1. Call to Order

Chairman Adair called the meeting to order at 0810 h. Each of the attendees introduced him/herself. (See Attachment 1 for the list of attendees.)

2. Approval of Agenda

Adair announced that the IEEE Activities report (Agenda Item 5) would be given by Sue Vogel, Manager, Technical Committee Programs, IEEE SA Standards Department; the presentation on new RF technologies (Agenda Item 9) would be given by Dr. Piotr Przybyszewski of Medtronics. Following a motion by Heynick that was seconded by Blick, the agenda was approved. (See Attachment 2.)

3. Approval of June 30, 2002 Minutes

Following a motion by Heynick that was seconded by Cohen, the minutes of the June 2002 meeting were approved without modification.

4. Executive Secretary’s Report

a) PARS and Balloting

Petersen reported the following:

- The request to extend the PAR for project P1466 (basis of RF safety programs) was approved by the SA-Standards Board (SASB) at the December 2002 meeting – a two-year extension was granted. Unfortunately the request to change the project number to C95.7 was not included in the extension request. Also, the PAR for the revision of C95.1 is valid through 2005.

- The reaffirmation of P1460 (measurement of quasi-static electric and magnetic fields) was approved at the December 2002 SASB meeting.
• The revision of C95.3 (RF measurements and computation) was approved at the December SASB meeting. However, as a result of the IEEE legal review, the following title change was required:

  “Recommended Practice for Measurements and Computations with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 100 kHz to 300 GHz”

to

  “Recommended Practice for Measurements and Computations of Radio Frequency Electromagnetic Fields with Respect to Human Exposure to Such Fields, 100 kHz to 300 GHz”

• C95.4-2002, which was approved by the SASB in November 2002, should go to the printers within the next few days. The delay was to wait for action by the SASB on C95.3 and 1460 so that those references could be updated, i.e., title and date, in the C95.4 draft.

• C95.6-2002, which was approved by the SASB in September 2002, is now under appeal. The appeals were heard on December 9th during the SASB meetings in Bonita Springs, FL. Those representing ICES were Adair, Jaffa and Reilly by teleconference and Petersen who was at the hearing.

b) Standards Board

Petersen explained that many of the SASB issues were already addressed above. He reported that IEC and IEEE signed a dual logo standards agreement. This means that IEEE standards projects for which an equivalent IEC project does not exist can be submitted for consideration as IEC/IEEE standards and published with the IEC and IEEE logos. The document would be submitted as an FDIS (Final Draft International Standard) for vote (yes or no) by the participating countries. He also reported that based on the results of an ANSI audit, open balloting on all IEEE standards may be required in the future. The plus side of this is that ICES may no longer have to request SASB approval of non-SA member invited experts. The down side is that it opens the gates to balloting by anyone, including those with agendas to stop certain standards from moving forward.

c) SCC-34 activities

Petersen reported that P1528 (SAR certification of hand-held wireless devices – experimental techniques) is ready for ballot. A revised PAR was required – arising from an IEEE legal review – and approved at the December 2002 SASB meeting. A revised draft incorporating the required changes (all considered editorial) will be sent to the IEEE Balloting Center within a week. SCC34 Subcommittee 2 decided not to address body-mounted devices since an IEC TC106 project team was addressing this and many of the SCC34 members are on the IEC project team. Instead, a Category “D” Liaison with the TC106 project team was requested and approved by the IEC Standardization Management Board
last month. Thus SCC34 will have direct input into the development of this standard. Petersen also reported that Working Group 2 of SCC34/SC2 has been revitalized to complete the recommended practice on assessing SAR in the human head from hand-held wireless devices – computational techniques. The first meeting will be held January 30-31, 2003 at the FCC Laboratories in Columbia, MD.

d) IEC TC-106

Petersen reported that IEC TC106 held its 2002 plenary and working group meetings at the IEEE Operations Center in Piscataway, NJ, November 18-20, 2002. A number of projects are now underway – several with scopes similar to ICES and SCC34 projects. The 2003 plenary meeting will be held in Montreal in October in conjunction with the IEC General Meeting. There is still some confusion on the part of some of the members of the project teams regarding reference to exposure limits in the TC106 standards. Unlike CENELEC, recommending exposure limits and conformity assessment to specific limits is not within the scope of TC106.

5. IEEE Standards Activities Report

Vogel reviewed the new IEEE SA website, described the balloting process including individual versus organizational balloting, described the forms for electronic submittal of PARs and standards and encouraged people to visit the site to learn more about the IEEE standards process. The site “Welcome to IEEE Standards Online” can be found at http://standards.ieee.org/resources/development/index.html. In response to a question from Petersen regarding open balloting, i.e., permitting anyone to join any balloting pool to vote on any standard, Vogel responded that this appears to be the way things are headed. Petersen pointed out the potential problems that could occur, e.g., organized opposition that could stop or defeat approval of specific standards and having people vote on standards that they understand little about. Vogel responded that the Standards Department is aware of this but so far it has not been problematic – based on experience with open balloting to SA members.

6. Chairman’s Report

a) Publications/ExCom Meetings

Adair began her report by holding up a copy of C95.6 and noting that it is now available for purchase from IEEE. She also mentioned the December issue of *IEEE Microwave Magazine* pointing out the article on solar power satellite systems by Osepchuk and noted that recent issues of *Health Physics* contain a number of articles authored by ICES members. She reported that the ExCom met the previous evening, in Quebec in June, and by teleconference in August. The ExCom tries to meet every three months – more frequently when necessary.
b) Membership

Adair then explained that she wished to speak on more serious matters, specifically the loss of two members. LTCdr James J. King wrote in November that he has received orders to detach from the Bureau of Medicine and Surgery (BUMED) on 22 November 2002 and report to the USS Enterprise in December 2002. He named his proposed successor, LT((JG) Jamaal Whitmore from the Naval Nuclear Training Command. LT Whitmore holds a BS in Electrical and Electronic Engineering (cum laude) from California State University. When he reports to BUMED in February 2003, he will be invited by Tom McManus to apply for ICES membership. Adair noted that LTCDR King will be missed and on behalf of ICES wished him Godspeed on his new mission. Hammer said that he will invite Whitmore to the Naval facility at Charleston and bring him up to speed on ICES activities.

Adair then said that she has the sad duty to announce the passing of a valued ICES member, Dr. Christian Bruce Wenger. Bruce died on 22 November of cancer. He was Chief Pharmacologist at the US Army Research Institute of Environmental Medicine at Natick, MA for 17 years. He was 60 years old and left his wife and 6-year old son. Bruce held two doctorates, MD and PhD, both from Yale University. Adair said that she came to know him in the early 1970’s when he worked at the Pierce Lab and studied for his PhD in thermal physiology under James D. Hardy, physicist and Director of the Pierce Lab at Yale. Bruce was a brilliant scholar, great teacher, dedicated and superb researcher, a quiet friend to all who knew him. Adair said that she had hoped that he would be a major contributor to the proposed thermal physiology workshop, now tentatively scheduled for Spring, 2004. Bruce reviewed papers for SC4 and participated in ICES balloting activities. He was always available for consulting, for providing his expertise, and for companionship. She asked for ICES to join her in a moment of silence in memory of Christian Bruce Wenger.

Adair also announced the resignation of Kent Jaffa, as Chairman of SC3. ICES is now searching for his replacement at the same time hoping that he will be available for consultation on new SC3 activities related to the implementation of the new C95.6 standard.

c) Fundraising

Adair explained that ICES continues to work closely with the IEEE SA Standards Department. She noted that members of the ExCom have interacted on several occasions with IEEE legal counsel, informing them of the policies and procedures under which ICES operates. The main committee and subcommittee membership now stands at more than 300 volunteers, each contributing unique expertise to the mission of ICES. She explained that the ExCom is working on many fronts to publicize ICES and its work internationally. The ExCom is also working with IEEE staff toward needed support for ICES, e.g., fundraising for travel support and for special projects. She noted that unlike ICNIRP, WHO, etc., ICES has no outside support other than registration fees for the semi-annual meetings. If the international effort to develop science-based standards for safety and
measurement and increase the international membership is to continue, ICES must find monetary support. This will be an important activity in 2003.

d) International Visibility
Adair explained that ICES continually works to enhance its domestic and international image. Standards are publicized whenever possible as is the open consensus process and broad scientific consensus of ICES. For example, in November, ICES interacted with COST 281 in London and agreed to collaborate on a joint meeting in the Spring of 2004 that may embody the postponed thermal physiology workshop. The venue may be Switzerland or perhaps Latvia. Plans will be finalized within the next few months,

e) Accomplishments
Adair reviewed the accomplishments of 2002. Specifically, four standards documents were finalized, balloted and approved by the SA Standards Board including the revision of C95.3, new IEEE Stds C95.4, C95.6, and the reaffirmation of P1460 (quasi-static field measurements). She pointed out that this is a magnificent achievement by all the members of ICES who labored so long and so diligently and expressed the appreciation of the ICES leadership.

Brecher asked why IEEE does not provide complimentary copies of the standards to all ICES members, or at least make them available to read online – if not downloadable. Petersen pointed out that IEEE policy is to provide a complimentary copy of a standard to each of the members of the working group or subcommittee that developed the standard and that the Standards Department is supported in part by the sale of standards. Heirman agreed and added that some committees, e.g., the Computer Society, include in their meeting registration fees funds for complimentary copies. Brecher responded by stating that IEEE should consider making standards available to SA members for reading online – adding that the dues could support this. Heirman pointed out that the dues do not support the SA. He noted that one method of making standards available is through a subscription model. For example, for some nominal yearly fee all standards relating to electromagnetics, e.g., the C63 EMC standards and the C95 standards, could be made available online to subscribers.

McManus said that he is sympathetic to Brecher’s position and, perhaps, discounts could be offered to committee members or standards could be offered for sale at meetings. He noted that the cost of the standard is small compared with the cost of travel and lodging while attending most meetings. Zipse supported McManus’s suggestion to have copies of the standards available for sale at the semi-annual meetings.

7. Treasurer’s Report
Varanelli briefly summarized the financial status of ICES (see Attachment 3 for statement).
8. Membership Chairman’s Report

a) New members

McManus reported that one new member was added since the Quebec meeting, Max Ammann, Professor of Radio Engineering at Dublin Institute of Technology, Ireland. Dr. Ammann is also a member of the IEEE Antennas and Propagation Society.

b) European Developments

McManus provided an update on related activities in Europe. He discussed the activities of COST 281 which is addressing the issue of health effects of mobile phone technology – 3G and up. (For more information visit the COST 281 website at www.cost281.org.) He pointed out that a 2-3 page newsletter, the COST Watchdog Report, is published once or twice a year. Also, at the request of the Swiss government, an opinion on base station epidemiology studies was prepared, which concludes that it would not be possible to carry out meaningful studies of people living near phone masts. He also reported that a mission was launched on mobile phones and the health effects on children, and a seminar on phone masts and health is scheduled to be held in Dublin, 15-16 May, 2003. The objectives of the seminar are to collect information, address gaps in the scientific knowledge, and identify research needs. The seminar is funded by various EU programs. Swicord said that he hopes COST 281 will not do its own thing in defining the research needs but will work through the WHO process – McManus replied that the COST 281 program will complement the WHO efforts.

McManus then discussed the proposed EU Information System on EMF noting that it will be based at the EU Joint Research Centre at Ispra in Italy. The activities will involve the following:

I Co-ordinating and setting up research consortia to provide:

- Support to international EMF exposure measurement standards
- Protocols for exposure monitoring
- Epidemiological and health impact studies in the vicinity of base stations
- Development of practices to monitor risk perception across EU
- Harmonization of practices for exposure assessment, health impact studies, risk perception monitoring and risk communication.

II Development and operation of a European information system on EMF

The initial targets or aims are:


The Swedish controversy was discussed next. McManus reported that the SSI review of epidemiological studies concluded that there is no evidence that cell
phones pose a cancer risk. A contradictory rebuttal by Mild, Hardell, Kundi & Mattsson concluded that: “… a causal association between use of cell phones and brain cancer cannot be ruled out.” McManus noted that the SSI report is SSI Report 16 September 2002.

In response to a request from McManus, Chikamoto reported that a Japanese ELF epidemiology study that was submitted to Lancet and turned down is now being revised.

9. International Liaison Chairman’s Report

a) WHO: 3rd EMF & Human Health. Conference on – Research & Standards

Murphy provided an update on international activities. (See Attachment 4 for selected slides from his presentation “ICES Heard Round the World.”) In a summary of the Russian meeting (WHO: 3rd EMF & Human Health Conference on Research & Standards, 23-27 September, 2002) he noted that the Russians still use power density as a basic restriction instead of SAR. When one of the Russian scientists at the meeting suggested considering SAR he was shouted down. Effects related to RF exposure are still considered cumulative, any bioeffects are considered potentially hazardous and RF bioeffects can occur at power densities down to 5 – 10 μW/cm². He explained that WHO is still advocating replication of controversial studies and the framework being developed by for standards and research is irrelevant to Russian scientists. Swicord noted that he has seen the results produced during the past five years by the Russians and there is not much there. Bodemann noted that a German research organization that summarized the Russian papers concluded that the “EMF syndrome” is based mainly on epidemiology studies of occupational groups. Murphy pointed out that immunology was a major topic of the Russian meeting and noted that there is little work being done in this field in the US. In response to a question from Brecher, Murphy replied that the low limits followed by the Russians could no longer be related to a lack of sources of exposure in that country.

Johnston said that based on her interactions with Russian and other East European scientists she has the impression that they appear to be reaching out for information, i.e., it seems difficult for them to obtain information from the west. Murphy agreed but pointed out that only the younger scientists appear to be reaching out. Heynick noted that based on the JPRS translations of Soviet studies from the 1970’s, much of the work is low quality. D’Andrea added that attempts in the US to replicate some of the Soviet CNS and behavioral effect studies from the 1970’s and 80’s failed. Although this work was prominent in setting their exposure limits, it is no longer mentioned at their meetings. Chou mentioned that he was involved in a cooperative research program with the Russians in the 1970’s at which time they were still standing by their early conclusions. Johnston noted that some studies being carried out in Poland are using SAR. Cohen recalled that while a number of Russian scientists participated at the 1st BEMS meeting, they were very reluctant to describe their exposure setups and laboratory protocols.
Murphy concluded by noting that a summary of the Russian meeting should appear on the WHO website and that the next WHO meeting would be held in Guilin, China, 18 – 22 April, 2003.

Brecher said that she was concerned about any campaign touting the lack of effects at typical levels to which the public, for example, are exposed. Along with the rapid buildout of the wireless infrastructure are stories in the press reporting the results of studies claiming that there are effects at low exposure levels. Although many of the studies are misrepresented or are of low quality, the public hears about this and by trying too hard to claim there are no effects raises questions and concerns by some that there are.

b) Other meetings

Johnston summarized a recent meeting she attended in Rhodes. The purpose of the meeting was to review the research on EMF. She said that Sheppard presented material on the 1 versus 10 g averaging volume for the peak spatial-average SAR – Johnston can provide an abstract. Marinelli presented an add-on paper describing his research, which he said resulted in the warnings on mobile phones. Johnston pointed out that Marinelli is affiliated with “Raymaster,” – a company that produces “RF shields.” She said that he also claimed that the result of his work is being used by Kuster as part of the “Reflex” Program. She added that Bersani pointed out that Marinelli’s work is substandard and accused him of fraud. Marinelli’s paper was rejected by Lancet. Johnston concluded by noting that members of the AFRL at Brooks AFB presented a review of the Air Force research, and provided a list of relevant meetings through 2004 (see Attachment 5).

10. -Presentation on New RF Technologies

Dr. Piotr Przybyszewski, from Medtronic, gave a presentation on “Medical Implant SAR and Thermal Modeling” (see Attachment 6 for a copy of the slides). Regarding the statement “AIMD [Active Implanted medical Devices] should not be subjected to IEEE C95.1” on the final slide, Bassen pointed out that C95.1 exempts medical devices. Also, new tools are becoming available that should simplify modeling, e.g., SEMCAD. Bassen also explained that in infarcted tissue, i.e., dead tissue, ΔT should increase more than shown in the slides. Przybyszewski explained that cortical tissue is representative of infarcted tissue and the results are similar. In response to a question from Fichtenberg regarding the final temperature being more important than ΔT, Przybyszewski explained that the results assume the normal baseline temperature as a starting point so that ΔT represents the final temperature. Brecher noted that 400 Hz (slide 4) is also used for railway communications, which could be a potential interferer with active medical devices. Swicord asked why a thermal discussion was not included – Przybyszewski responded that the analysis presented represents worst case. Swicord noted that the middle step in slide 17 could probably be eliminated if the EM simulation assumed all the energy is located in one spot. Johnston pointed at the URSI meeting Ivans reported that the signals from the implanted devices may
interfere with communications devices but on follow-up it appears not to be an issue – at least not in the UK.

11. Report on ICES, Fundraising, Media Interactions

a) Fundraising

Discussed earlier.

b) Interactions with the Media

Adair explained that effective interaction with the media is being hampered by the oversight function of IEEE legal counsel. She recalled the attempt in August to rapidly respond to the Kasevich opinion piece in IEEE Spectrum. The initial draft was revised to satisfy legal counsel’s concerns and was finally published in the December issue. She said that the ExCom will try to work with IEEE staff to resolve this issue. Osepkuch noted that the Public Information Department agreed to assist with correcting misinformation and presenting new information. McManus observed that anyone can write to Spectrum and get published. However, when done under the banner of a committee, it has to go through tortuous legal review and delay. He suggested having individuals submit responses that reflect the position of ICES as a means for moving things forward. Osepkuch noted that this may not be perfect either because Spectrum does not publish everything.

Heirman explained that the issue of rapid response and position statements is an active subject with the SA Board of Governors. He noted that there are procedures for public release of statements in the policies and procedures and operating procedures of the SA and the IEEE. (See excerpts in Attachment 7.) A template with a disclaimer for such statements will made available and may go into effect mid-year.

Varanelli said that he was concerned that some of the material published by Spectrum, an official organ of the IEEE, is poor quality. Efforts to reply are thwarted by not only IEEE legal but by the editors of Spectrum. He feels they have a real attitude problem, do not serve well the volunteers working on IEEE standards and other projects, and the issue should be addressed at some high level within IEEE. Heirman said that this is ongoing now. Cohen asked if the levels of review are also required for the release of interpretations – Heirman replied that they are not. There is, however, an issue with clarifications since some may encroach on consultant’s activities. Brecher criticized the ICES website pointing out that in her opinion it is lacking and cumbersome to use. She noted that she could not find the ICES brochure on the site and, if it’s not there, it should be. Varanelli responded that it’s an IEEE website subject to IEEE rules but he would see what could be done.
12. Reports from the ICES Subcommittees

a) SC1 (Measurements and Computation)

Bassen reported that the revision of C95.3-1991 and the reaffirmation of P1460 – quasi-static field measurement – was approved by the SA Standards Board at the December meeting. SC-1 will next meet 29 January, 2003 in the DC area to begin work on either expanding P1460 or developing a new practice for the measurement of fields up to 100 kHz. This would cover anti-theft and article surveillance devices.

b) SC2 (Warning Symbols and Hazard Communication)

Tell provided the following report that was read into the record:

Subcommittee 2 (Terminology, Units of Measurement, and Hazard Communications) met 13 December 2002, at the IEEE Operations Center, Piscataway, NJ.

- 30 in attendance (60 Members currently on roster)
- Principal discussion items:
  - PAR revision approved to extend the project deadline date
  - Glossary of EMF Safety Related Terms
    - This has been an ongoing discussion
    - Several action items were assigned to input from specific sources
    - Plan to generate PAR when initial objectives met
  - Send input to Ric Tell & Ron Petersen
    - rtell@radhaz.com
    - r.c.petersen@ieee.org
  - Draft RF Safety Program Guide
    - Reviewed a draft presented by Don Haes and Art Varanelli
    - Extensive discussion on outline and content
    - Goal is to present final proposal to parent committee by June meeting
  - Next meeting planned in conjunction with ICES Committee, June 2003, Maui, Hawaii

c) SC-3 (Safety levels – 0 to 100 kHz)

Osepchuk gave the report for SC-3. He reported that SC-3 met yesterday – he served as acting chair. Accolades were given to the working group that produced C95.6. He said that McManus was working on a draft relating to long-term effects that was discussed at the meeting. An application guide for C95.6 is being prepared and the issue of non-uniform exposure is being addressed by Bailey and others – Bailey gave a presentation on the subject at the SC-3 meeting. Osepchuk
also reported that the consensus of the committee is to keep C95.1 and C95.6 separate, at least until the revision of C95.1 is published. After that time either a single standard should be considered or if two separate standards are retained the frequency break point should be 100 kHz rather than 3 kHz. Osepchuk concluded by reviewing the SC-3 membership rules – two missed meetings without excused absences results in removal from the subcommittee.

d) SC-4 (Safety Levels – 100 kHz to 300 GHz)
D’Andrea reported that SC-4 held its meeting Friday afternoon and Saturday morning. The following is a summary of the highlights of the meeting:

- C.K. Chou gave an update on the white papers. SC4 decided that white papers written by SC4 members were an appropriate way to review and document a very large literature. These were presented at the Air Force Workshop in June at the Bioelectromagnetics meeting in Quebec. The 13 white papers have been submitted to Bioelectromagnetics and are in the peer review process.

- C.K. Chou reported on the 6th Working group meeting held at the FCC building September 9-10, 2002. Several motions were passed at that meeting and section leaders for the draft standard were chosen to coordinate and lead the writing process. The WG agreed on the following:
  - Keep the definitions agreed to in Quebec from the 1991 C95.1 but drop the term “extremity.”
  - Base the peak spatial-average SAR limit on absolute temperature and not \( \Delta T \).
  - Remove Annex D (Comparison with other standards).

- The in vivo literature review is nearing completion although Lou Heynick, head of the Literature Surveillance Working Group, announced that 160 new papers have been added to the list. The Engineering review is moving nicely and should be done soon also.

- The literature review process will stop accepting new reports for review at the end of this calendar year.

- The majority of the meeting time was spent on various discussions of the draft document. The Normative and Informative Sections of the document were reviewed and discussed with the committee by Ric Tell and Mays Swicord. Bob Cleveland presented ideas on exposure limits and on averaging time. The proposal on averaging time for the range of 6 GHz to 300 GHz prepared by John Osepchuk and Ken Foster two years ago was reviewed and will be adopted because of its basis in tissue thermal relaxation time. Much text has been added to the draft document, but much more is needed. Several other discussions were held regarding details of these major sections. Annex chairs Sakari Lang and John Defrank reviewed Annexes C and H with a variety of lively discussions.
• C.K. Chou requested that SC4 members send him their short biography with a picture to be placed on the SC4 website.

• Sheila Johnston gave a review of a meeting she attended in Lowenstein Germany on genotoxic studies. Femme-Michele Wagnenaar gave a demonstration of software to show SAR on the body parts allowed by the current and draft C95.1 standards and the ICNIRP guidelines.

• The 7th Revision Working Group meeting, will be held at the FCC building in Washington DC April 3-4. The next SC4 meeting will be held in Maui, 21 June 2003, prior to the BEMS meeting.

e) SC-5 (Safe Distance for the use of Blasting Caps)

DeFrank reviewed the status of the draft statement on the use of cell phones in gasoline stations. He reported that the subcommittee met last evening during which time the draft was reviewed in detail and revisions suggested. A final draft should be ready by the beginning of February. Co-chairs Koban and DeFrank then presented a very clever plaque to Petersen for helping move the C95.4 standard through the IEEE process. The plaque contains a wire stick-figure of a man laying out a firing circuit, complete with an inert(?) initiator, i.e., a replica of one of the figures in C95.4. Petersen expressed his appreciation and thanks.

13. New Business

No new business.

14. Plans for Future Meetings

Adair announced that the next ICES meeting will be held in conjunction with the 25th BEMS Annual Meeting in Maui, Hawaii. The tentative schedule of meetings is as follows:

Thursday, June 19       SC-1 (Afternoon)
Friday, June 20         SC-2 (Morning)
                        SC-3 (Afternoon)
Saturday, June 21       SC-4 (All Day)
Sunday, June 22         ICES main Committee (Morning)

The Air Force Workshop will probably be held Sunday afternoon. Petersen announced that the SCC-34 parent Committee would meet Thursday, June 19th in the morning. Adair said that a venue for the fall 2003 meeting has not been decided.

15. Adjournment

There being no further business, following a motion by Heynick that was seconded by D’Andrea, the meeting was adjourned at 1140 h.
## Attendance List

**ICES SC-4 Meeting**  
**IEEE Operations Center**  
**Piscataway, NJ**  
**December 15, 2002**

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<tr>
<th>Last Name</th>
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<tr>
<td>1. Adair</td>
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<td>13. Fichtenberg</td>
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<td>16. Hammer</td>
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<td><a href="mailto:hammerw@spawar.navy.mil">hammerw@spawar.navy.mil</a></td>
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<td>17. Heirman</td>
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<td><a href="mailto:d.heirman@ieee.org">d.heirman@ieee.org</a></td>
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M = Member  
O = Observer
IEEE ICES Main Committee
IEEE Operations Center
445 Hoes Lane, Piscataway, NJ 08855-1331
December 15, 2002
0800 – 1200 h

Preliminary Agenda

1 Call to Order

2 Approval of Agenda

3 Approval of June 30, 2002 Minutes

4 Executive Secretary’s Report

5 IEEE Standards Activities Report

6 Chairman’s Report

7 Treasurer’s Report

8 Membership Chairman’s Report

9 International Liaison Chairman’s Report
   Presentation on New RF Technologies

10 Report on ICES, Fundraising, Media Interactions

11 Reports from the ICES Subcommittees

12 New Business

13 Plans for Future Meetings

14 Adjournment

Adair

Petersen

Ortiz

Adair

Varanelli

McManus

Murphy

V. Ivans

Adair /Osepchuk

Adair

Adair

Adair

Adair
# Treasurer’s Report

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**NOTE:** Includes credits and debits from the Piscataway meeting
ICES Heard ‘Round the World’

- European Bioelectromagnetics (EBEA) Meeting, Helsinki, Sept 01
  - Excellent talk emphasizing ICES standards by David Black

- WHO EMF Regional Meeting, Seoul, South Korea, Oct 01
  - ICES represented by Patrick Mason (30 min talk)

- European Commission EMF Meeting, Luxembourg, Dec 01
  - ICES represented by Ellie Adair

- ICES Special Meeting, Luxembourg, December

- WHO EMF Regional Meeting, Cape Town, South Africa, December
  - ICES represented by Vitas Anderson (45 min talk), Dec 01

- Air Force/ICES Workshop at BEMS, 23-27 June 02, Quebec City

- WHO EMF & Human Health 3rd Conference in Russia, 23-27 Sept 02
  - Standards roundtable – C. K. Chou represents SC4 ICES

• Moscow: Institute of Biochemical Physics

• In St. Petersburg: North-West Scientific Center of Hygiene and Public Health

• During the discussions on standards, Dr. Grigoriev and Dr. Rubstova made a passionate defense of the very restrictive Russian standards for EMF. They insisted that all the “data” be considered, including the reports of non-thermal effects from the West and the voluminous reports from Russian labs, mostly from the 1970’s and published only in Russian, if published at all.
  • Much of the Russian literature is being summarized in English, but the prospects are not good for much of use

• 70 – 100 attendees. Considerably more Western participants than at the previous two WHO conferences in Russia
Future Meetings

• WHO Regional Meeting on EMF Health and Standards Harmonization
  • Guilin, China, April 2002  http://www.who.int/peh-emf/
  • International “Framework for Standards Harmonization,” a main topic

• ElectroMed2003 – 11-13 June 2003 – San Antonio Texas
  - Non-Thermal EMF Effects for Medical & Biological Applications
  - Hosted by the USAF – M. Murphy

• BEMS – Maui, Hawaii - 22-26 June 2003
  - ICES meetings

• Asia Pacific EMF Conference, Bangkok Thailand – 6- 12 Nov 2003
  - Supported by WHO, USAF, Thai Ministry of Public Health
  - Co-Organizer – Art Thansandote, Health Canada
  - Standards will be a main topic

• European Bioelectromagnetics Association (EBEA)
  - Budapest, Hungary – 13-15 Nov 2003; Chair: Gyorgy Thuroczy
Tentative Agenda


- Research on Biological Effects and Dosimetry
- Standards Harmonization: The WHO Framework
- A Framework for Regulation & Compliance
- Public Policy and Acceptance
- Electromagnetic Interference of Medical Devices
- Tutorial: Introduction to EMF Health Issues
EMF Conferences: Nov 2002—2004 Source Sheila Johnston PhD

EMF Conferences: Nov 2002—2004


Location: The Royal Society Carlton House Terrace http://www.royalsoc.ac.uk/royalsoc/con_fr.htm


Nov 20, 2002- Feb 4th 2003. National Conferences on the Sixth Framework Programme: Launch date by country: Hungary, Budapest, 05/11/02; Poland, Warsaw, 25-27/11/02; Finland, Helsinki, 26/11/02; United Kingdom, London, 2811/02; Switzerland, Bern, 6/10/02; Netherlands, Rotterdam, 10/12/02; Germany, Hannover 3-4 /02/03). For details, please see http://europa.eu.int/comm/research/fp6/conferences_en.html


February 24-26, 2003. WHO/EU/NIEHS meeting on the "Application of the Precautionary Principle" (PP). Luxembourg. First day will be open; speakers on the PP and how it may apply to EMF. Next two days (invited) is a closed working group re relation of PP to EMF. Contact WHO EMF Project.

February 27-28, 2003. Institute of Physics (IoP), London, UK. RF Interactions with Humans: Mechanisms, Exposure and Medical Applications http://physics.iop.org/IOP/Confs/ENV/ The IoP & the IEE conference will address the effects and mechanisms of RF interactions with humans and the application of microwaves in both therapeutic & diagnostic medicine. Friday 6 December 2002: deadline for receipt of abstracts
April 14-17, 2003 International Conference on Non Ionizing Radiation (ICNIR) Kuala-Lumpur, Malaysia. Theme: electromagnetic fields and our health.
http://www.uniten.edu.my/go/icnir2003/


May 15 –16, 2003 Dublin, Ireland "Health Effects of Phone Masts"...details will be found at  www.cost281.org

May 23-25\textsuperscript{th}, 2003 Vienna, Reflex Group Meeting (Invited)


June 9-11 The Society for physical Regulation in Biology & Medicine’s 22\textsuperscript{nd} Scientific Conference. Westin Hotel, Riverwalk, San Antonio Texas, USA www.westin.com/riverwalk contact gloriaparsley@aol.com, fax 301 694 4948


June 20-22, 2003, ICES meeting, The Outrigger Wailea Resort, Maui Hawaii http://grouper.ieee.org/groups/scc28/ email Dr Tom McManus tommcmanus@dpe.ie

June 22-26 2003 The Bioelectromagnetics Society 25\textsuperscript{th} Annual Meeting at The Outrigger Wailea Resort, Maui Hawaii $155 USD/per/diem. 3700 Wailea Alanui Wailea, Maui, HI  96753-8332 Ph: 808-879-1922 Fax: 808-874-833. Meeting Contact Gloria Parsley  BEMSoffice@aol.com Tel 301 663 4252, fax 301 694 4948 http://www.bioelectromagnetics.org


May 23-28, 2004, IRPA International Congress. Madrid Spain, email: secretaria.sociedades@medynet.com

June 20-24 2004, The Bioelectromagnetics Society 26th Annual Meeting. Omni Shoreham Hotel, Washington DC $155 USD. Meeting Contact Gloria Parsley BEMSoffice@aol.com Tel 301 663 4252, fax 301 694 4948 [http://www.bioelectromagnetics.org]

Source Sheila Johnston PhD
Workshop Summary

GENETIC AND CYTOGENETIC ASPECTS OF RF-FIELD INTERACTION

Löwenstein, Germany
24th - 27th November 2002

Organized by
FORSCHUNGSGEMEINSCHAFT FUNK E.V.
COST 281
MINISTERIUM FÜR UMWELT UND VERKEHR BADEN-WÜRTTEMBERG
BERUFSGENOSSENSCHAFT FÜR ELEKTROTECHNIK UND FEINMECHANIK

SHEILA JOHNSTON PhD
NEUROSCIENCE CONSULTANT

http://rfsciencefaqs.com
sajohnston@btclick.com

Introductory Remarks

• **G. Friedrich FGF**: Opened workshop on RF exposure & cytotoxic and genotoxic effects.

• **Dr. O Grözinger**, Head Dept. Emission Protection, Min Environ & Trans Baden-Württemburg funded the workshop in great part and supports RF research projects.

• **N. Leitgeb**, chair COST281, support review of child development re RF exposure & RF related cytotoxic and genotoxic research & new proposals. Preparing a statement on base site research, not advising it on scientific grounds.

• **L. Goldstein**, WHO EMF, need for base site studies, personal meters possible, concerns about children lifetime exposure. Share concerns on cytotoxic and genotoxic RF research. WHO Handbook on establishing a dialogue on risks from EMF fields available since April 2002.
Vijayalaxmi: RF exposure and genotoxicity: Fact or Fiction?
Müller: Assays identify damage to genome: possibilities & limits.
Korenstein: RF Non-thermal induc’n of genomic instability in human lymphocytes.
Scarfi: Eval of genotoxic effects (MN) in RF exposed h lymphocytes.
Leszczynski: Mobile phone RF-induced gene expression might be cell genotype-dependent.
Verschaeve: In vitro & vivo genetic effects of RF with another environmental factor.
Stephan: Chromosome damage in human lymphocytes following RF: methodical aspects.
Simko: Synergistic effects after exposure to ELF & other influences.
Glaser: What are "non-thermal" effects?
Foster: Can biophysical arguments prove genetic effects of RF energy are impossible?
DNA Strand Breaks

Chromosomal Aberrations

Micronuclei

Sister Chromatid Exchanges

Vijayalaxmi


CYTOTOXIC
Positive Cytotoxic RF Papers: Presence of RF effects on DNA single strand breaks

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<td>2 h</td>
</tr>
<tr>
<td>Zotti-Martelli et al</td>
<td>2000</td>
<td>HBL</td>
<td>In vitro</td>
<td>2450, CW</td>
<td>???</td>
<td>15, 30, 60 m</td>
</tr>
<tr>
<td>d’Ambrosio et al</td>
<td>2002</td>
<td>HBL</td>
<td>In vitro</td>
<td>1748, PW</td>
<td>5</td>
<td>15 m</td>
</tr>
<tr>
<td>Tice et al</td>
<td>2002</td>
<td>HBL</td>
<td>In vitro</td>
<td>837</td>
<td>1, 2.5, 5, 10</td>
<td>3, 24 h</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>1909.8</td>
<td>1, 2.5, 5, 10</td>
<td>3, 24 h</td>
</tr>
<tr>
<td>Sykes et al</td>
<td>2001</td>
<td>Mice</td>
<td>In vivo</td>
<td>900</td>
<td>4</td>
<td>30 m / 1, 5, 25 d</td>
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</table>
### Negative Genotoxic RF Studies: Absence of RF effects determined by CA, MN and SCE.

<table>
<thead>
<tr>
<th>Authors</th>
<th>Year</th>
<th>Cell Line</th>
<th>Experiment Type</th>
<th>RFR - MHz</th>
<th>SAR ( W / Kg )</th>
<th>Exposure</th>
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<tr>
<td>Antonopoulos et al</td>
<td>1997</td>
<td>HBL</td>
<td>In vitro</td>
<td>380, 900, 1800 PW</td>
<td>0.08, 0.2, 1.7</td>
<td>48 – 68 h</td>
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<td>Maes et al</td>
<td>2000</td>
<td>HBL</td>
<td>In vitro</td>
<td>455.7</td>
<td>6.5</td>
<td>2 h</td>
</tr>
<tr>
<td>Maes et al</td>
<td>2001</td>
<td>HBL</td>
<td>In vitro</td>
<td>900, CW</td>
<td>0.4, 2, 3.5, 5.5, 10</td>
<td>2 h</td>
</tr>
<tr>
<td>Vijayalaxmi et al</td>
<td>1997</td>
<td>HBL</td>
<td>In vitro</td>
<td>2450, CW</td>
<td>12.5</td>
<td>1.5 h, 3x0.5 h</td>
</tr>
<tr>
<td>Vijayalaxmi et al</td>
<td>2001</td>
<td>HBL</td>
<td>In vitro</td>
<td>835.6, CW</td>
<td>4.4, 5.0</td>
<td>24 h</td>
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<tr>
<td>Vijayalaxmi et al</td>
<td>2001</td>
<td>HBL</td>
<td>In vitro</td>
<td>847.7, CW</td>
<td>4.9, 5.5</td>
<td>24 h</td>
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<tr>
<td>Vijayalaxmi et al</td>
<td>2002</td>
<td>HBL</td>
<td>In vitro</td>
<td>2450, PW</td>
<td>2.1</td>
<td>2 h</td>
</tr>
<tr>
<td>Vijayalaxmi et al</td>
<td>2002</td>
<td>HBL</td>
<td>In vitro</td>
<td>8200, PW</td>
<td>20.7</td>
<td>2 h</td>
</tr>
<tr>
<td>Bisht et al</td>
<td>2002</td>
<td>C3H</td>
<td>In vitro</td>
<td>835.6, CW</td>
<td>3.2, 5.1</td>
<td>3, 8, 16, 24 h</td>
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<tr>
<td>d’Ambrosio et al</td>
<td>2002</td>
<td>HBL</td>
<td>In vitro</td>
<td>1748, CW</td>
<td>5</td>
<td>15 m</td>
</tr>
<tr>
<td>Vijayalaxmi et al</td>
<td>1997</td>
<td>Mice</td>
<td>In vivo</td>
<td>2450, CW</td>
<td>1</td>
<td>20 h / 7 d / 1.5 y</td>
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<tr>
<td>Vijayalaxmi et al</td>
<td>2001</td>
<td>Rats</td>
<td>In vivo</td>
<td>2450, CW</td>
<td>12</td>
<td>24 h</td>
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<tr>
<td>Vijayalaxmi et al</td>
<td>2002</td>
<td>Rats</td>
<td>In vivo</td>
<td>1600</td>
<td>0.16, 1.6</td>
<td>2 h / 5d / 2 y</td>
</tr>
</tbody>
</table>
If free radicals are induced either directly or indirectly by RFR, the effect should have been observed immediately after the RFR exposure or at 4 hours post-exposure.

Radiofrequency Radiation - Mobile Phones

Majority of the Investigations

No Significant Genotoxic Effect

SAR < 5.0 W/kg

Vijayalaxmi
Limitations: RF Research

- Micronuclei
  Pub: less
  Req’d: 2000

- Chromosome Aberrations
  Pub: less
  Req’d: 1000

- Sister Chromatid Exchange
  Pub: less
  Req’d: 100

These require mitosis & open the possibility of selection against heavily damaged cells, non-or slowly proliferative ones, and cells that divide too fast. W-U. Müller. Because cell cycle can be controlled in human blood lymphocyte cultures are used to test for RF-induced direct & indirect effects on chromosome damage. G. Stephan
Proposed RF-Genotoxicity Mega Project

• MN, SCE, CA
• 7 labs: Vijayalaxmi, Lagroye, Korenstein, Simco, Obe, Stephens, Verschaeve, double-blind
• 1.5 years, 750,000 euro
• RF 1800-GSM, Sham x3, Sham/RF-IR, Sham/RF-MMCM(UV)
• SAR ?, 2, 3.5 W/kg, 2-4 hr exp,
• HBL, 3 young men & 3 young women
• MN 2000, CA 1000, SCE 100 per sample
• Proposal & Funding: COST281, FGF, German Gov’ts
EMF Conferences: Nov 2002—2004


Nov 20, 2002- Feb 4th 2003. National Conferences on the Sixth Framework Programme: Launch date by country: Hungary, Budapest, 05/11/02; Poland, Warsaw, 25-27/11/02; Finland, Helsinki, 26/11/02; United Kingdom, London, 2811/02; Switzerland, Bern, 6/10/02; Netherlands, Rotterdam, 10/12/02; Germany, Hannover 3-4 /02/03). For details, please see http://europa.eu.int/comm/research/fp6/conferences_en.html


February 24-26, 2003. WHO/EU/NIEHS meeting on the "Application of the Precautionary Principle" (PP). Luxembourg. First day will be open; speakers on the PP and how it may apply to EMF. Next two days (invited) is a closed working group re relation of PP to EMF. Contact WHO EMF Project.

February 27-28, 2003. Institute of Physics (IoP), London, UK. RF Interactions with Humans: Mechanisms, Exposure and Medical Applications http://physics.iop.org/IOP/Confs/ENV/ The IoP & the IEE conference will address the effects and mechanisms of RF interactions with humans and the application of
microwaves in both therapeutic & diagnostic medicine. Friday 6 December 2002: deadline for receipt of abstracts


May 15 –16, 2003 Dublin, Ireland "Health Effects of Phone Masts"…details will be found at www.cost281.org

May 23-25th, 2003 Vienna, Reflex Group Meeting (Invited)


June 9-11 The Society for physical Regulation in Biology & Medicine’s 22nd Scientific Conference. Westin Hotel, Riverwalk, San Antonio Texas, USA www.westin.com/riverwalk contact gloriaparsley@aol.com, fax 301 694 4948


June 20-22, 2003, ICES meeting, The Outrigger Wailea Resort, Maui Hawaii http://grouper.ieee.org/groups/scc28/ email Dr Tom McManus tommcm anus@dpe.ie

June 22-26 2003 The Bioelectromagnetics Society 25th Annual Meeting at The Outrigger Wailea Resort, Maui Hawaii $155 USD/per/diem. 3700 Wailea Alanui Wailea, Maui, HI 96753-8332 Ph: 808-879-1922 Fax: 808-874-833. Meeting Contact Gloria Parsley BEMSoffice@aol.com Tel 301 663 4252, fax 301 694 4948 http://www.bioelectromagnetics.org


Chairperson György Thuróczy Email: nirdept@hp.osski.hu


May 23-28, 2004, IRPA International Congress. Madrid Spain, email: secretaria.sociedades@medynet.com

June 20-24 2004, The Bioelectromagnetics Society 26th Annual Meeting. Omni Shoreham Hotel, Washington DC $155 USD. Meeting Contact Gloria Parsley BEMSoffice@aol.com Tel 301 663 4252, fax 301 694 4948 http://www.bioelectromagnetics.org

Source Sheila Johnston PhD
Medical Implant SAR and Thermal Modeling

Piotr Przybyszewski, Ph.D.
E-mail: piotr.przybyszewski@medtronic.com

December 15, 2002
Medical Implant SAR and Thermal Modeling

- Potential technological developments
- Safety requirements for AIMD
- Bio-heat transfer equation
  - Thermal properties of tissues
  - Solutions for special cases
- Heating safety analysis
  - Proposed analysis flow
- Tools
- Conclusions
Potential technological developments (1)

- **AIMD (Active Implantable Medical Devices)** currently communicate with programmer via telemetry/inductive magnetic fields

- **Current technology limitations:**
  - Works at relatively short distance – programmer head must be in the sterile field at implant
  - Low communication speed
Potential technological developments (2)

- AIMD manufacturers have been granted secondary use of the 402-405 MHz band allocated to Meteorological Aids (Recommendation ITU-R SA.1346, 1998)

- RF requirements:
  - ETSI EN 301 839,
  - FCC Rep.&Order 99-66
  - Max output power – 25 µW
  - Max bandwidth – 300 kHz
  - “Listen before talk” protocol
Safety requirements for AIMD (1)

• **Current requirements for AIMD:**
  - ISO 14971 – Risk/Hazard Analysis
  - Temperature rise limit during normal operation (per CENELEC PrEN 45502-2-1)
    - $\Delta T < 2 ^\circ C$
    - requirement directly related to tissue damage
Safety requirements for AIMD (2)

- **FCC regulations:**
  - **SAR limit**
    - 1 g average SAR < 1.6 W / kg
    - requirement indirectly related to tissue damage: SAR causes heating
  - SAR modeling (or) measurements – sufficient for safety verification
Safety requirements for AIMD (3)

1g average SAR < 1.6 W / kg

\[ \Delta T < 2 \, ^\circ C \]

• Is this always true?
  or
• Under what conditions?
Heat Transfer

\[ \rho c \frac{\partial}{\partial t} T = \nabla \cdot k \nabla T - c_b W (T - T_b) + Q_e \]

- **Temp. change vs time**
- **Thermal conduction**
- **Blood perfusion**
- **External heat source**

**Variables**

- \( \rho \) [kg/m\(^3\)]: density
- \( c \) [J/(kg\(^o\)C)]: specific heat
- \( c_b \) [J/(kg\(^o\)C)]: specific heat of blood
- \( k \) [W/(m\(^o\)C)]: thermal conductivity
- \( W \) [kg/(m\(^3\)s)]: blood perfusion rate
- \( T_b \) [\(^o\)C]: temperature of blood

**Equation**

\[ Q_e = \rho \cdot SAR \]
## Thermal Properties of Tissues

<table>
<thead>
<tr>
<th>tissue</th>
<th>$k$  [W/(m·°C)]</th>
<th>$c$  [J/(kg·°C)]</th>
<th>$W$ [kg/(m³·s)]</th>
<th>$\rho$ [kg/m³]</th>
</tr>
</thead>
<tbody>
<tr>
<td>skin</td>
<td>0.442</td>
<td>3600</td>
<td>1.899</td>
<td>1125</td>
</tr>
<tr>
<td>fat</td>
<td>0.210</td>
<td>2260</td>
<td>0.540</td>
<td>943</td>
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<tr>
<td>muscle</td>
<td>0.542</td>
<td>3474</td>
<td>0.37–3.69</td>
<td>1059</td>
</tr>
<tr>
<td>active muscle</td>
<td>0.542</td>
<td>3474</td>
<td>18.658</td>
<td>1059</td>
</tr>
<tr>
<td>heart</td>
<td>0.542</td>
<td>3474</td>
<td>15.641</td>
<td>1059</td>
</tr>
<tr>
<td>blood</td>
<td>0.506</td>
<td>3893</td>
<td>–</td>
<td>1057</td>
</tr>
<tr>
<td>cortical bone</td>
<td>1.450</td>
<td>1256</td>
<td>0.540</td>
<td>1850</td>
</tr>
</tbody>
</table>
Medical Implant SAR and Thermal Modeling

Solution of bio-heat equation: special case (1)

- **No blood perfusion**
- **No thermal conduction**

\[ \Delta T = \frac{\text{SAR}}{C} \cdot t \]

<table>
<thead>
<tr>
<th></th>
<th>cortical bone</th>
<th>fat</th>
<th>muscle</th>
<th>skin</th>
</tr>
</thead>
<tbody>
<tr>
<td>$C$ [J/kg°C]</td>
<td>1256</td>
<td>1440</td>
<td>2260</td>
<td>3474</td>
</tr>
<tr>
<td>$\Delta T_{30\text{min}}$ [°C]</td>
<td>2.293</td>
<td>2.000</td>
<td>1.274</td>
<td>0.829</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.800</td>
<td></td>
</tr>
</tbody>
</table>
Solution of bio-heat equation: special case (2)

- **Blood perfusion**
- **No thermal conduction**

\[ \Delta T = \frac{\rho \cdot SAR}{c_b W} \left[ 1 - \exp \left( -\frac{c_b W}{\rho c} t \right) \right] \]

\[ \Delta T_{\infty} = \frac{\rho \cdot SAR}{c_b W} \]

<table>
<thead>
<tr>
<th></th>
<th>cortical bone</th>
<th>fat</th>
<th>muscle (high)</th>
<th>skin</th>
</tr>
</thead>
<tbody>
<tr>
<td>( \Delta T_{30\text{min}} \left[ ^\circ C \right] )</td>
<td>1.132</td>
<td>0.596</td>
<td>0.595</td>
<td>0.234</td>
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<tr>
<td>( \Delta T_{\infty} \left[ ^\circ C \right] )</td>
<td>1.408</td>
<td>0.718</td>
<td>1.176</td>
<td>0.243</td>
</tr>
</tbody>
</table>
Solution of bio-heat equation: special case (3)

- Hot spots – field close to singular
  - Singularity near metal edge
  - Neumann boundary conditions (no thermal conduction)
  - Maximum SAR at the boundary
  - Case (2) at the boundary
Medical Implant SAR and Thermal Modeling

Solution of bio-heat equation: special case (4)

- **Problem: SAR averaging**

\[
\frac{SAR_{\text{max}}}{SAR_{\text{avgmax}}}
\]

![Graph showing SAR max and SAR avgmax ratio over averaging distance/radius]

\[
E_r \sim \frac{1}{r^\alpha}
\]

\[
\text{SAR} \sim \frac{1}{r^{2\alpha}}
\]

\[
\alpha = 0 \ldots 1 \ldots 2
\]
Medical Implant SAR and Thermal Modeling

Equivalence of SAR and temperature limits

1g average SAR $< 1.6 \text{ W / kg}$

$\Delta T < 2 \, ^\circ\text{C}$

Conditions:

- No singularities
- No worst case tissues
- Time limit
- Further analysis required
Analysis of safety (1)

Temperature limit

$\Delta T < 2 \, ^\circ\text{C}$

SAR limit

- Under appropriate conditions:
  1g average SAR < 1.6 W/kg
Analysis of safety (2)

SAR limit

1g average SAR < 1.6 W/kg

1g average SAR < 1.6 mW/g

Power limit

Worst case:

all the power absorbed in 1g of tissue:

\[ P_{\text{available}} < 1.6 \text{ mW} \]
Medical Implant SAR and Thermal Modeling

Proposed Analysis Flow

- Power balance calculation / measurements
  - Power limit
    - \( P < 1.6 \text{ mW} \)
      - Y
    - N
  - SAR
    - SAR limit
      - SAR < 1.6 W/kg
        - Y
      - N
  - Bio-heat transfer simulation / measurements
    - Temperature limit
      - \( \Delta T < 2 \text{ °C} \)
        - SAFE
      - UNSAFE
Medical Implant SAR and Thermal Modeling

Tools

- Power balance
- Electromagnetic solver
  - Finite-Difference Time-Domain (FD-TD)
- Bio-heat transfer equation solver
  - Based on finite difference technique
Medical Implant SAR and Thermal Modeling

Model of Human Body  Human Body Mesh
Conclusions (1)

- AIMD are subjected to existing safety standards for medical devices
- Heating safety conditions should be tested in the following order:
  - Power < 1.6 mW
  - 1g average SAR < 1.6 W/kg
  - Temperature < 2 °C
  - If one of the steps is satisfied, the subsequent steps do not have to be tested
Conclusions (2)

- Thermal modeling is complex and thus not recommended
- AIMD should not be subjected to IEEE C95.1
5.1.4 Position statements on standards to legislative bodies, government agencies, and international organizations

As stated in the IEEE Policy and Procedures, the Institute recognizes the need for public statements on topics within the scope and purposes of the IEEE. Each IEEE Standards Sponsor shall have policies and procedures in place concerning the creation and handling of position statements on standards prior to sending any such statements to any governmental body or international standards organization. These procedures should state a means for determining a Sponsor position and a methodology for presentation of position statements. These procedures shall also conform to the IEEE-SA procedures as administrated by the IEEE-SA Board of Governors (BOG) and stated in subclause 6.5 of the IEEE Standards Association Operations Manual.

Each position statement shall clearly state the group forming this position in its opening paragraph. The IEEE-SA Standards Board shall include a cover letter with each position statement at the time such statements are forwarded to the IEEE-SA BOG. This cover letter shall include, at a minimum, the intended recipient of the position statement; the time sensitivity of the position statement; and why the position statement is needed.

Electronic copies of all position statements shall be sent to the Secretary of the IEEE-SA Standards Board and the Secretary of the IEEE-SA BOG, who shall forward such statements to the IEEE-SA BOG for appropriate action. A consolidated listing of all such position statements shall be maintained on the IEEE Standards website. The rules in Section 15 of the IEEE Policy and Procedures shall be followed in developing Sponsor procedures.

If the Sponsor wants to create an entity position statement on standards that represents the viewpoint of the IEEE Standards Association, the rules in the IEEE Standards Association Operations Manual shall be followed. If the Sponsor wishes to go to another IEEE entity (as defined in Section 15 of the IEEE Policy and Procedures) to have that entity offer a position statement on a standards matter, they shall do so after agreement from the IEEE-SA BOG.

6.5 Position statements

As stated in the IEEE Policies, the Institute recognizes the need for public statements on topics within the scope and purposes of the IEEE. The IEEE-SA BOG shall be the sole entity to approve position statements representing the IEEE Standards Association. The BOG may request that another IEEE entity (as defined in Section 15 of the IEEE Policies) offer a position statement on a standards matter. The rules in Section 15 of the IEEE Policies shall be followed in developing position statements. In addition, the BOG will accept for review and action any position statement presented to it by another body for issuance as an IEEE-SA position statement.

Any position statements representing the IEEE Standards Association shall be approved by a simple majority of the voting members of the IEEE-SA BOG through a
15-day ballot. The IEEE-SA BOG shall call upon such expertise as may be required to draft a position statement.

The Secretary of the IEEE-SA BOG shall forward any approved IEEE Standards Association position statements to the target recipient of the position statement and to appropriate entities within the IEEE. A consolidated listing of all such position statements shall be maintained on the IEEE Standards website.

Excerpted from the *IEEE Policies*

**SECTION 15 - IEEE POSITION PAPERS, ORGANIZATIONAL UNIT POSITION STATEMENTS, AND TESTIMONY BEFORE GOVERNMENT BODIES**

**15.1 - OBJECTIVES**

The IEEE recognizes the need for public statements on topics within the scope and purposes of IEEE. Such statements and papers can provide timely information to the public, media, public agencies, and IEEE members.

Such statements and papers can be developed and used primarily by an individual IEEE organizational unit, under the title of "Organizational Unit Position Statement," or they may be developed with a broader IEEE-wide base in mind under the title of "IEEE Position Paper."

Individual IEEE members are encouraged to participate actively in the discussion of such issues and are, of course, free to express their personal views, clearly identified as such, in any appropriate public forum. When presenting views publicly that purport to represent specific segments of the IEEE or the IEEE as a whole, the procedures outlined in this section should be followed to obtain approved positions upon which such views can be based.

These procedures establish a framework that will enhance and support the objectives of the IEEE by allowing expression of views that represent, on a case-by-case basis, as large a fraction of the membership as possible. It is not intended to preclude expression of opposing or differing views by IEEE organizational units. However, recognizing that IEEE objectives are best pursued when concerted, consensus positions can be articulated, organizational units are encouraged to seek common ground for expression of their views by submitting proposed organizational unit position statements for approval at the highest level within the IEEE appropriate to the issues involved and their position within the IEEE.

In the special case of formal testimony presented to government bodies, covered in Section 15.8, it is the policy of IEEE to speak with a single voice, since conflicting or opposing views delivered on behalf of different IEEE organizational units can be harmful to the image of the IEEE and confusing to the recipient of such statements. Therefore, in the case of testimony, these procedures are intended to establish central coordinating points for clearance of the statements and a method for reacting quickly in order to respond to government needs on a timely basis. Where resolution of possible conflicting views cannot be obtained, it should normally be the practice for an IEEE organizational unit to decline to deliver testimony rather than have divergent or contradictory views presented.
Where it is apparent that a significant number of members hold a minority, but deeply felt view on an issue, this fact should be recognized and taken into account in developing positions or testimony. The determination of "significant number" and "deeply felt" in such cases is not quantified in this policy statement.

15.2 - DEFINITIONS OF TERMS

The following definitions of terms are provided:

A. **An IEEE Organizational Unit is a formally constituted body within IEEE.** An organizational unit has a formally adopted and approved Charter and/or scope and has a formal place within the hierarchical structure of IEEE. It is understood that the word "organizational unit" as used in these guidelines will be replaced by the actual name of an IEEE Organizational Unit. An organizational unit has a formally adopted and approved Charter and/or scope and has a formal place within the hierarchical structure of IEEE. It is understood that the word "organizational unit" as used in these guidelines will be replaced by the actual name of the organizational unit in the actual position document developed.

B. **Organizational Unit Position Statement** - A document, issued in the name of an organizational unit, developed to express an opinion by an IEEE organizational unit on a specific topic. This document should be subjected to a review procedure by the organizational unit in accordance with Sections 15.3 and 15.4.

C. **IEEE Position Paper** - document, issued in the name of the transnational, multidisciplinary IEEE, developed to express a formal opinion on a specific topic. This document shall be subjected to a formal review and approval process in accordance with Sections 15.5 and 15.6.

15.3 - PREPARATION OF ORGANIZATIONAL UNIT POSITION STATEMENTS

An Organizational Unit Position Statement may be prepared and issued by any organizational unit of the IEEE provided that:

A. The subject of the Organizational Unit Position Statement lies within the purposes of the IEEE as set forth in the IEEE Constitution, Bylaws, or Policies and Procedures.

B. The subject of the Organizational Unit Position Statement lies within the approved scope of the organizational unit developing and issuing the Organizational Unit Position Statement.

C. The issuing organizational unit specifies the need for and the intended use of a particular Organizational Unit Position Statement.

D. The identity of the organizational unit issuing the statement is clearly specified in the text of the statement and the statement is signed and dated by the highest officer of that organizational unit or, in the case of his unavailability, by a responsible officer acting in his name.

E. The organizational unit shall send a copy of the Organizational Unit Position Statement to the IEEE Executive Director, upon issuance, where a consolidated listing of all such statements will be maintained.
F. When the Organizational Unit Position Statement has been approved and issued, it (or a suitable summary) should be published in the issuing organizational unit's newsletter or other publication reaching the members of that organizational unit, and be given such other circulation within the IEEE as may be appropriate, including, specifically, the public information officers of the IEEE.

15.4 - PROCEDURE FOR APPROVAL OF AN ORGANIZATIONAL UNIT POSITION STATEMENT

An Organizational Unit Position Statement may be issued when either of the following two conditions is met:

A. The Organizational Unit Position Statement has been approved by a majority vote of that organizational unit at a meeting at which business may be conducted.

B. The Organizational Unit Position Statement has been approved by a 2/3 vote of the AdCom, OpCom, or other formally constituted management group of the organizational unit.

15.5 - PREPARATION OF AN IEEE POSITION PAPER

A draft IEEE Position Paper may be originated provided that:

A. The subject of the IEEE Position Paper lies within the purposes of the IEEE as set forth in the IEEE Constitution, Bylaws, or Policies and Procedures.

B. The subject of the IEEE Position Paper lies within the approved scope of the organizational unit developing the IEEE Position Paper.

C. The developing organizational unit specifies the need for and the intended use of a particular IEEE Position Paper, and follows the procedures set forth in these guidelines.

D. The paper has been approved by majority vote of the IEEE Major Board of which the organizational unit is a part. This Board becomes the originating Board and is responsible for carrying out the procedures outlined in Section 15.6.

15.6 - PROCEDURE FOR APPROVAL OF AN IEEE POSITION PAPER

A. The completed IEEE Position Paper and a one-page Position Digest are to be sent by the originating Board to the Chairmen of the other IEEE Major Boards, with notification that it is intended that the Position Paper be considered by the Board of Directors. A Board desiring to review the paper should so indicate.

B. For each Board expressing a desire to review the proposed IEEE Position Paper, the paper must be approved by a majority vote of the Board or by a 2/3 vote of its formally constituted management group.

C. Failure to approve a proposed IEEE Position Paper by any major interested Board should be accompanied by a statement to the originating Board explaining the basis for such rejection and, if possible, recommended changes that would make the Position Paper acceptable.

D. Upon approval by the major interested Boards, the paper shall be brought to the Board of Directors. A majority vote is required for final approval.
E. A copy of every approved IEEE Position Paper and a consolidated listing of such Position Papers shall be maintained in the office of the IEEE Executive Director.

F. When an IEEE Position Paper is approved and issued, it (or a suitable summary) shall be published in an IEEE-wide publication. (Should the originating organizational unit have a newsletter or other publication, it is recommended that the IEEE Position Paper also be published therein.) A listing of extant IEEE Position Papers shall be published periodically in an IEEE-wide publication.

15.7 - PERIODIC REVIEW

All Organizational Unit Position Statements and IEEE Position Papers shall be reviewed by the issuing organizational unit for current applicability at intervals of no longer than five years. Extension or interpretations may result from such reviews, as well as withdrawals.

15.8 - TESTIMONY BEFORE GOVERNMENT BODIES

A. When issues of interest to the IEEE are considered by government bodies, the concerned IEEE organizational units whose charters encompass the issues are encouraged to develop formal testimony. When an IEEE Position Paper is available on the issue, this document should form the basis for such testimony. When such a position has not been previously developed, the person(s) preparing the testimony should derive material for the testimony from concerned organizational units within the IEEE as much as possible. Any existing Organizational Unit Position Statements shall be considered in the preparation of the testimony. Such testimony should be sponsored by the Committee, Task Force, or Society responsible for the matters covered, if such exists. The proposed testimony should clearly identify the organizational unit whose position the testimony represents.

B. For testimony before United States government bodies, the copy must be reviewed and approved by the Chairman of the IEEE-USA (or his/her IEEE-USA member designate) and one Delegate/Director member of IEEE-USA, selected on the basis of the relevance of his/her background or current responsibility to the issues being considered. If the testimony involves matters specifically within the purview of RAB, TAB, PSPB, or Standards, the testimony shall also be subject to review and approval by the Chairman of the appropriate Board or, at his/her direction, other members of the Board, whose scopes cover the technical areas involved. In the event the IEEE-USA Chairman shall fail to approve a testimony, the said testimony with the Chairman's written comments shall be referred to an Ad Hoc Committee, composed of an equal number of volunteers appointed from IEEE-USA OpCom and the management body of the organizational unit preparing that testimony, for a telephone conference, discussion and resolution of the matter in a speedy manner. The IEEE Washington office will keep a record of all testimony, written and oral, that is submitted to United States government bodies.

C. None of the procedures required in paragraphs A and B above shall be interpreted to be required for the normal private working interactions between TAB bodies and related government groups on purely technical matters or similar interactions between bodies of the Standards Board and related government groups on the development of Standards.

D. For testimony before government bodies, other than the U.S. Government, the highest ranking volunteer (or his/her designate) for the geographic organizational
unit encompassing that government's jurisdiction, along with one other volunteer officer from that geographic organizational unit, should review and approve the testimony. If the testimony involves a field of technology, then an additional IEEE volunteer, who shall be a designated representative of that field of technology, shall review the testimony for its technical content. Such technical representative shall be designated by the Vice President - Technical Activities.