishing basic restrictions in terms of whole-body-averaged SAR and cataract formation in the lens is appropriate for establishing basic restrictions in terms of peak spatial-average SAR. Ziskin agreed noting that effects to sensitive tissues, e.g., the testes, occur at temperatures higher than what would be expected if the basic restrictions are met. Martin pointed out that while the lower tier may be OK for 24 hour/day exposures for people in all states of health, and questioned whether an added heat load could be significant and whether some form of caveat may be warranted. Chou explained that the large safety factor incorporated into the lower tier would protect against effects related to typical additional heat loads. Bodemann noted that in his opinion, the workshop provided important information that should be considered by ICES. However, the conclusions of a few papers were irrelevant for standard setting. For example, based on an extrapolation of the Arrhenius equation, effects on cells could be expected if the temperature of the culture was maintained at 38° for 10^6 minutes. The overall conclusion of the attendees of this meeting was that it was an important workshop that provided information useful to SC3 and SC4.

9. Date and Place of Next Meeting

The next TC95 meetings will be held in Seoul, South Korea, tentatively 11-12 June 2010—immediately before the 32nd Annual Meeting of the Bioelectromagnetics Society. Nam Kim agreed to help with the meeting arrangements.

10. Adjourn

There being no further business, the meeting was adjourned at 1510 h.

Actions Arising from this Meeting

	Action	Assigned to	Completed by	Status
1.	Try to determine the arrangements between *Health Physics* and ICNIRP that permit downloading pdf files of published ICNIRP papers at no charge.	Bodemann	11 June 2010	
2.	Lead an ad hoc group comprised of Bodemann, Cotton, D'Andrea Erdreich, Klauenberg and Morrissey that will develop a document summarizing the salient points of the normative sections of C95.1-2005 for publication.	Chou	31 December 2010	

ATTACHMENT 1

List of Attendees
TC95/SC3/SC4 Meeting
13 January 2010
FDA White Oak Campus, Silver Spring, MD

	Last Name	M.I.	First Name	Affiliation	Member Status	E-mail
1.	Bailey	H.	William	Exponent Inc.	SC3/SC4	wbailey@exponent.com
2.	Baron		David	AIHA Representative	SC3/ SC4	d.baron@ieee.org
3.	Bassen		Howard	FDA/CDRH	SC3/ SC4	Howard.bassen@fda.hhs.gov
4.	Bodemann		Ralf	Siemens AG	SC3/ SC4	ralf.bodemann@siemens.com
5.	Bowman*	D.	Joseph	NIOSH	O/O	kirkbow@gmail.com
6.	Bushberg	T.	Jerrold	U. of California, Davis	O/SC4	jtbushberg@ucdavis.edu
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ATTACHMENT 1

	Last Name	M.I.	First Name	Affiliation	Member Status	E-mail
21.	Kainz*		Wolfgang	FDA/CDRH	SC3/SC4	wolfgang.kainz@fda.hhs.gov
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* Via telephone
O = Observer

ATTACHMENT 2

IEEE

ICES

International Committee on Electromagnetic Safety

Unapproved Agenda (*Revised*)

IEEE/ICES TC95 Subcommittee 3

Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0 - 3 kHz

and

IEEE/ICES TC95 Subcommittee 4

Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz

FDA Campus (White Oak), Silver Spring, Maryland
WO-Bldg 02, Room 2031
13 January 2010 (Wednesday)
0900 – 1600 h

1. **Call to Order** *Ziskin*
2. **Introduction of those Present** *Ziskin*
3. **Approval of Agenda** *Ziskin*
4. **Approval of the SC3/SC4 Minutes (June 2009 Meeting)**
5. **Secretary's Report** *Petersen*
6. **Chairmen's Report** *Ziskin*
   a. Recent ICNIRP reviews – RF bio-effects and mobile phones & tumor risks
   b. ICES comments to ICNIRP draft ELF guidelines
   c. ICNIRP and ICES harmonization *Chou/Klauenberg*
   d. Status of Australian ELF standard
7. **Issues on Merging of C95.1 and C95.6** *Ziskin*
   a. Literature surveillance and review/evaluation *Morrissey*
   b. Report from Editorial Committee – status of the merging work *Chou*
   c. Numerical computations at ELF *Reilly*
   d. NATO standards *Klauenberg*
8. **Other New Business** *Ziskin*
9. **Date and Place of Next Meeting** *Ziskin*
10. **Adjourn**