Approved Minutes

IEEE/ICES TC95 Subcommittee 3
Safety Levels with Respect to Human Exposure to Electromagnetic Fields, 0 - 3 kHz

IEEE/ICES TC95 Subcommittee 4
Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields,
3 kHz to 300 GHz

Part 1

1300 – 1600 h
Friday, 12 June 2015
The Pacific Grove Community Center
300 Forest Avenue
Pacific Grove, California, USA

1. Call to Order
Co-chairman Ziskin called the meeting to order at 1320 h.

2. Introduction of those Present
Each of the attendees was asked to introduce her/himself. (See Attachment 1 for attendance list.)

3. Approval of Agenda
Following a motion by Cotton, seconded by Baily, the agenda was approved with the following additional items: 7 e) – Update on WHO consultation document (Bodemann); 7 f) – Update on NIOSH adoption of ICES basic restrictions (Bowman); and, under New Business, Policy statement regarding review of papers missing information. (See Attachment 2.)

4. Approval of the Minutes of the 10 September 2014 Meeting
Following a motion by Bodemann, seconded by Wessel, the minutes of the 10 September 2014 SC3/SC4 meeting were approved as presented.

5. Secretary's Report
Petersen reported that he will be giving a detailed report at the TC95 Meeting. He noted that although a PAR extension request for the revision of IEEE Std C95.1-2005 was approved by the IEEE-SA Standards Board at the December 2014 meeting—the extension is only valid until 31 December 2016.

6. Chairmen’s Reports
Ziskin briefly discussed a lawsuit filed in the Superior Court of the District of Columbia concerning the IEEE C95 standards related to cellular telephone safety. (See Attachment 3). He explained that since the names of subcommittee members are listed in the front matter of the
standards, and those named may be in possession of relevant documents, everyone should be aware of this matter in the event further action is required. The case was resolved but the statements from the letter from the Managing Director of the IEEE Standards Association, Konstantinos Karachalios, generally applies.

Ziskin reviewed progress on the WHO Environmental Health Criteria Consultation Draft, which will be used for updating the 1993 WHO monograph on RF fields. Following up on the invitation to provide comments on the draft, ICES provided 40 pages of detailed comments, which were submitted 3 December 2014.

Ziskin thanked Hirata and Reilly for their efforts to organize a new TC95 subcommittee, SC6 – EMF Modeling and Dosimetry – chaired by Hirata. He noted that SC6 sponsored a well-attended workshop at the Asilomar Conference Grounds, Pacific Grove, CA, immediately before the opening of BioEM2015.

Ziskin briefly discussed the WHO/ICNIRP Workshop held in Istanbul, Turkey, 26 – 28 May 2015. He, and ICES members Foster and Hirata gave presentations at the workshop – links to the presentations can be found at: http://www.icnirp.org/en/workshops/article/workshop-thermal-damage.html. He noted that many of the topics discussed are relevant to SC3 and SC4 regarding the revision of C95.1-2005 (see slide 16 of Attachment 3).

7. Progress on Revision of IEEE Std C95.1-2005

a) Update on the revision of C95.1-2005 and C95.6-2002

Chou provided a brief history of Standards C95.1-2005 and C95.6-2002 noting the decision in 2007 to combine both standards into a single standard covering the 0 Hz to 300 GHz frequency range. He pointed out that the preliminary effort of combining the two standards was directed towards the development of IEEE Std C95.1-2345-2014, which covers the 0 Hz to 300 GHz frequency range but does not include an updated literature evaluation/review.

The current effort is to move forward with the revision updating Annex B (summary of the literature). A systematic literature evaluation process is now being developed — leaders for each topic area, e.g., thermoregulation, epidemiology studies, blood-brain-barrier permeability, have been identified. Some of the topic leaders are not ICES members but are leaders in the field, some of whom have been involved in the WHO literature review process. Recently Mike Repacholi, formerly with the WHO EMF Project, agreed to lead the effort on the review of the animal study literature. Repacholi also agreed to draft a paper on defining a systematic review process. A revised draft, which contains improvements over the WHO process, was recently submitted to the Literature Evaluation Working Group for comment.

b) Literature surveillance

Elder provided an update on the literature surveillance effort (see Attachment 4). He discussed the database now located on the ICES website, which lists close to 6000 citations, many with abstracts. The abstracts are available to everyone – the full papers are available only to members of the literature evaluation working groups. He pointed out that the lists are downloadable by subject area/category.

Meltz reviewed a 1987 paper that he and Dave Erwin published in the BEMS Newsletter1 that listed 15 criteria for literature evaluation that the reviewers should be aware of. He also noted that the draft papers prepared by Repacholi applied mostly to papers describing

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epidemiological studies. In response to a question regarding papers that are not in the database, Elder responded that all available relevant papers published in the English language are included.

c) Progress on literature review papers
Faraone provided an update on the literature review. (See Attachment 5.) He reviewed the history of the Literature Review Working Group, which was organized in February 2015. Goals and timelines have been set, topic leaders identified, and about 50% of the literature for review has been selected. Reilly noted that one of the reasons why SC6 was created was to ensure proper review of the low-frequency papers. Baily questioned whether the low-frequency reviews can be completed in time for publication of the revised standard and, if not, how the issue will be treated. There was no consensus on this issue – a caveat regarding the low-frequency literature may be necessary. It was agreed that it would be inappropriate to not include a review of the low-frequency literature since the revision is the merging of C95.6-2002 (0 Hz to 3 kHz) and C95.1-2005 (3 kHz – 300 GHz). In response to a suggestion that SC6 could solicit from its members a list of relevant papers that should be reviewed—Reilly responded noting that SC6 has already identified a list of 24 items needing review. Kavet pointed out that bioassays (animal studies) and epidemiology studies should take preference in the low-frequency literature review—in vitro studies can wait. Reilly agreed noting that most of the members of SC3 (0Hz to 3 kHz) are mostly interested in RF, that’s one of the reasons for establishing SC6 whose members are devoted to studying effects at low frequencies. Bailey pointed out that the in vitro literature should at least be scanned for evidence of DNA damage. In response to a question from Meltz as to whether or not SC6 is reviewing all of the low-frequency literature, Reilly explained that the selection criteria has to be selective—there are thousands of papers reporting effects at levels well below the electrostimulation threshold. Reviewing this database would be time-consuming and irrelevant for the charge of SC6. Kavet commented that while papers reporting effects at low levels are not relevant with respect to induction models, they are important to some members of the public and should be reviewed. In response to a question regarding whether we are obligated to combine C95.1 and C95-6, Faraone explained that this decision was agreed on by the committee. Meltz suggested that the literature review group examine the database to establish the number of papers for review in each category to get a sense of the most efficient way to move forward with the low-frequency reviews. Ziskin agreed adding that the consensus is that all relevant low frequency and RF papers should be included in the literature review.

Faraone pointed out that even though only relevant papers published after 2002 – 2003 are being considered, completion of the review may not occur in time for balloting on the revision before 31 December 2016, which is when the PAR expires. Another extension request may be needed.

d) Update on NATO standard C95.1-2345
Klauenberg provided an update on the status of IEEE Std C951-2345-2014 with respect to the NATO ratification process of adopting the standard as a replacement for NATO Standards Agreement (STANAG) 2345). (See Attachment 6.) He reviewed the history of the project beginning with the 2009 agreement between IEEE and the NATO Standardization Agency up to the current status – ratification of adoption of IEEE C95.1-2345-2014 as a civil
standard to replace STANAG 2345. Klauenberg was optimistic that the process would conclude favorably within several months.

e) Update on WHO consultation document
Bodemann reported on the status of the WHO consultation document. He noted that some sections are incomplete, e.g., there are no conclusions regarding hazards. Currently the draft is approximately 400 pages in length printed with a somewhat small font. He noted that drafting task group will meet in the fall of 2015 to decide which papers to include. There will be further meetings to discuss hazard criteria. The goal is to complete the document by the end of 2016. Bodemann noted that ICNIRP also plans to issue an update of their 1998 guidelines for limiting exposure to time-varying electric, magnetic and electromagnetic fields (up to 300 GHz).

f) Update on NIOSH adoption of ICES basic restrictions
Bowman provided an update on his September 2014 SC3/SC4 meeting presentation on how NIOSH can adopt the ICES basic restriction as its recommended exposure limit at low frequencies (see Attachment 7). He pointed out that the reason for not adopting the ICES low frequency exposure reference levels are they appear to be extremely conservative without the basic restrictions included. The proposal is to adopt the BR for the internal E-field as its exposure limit with the assumption that an internal E-field meter, i.e., a basic restriction meter, can be developed with a response shaped to the ICES frequency response. A possible partner to design a suitable instrument has been identified. He described the “basic restriction meter in detail (see slides). In response to a number of questions Bowman explained that the device could possibly be patentable. Also, potential conflict of interest issues have to be investigated as would the relationship between NIOSH and a commercial developer of the device. He concluded by noting that he will work closely with TC95 and will rely on ICES moving forward with the revision of C95.1-2005.

8. Developing a WHO Standard on Non-ionizing Radiation
Bodemann reported that a core group was established to draft recommendations—members include Emily van Deventer and John O’Hagan. A number of organizations have been identified to serve various roles in the development of the new standard. Right now the work is being carried out at a high level. Eventually relevant groups such as ICES, ICNIRP, ITU and others will be included in the process as developers, not observers. The goal is to produce a UN standard that can be adopted by member countries by end-of-year 2018.

Part 1 of the SC3/SC4 Meeting was adjourned at 1635 h.
Chairman Ziskin called Part 2 of the meeting to order at 0910. Each of the attendees introduced her/himself. See Attachment 1b for the list of attendees.

Agenda (Continued)

9. Technical presentations
   
a) Stimulus-response relationships and dosimetric uncertainty
   
   Kavet provided a perspective on stimulus-response relationships and dosimetric uncertainty as it applies to the work of SC3, SC4 and SC6. (See Attachment 8.) He noted that the presentation is based on an early draft of a paper he submitted to *Health Physics*—the paper is now in the review process.2 An early draft was reviewed by Reilly and Tell. He compared the ICNIRP models with those of ICES (see slides 4 and 5) pointing out that it is not clear whether the ICNIRP values for peripheral nerve stimulation are peak or RMS values. He noted the work of Dimbylow in 2005 that led to the model used by ICNIRP relied mostly on coupling to the head. Reilly pointed out that the upper limits in the C95.6-2002 standard, which are based on experimental data from a variety of sources, protect 99% of the population and that a log-normal curve fits the empirical data closely. Following a question regarding the health and disabilities of those exposed, e. g., persons with a high sensitivity to pain, and whether such people were included in any of the studies, Kavet noted that “all persons” is defined in statements such as “protects all persons…” but ICNIRP does not provide a definition. In the C95 standards, the median stimulus divided by 3 is considered the value that protects more than 99% of the population. He concluded his presentation noting that going forward, empirical and dosimetric data can be used together to set the basis for appropriate safety factors.

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2 “R Kavet, Dosimetric uncertainties: Magnetic field coupling.”
b) Development of Averaging Times for Frequencies above 3 GHz

Foster provided a history and rationale of the development of averaging times. (See attachment 9). He noted that there seems to be some confusion about the thermal averaging time values which to some seem subjective—but reasonable. He discussed application of Pennes’ bioheat equation noting that it seems to work better at millimeter-wave frequencies because of the thinner layer of energy absorption. Faraone noted that part of the literature review related to the relationship between temperature and SAR and asked whether or not the bioheat equation was valid at lower RF frequencies. Foster noted that it is for some approximations, e.g., SAR in the brain associated with exposure to a mobile phone where the change in temperature is small – tenths of a degree. He pointed out that a useful definition of averaging time is the maximum allowable steady state temperature increase divided by the peak SAR. The question arose as to how the present limits address health risk in the general population and should anything be done to address the issue. The general consensus was that it would be appropriate to identify a realistic risk to protect against and protect against that risk—not against all risks. Tell raised the issue of exactly what risk are we protecting against – thermal discomfort? He pointed out that the basic restrictions are based mainly on animal data and animals have a less efficient thermoregulatory system than humans. Perhaps the current limits are too conservative. There being no action on a decision addressing this issue, Foster concluded by noting that the averaging time first proposed, i.e., 6 minutes, was somewhat arbitrary, but turned out to be reasonable, and asked rhetorically “how much precision is needed and at what cost in complexity?”

10. New Business

a) Review of Repacholi draft criteria for determining causation paper

Chou reported that a small review task group (Task Group) was formed to review a draft paper “Determining whether physical agent exposure causes adverse health effects” prepared by Mike Repacholi for use by the literature evaluation working groups. The Task Group members include Bailey, Bushberg, Chou, Elder, Faraone, Meltz and Ziskin. Chou noted that the 1st draft had been circulated and comments/suggestions forwarded to Repacholi. Baily pointed out that the draft is very general—Chou noted that the 2nd draft is much improved and more specific. The goal of the Task Group is to judge the usefulness of the paper with respect to the ICES literature evaluation process.

ACTION ITEM 1:
Chou to contact Repacholi and request that he move forward and address comments and produce a 2nd draft of his paper Determining whether physical agent exposure causes adverse health effects.

ACTION ITEM 2:
Chou to distribute the Repacholi paper and a comment matrix to TC95 for comment.

Foster noted that the literature evaluation process appears to be very complex. Perhaps an examination of the value of the initial evaluation for the 2005 standard is in order. Questions were raised concerning the process used for the C95.1-2005 standard and whether that process could be followed to expedite moving forward, e.g., the process used by WHO, IARC, EPA, etc. Bailey suggested that the detailed process followed by the National Toxicology Program should certainly be considered by the Task Group.
ACTION ITEM 3:
The Task Group will discuss the comments received to date and discuss their conclusions with Repacholi.

b) Policy statement regarding treatment of papers missing information
Elder pointed out that a policy statement regarding the value of certain studies and their relevance is needed. For example, how shall studies be handled that are missing information on exposure? Should papers missing dosimetry data be declared irrelevant for evaluation purposes? Klauenberg suggested that not only papers missing dosimetry data, other missing data, e.g., relevant sample size in epidemiology papers, should also be included. Elder noted that the evaluation for the 2005 standard included only papers that reported the dosimetry. He pointed out that the goal is to make the literature evaluation process as uniform as possible. Issues such as missing dosimetric data, relevant sample size, should be considered by the Task Group when defining the process.

11. Other new business
Faraone asked whether ICES should be involved in the Industry Canada review “General Methods for Assessing Compliance to Peripheral Nerve Stimulation (NS) limits of RSS-102” noting that the deadline for indicating interest is 19 June 2015. Reilly noted that his understanding of program is an exchange of information with other expert bodies. Industry Canada does not recommend exposure limits; the limits are developed by Health Canada—Industry Canada is looking for the means for complying with the Health Canada limits. There was consensus that ICES would provide comments. Anyone interested in participating in the review should inform Faraone.

12. Date and Place of Next Meeting
The next meeting will be held in January at the Motorola Solutions facility in Plantation, FL—the exact dates to be announced. The summer 2016 meeting will be held in Ghent, Belgium, immediately before BioEm2016 (tentative dates: June 2, 3 and 4).

13. Adjourn
There being no further business, the meeting was adjourned at 1200 h.

Attachments

1. List of Attendees
2. Approved Agenda
3. SC-4 Chairman’s Report (Ziskin)
4. IEEE Database (Elder)
5. IEEE ICES Literature Review (Faraone)
6. STANAG 2345 – Ratification Process (Klauenberg)
7. How NIOSH can adopt the ICES Basic Restriction as its Recommended Exposure Limit for ELF-EMF (Bowman)
8. A Perspective on Stimulus-Response Relationships and Dosimetric Uncertainty (Kavet)
9. Comments on Thermal Averaging (Foster)
## Action Items From June 2015 SAC3/SC4 Meetings

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# Sign-in Sheet

**TC95 SC3 & SC4 Meeting**  
*1300 – 1630 h, Friday 12 June 2015*  
**City of Pacific Grove Community Center (Lebeck Room)**

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# Sign-in Sheet

**TC95 SC3 & SC4 Meeting**

0900 – 1200 h, Saturday 13 June 2015

City of Pacific Grove Community Center (Lebeck Room)

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<td>Ron</td>
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<td>J Patrick</td>
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<td>Ziskin</td>
<td>Marvin</td>
<td>Temple University</td>
<td>US</td>
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</table>
Approved Agenda

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

1300 – 1600 h
Friday, 12 June 2015

and

0900 – 1200 h
Saturday, 13 June 2015
The Pacific Grove Community Center
300 Forest Avenue
Pacific Grove, California, USA

1. Call to Order
2. Introduction of those Present
3. Approval of Agenda
4. Approval of the Minutes of the 10 September 2014 Meeting
5. Secretary's Report
6. Chairmen’s Reports
7. Progress on revision of IEEE Std C95.1-2005
   a) Update on the revision of C95.1-2005 and C95.6-2002
   b) Literature surveillance
   c) Progress on literature review papers
   d) Update on NATO standard C95.1-2345
   e) Update on WHO consultation document
   f) Update on NIOSH adoption of ICES basic restrictions
8. Update on New Subcommittee (SC-6): Dosimetry issues
9. Developing a WHO Standard on Non-Ionizing Radiation
10. Technical Presentations
    a) Stimulus-response relationships and dosimetric uncertainty
    b) Development of Averaging Times for Frequencies above 3 GHz
11. New Business
    a) Policy statement regarding review of papers missing information
12. Date and Place of Next Meeting
13. Adjourn

NOTE—Presenters/participants who intend to display MS PowerPoint/Word files, please send a copy to Ron Petersen (r.c.petersen@ieee.org) for the minutes.
SC-4 Chairman’s Report

SC-4 Co-Chairmen

Art Thansandote
Marv Ziskin
Dear IEEE ICES (SCC 39) Volunteer,

• IEEE was recently named in a lawsuit filed in the Superior Court of the District of Columbia concerning the IEEE C95 standards related to cellular telephone safety, including but not limited to the IEEE C95.1, IEEE C95.3, and IEEE 1528 standards. Since the names of working group members are listed in the front matter of the standards and because you may be in possession of relevant documents, we would like to make you aware of this matter in the event further action is required.
IEEE and its Standards Association take no position on the issue of cell phone safety.

IEEE develops voluntary standards that contain recommendations, based on published, peer reviewed studies, to protect against established adverse effects to human health.

IEEE administers the standards development process and establishes rules to ensure its fairness; IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in the standards and makes no warranties with respect to such information.
Letter from Director of IEEE-SA

In the event you are approached regarding any IEEE standards you should take steps to ensure that you do not create any impression that you are speaking or acting on behalf, at the direction, or with the approval of IEEE, or any Standards Association committee, subcommittee, or working group.

Only representatives authorized by the IEEE Board of Directors or the IEEE-SA Board of Governors can represent or speak on behalf of IEEE on matters concerning IEEE standards and standards activities.
Letter from Director of IEEE-SA

Should this case proceed, IEEE may be required to produce certain documents as part of the discovery process. Do not delete, destroy, modify, or otherwise alter any document that relates to the pertinent standards.

This instruction applies to all “documents” in written or electronic form including, but not limited to, the original; all interim drafts; and each copy, whether printed, typed, handwritten, or preserved on other media.

The obligation to retain all documents will continue until the lawsuit is concluded or the issue is resolved and you are given notice that you are no longer required to retain these things.

If you hold any material in your personal files and you believe the material should be retained by IEEE, you should provide these materials to the IEEE.
Letter from Director of IEEE-SA

Thank you very much for your cooperation and valued service on ICES.

Sincerely,

Konstantinos Karachalios
Managing Director, IEEE-SA
WHO – Health Risks of RF Electromagnetic Fields

The World Health Organization is undertaking a health risk assessment of radiofrequency electromagnetic fields, to be published as a monograph in the Environmental Health Criteria Series. This publication will complement the monographs on static fields (2006) and extremely low frequency fields (2007), and will update the monograph on radiofrequency fields (1993).
WHO – Health Risks of RF Electromagnetic Fields

Twelve detailed chapters covering physics, instrumentation, and bioeffects.

The draft chapters of this document were opened for technical consultation by RF experts.

WHO was seeking comments on the accuracy and completeness of the information contained in these chapters.
WHO – Health Risks of RF Electromagnetic Fields

ICES Response:

40 pages of detailed comments

Submitted December 3, 2014
Progress on Standards

All C95.XX Standards are now available free of charge.

http://standards.ieee.org/about/get/index.html

Thanks to
US Air Force,
US Army
US Navy
Progress on Standards

NATO Standard C95.1-2345

NATO ratification of the adoption IEEE C95.1-2345 as a NATO standard is ongoing.

The publication of IEEE C95.1-2345-2014 should help generate awareness and international recognition of ICES.
Progress on Standards

Combined C95.1 and C95.

Limits have been developed.

Literature review update needed
EMF Modeling and Dosimetry

A new Sub-Committee has been formed, SC-6

Thanks to Pat Reilly and Aki Hirata

Aims:

To resolve uncertainties in Dosimetry used in development of DRLs and ERLs

To enhance harmonization with ICNIRP
THRESHOLDS OF THERMAL DAMAGE

26-28 MAY 2015 ISTANBUL / TURKEY
ICNIRP/WHO Workshop, 26-28 May in Istanbul, Turkey
“A closer look at the thresholds of thermal damage”

Scope
In view of updating the guidance on limiting exposure to high frequency (HF) fields, ICNIRP will review the current scientific knowledge on the thresholds of thermal damage. The current workshop will revisit the ICNIRP 1998 concept, namely that the health relevant increase of body core temperature is approximately 1°C and a whole-body exposure with an average SAR of 4 W/kg result in a core temperature increase of less than 1°C within 30 min. Details of this concept as well as thresholds for partial/local body exposures are subjects to review.
Amongst others, the following topics and questions will be addressed:

**Definition/Specification of the threshold for thermal damage:**

a) with respect to
   - the whole body,
   - parts of the body (limbs, trunk, head),
   - different organs (i.e. brain, eye, testis, skin etc.)
   - different tissues (muscle, fat, nerve, connective tissue)

b) regarding frequency dependence

c) with respect to external conditions (cold and hot environment, humidity, clothing)

d) with respect to internal/individual conditions (interindividual variations, age-dependence, health status, metabolic status, medication, compromised thermoregulation, pregnancy,...)

**Definition/Specification of the health relevant quantity** (SAR, power flux density, temperature, thermal dose/CEM43°C, Arrhenius thermal dose rate)

Is our thermoregulation (evolved to respond to physical work and hot environments) effective in responding to local (internal) HF-induced heating?

Is the averaging time of 6 min and the averaging mass of 10g of contiguous tissue appropriate?

Has exposure duration to be taken into account (even at low exposure levels)?
Session 3: Thermal effects due to HF exposure, HF dosimetry - Chair: James C. Lin

14.00
Ken Foster, University of Pennsylvania, Philadelphia, US
(Thermal) mechanisms of interaction between HF and biological systems

14.30
Akimasa Hirata, Nagoya Institute of Technology, Japan
Computational age dependence of heating, heating of the eye, relationship between SAR and temperature, thermal model for pregnant woman (ambient heat versus HF)

15.00
Marvin Ziskin, Temple University Medical School, Philadelphia, US
Frequency dependence of heating, thermal threshold for teratogenicity, reproduction and development, mm-wave exposure of the skin
Link to See Presentations

The primary purpose of the IEEE (Institute of Electrical and Electronics Engineers) database (ieee-emf.com/) is to provide a comprehensive database of the world’s English language literature on radiofrequency (RF) energy to support the review and revision, if needed, of RF safety standards published by IEEE. The goal is to identify all peer-reviewed research papers and other relevant reports such as peer-reviewed review articles and letters to journal editors. In March 2011, the database had over 5000 references of which over 3200 are research papers. Each entry has a brief description of the experimental approach/model and results; in addition, many of the research papers have a link to abstracts in PubMed. The database can be searched by a number of ways (author, study type, key word, year, frequency range, etc.). The core of the database is available without charge to the public; however, members of IEEE ICES (International Committee on Electromagnetic Safety) who are writing reviews of specific research areas have access to a password-protected area to support their work.”
Currently, Database has

5967 citations* distributed in 2475 projects and 5319 PDF files.

* A number of entries are blank due to deletion of duplicate citations and other errors.
Disclaimer

If I missed, lost, or erased by mistake your email and as a consequence your contribution is not properly reported, please assign the blame in the following order

- Google Mail for Enterprise (a.k.a. Gmail++)
- Yours Truly

Thank you!
Summary

Kick-off February 2015

- Identified topics and (lead) reviewers
- Defined (initial) review time-span 2003-2014
- Established timeline – goal to have review manuscripts in 4Q15
  - Contacted Bioelectromagnetics Editor to host review publication
  - Substantial expense (~$30k funding to be addressed)

- Provided/suggested literature search resources
  - IEEE ICES database (http://ieee-emf.com/index.cfm)

  - Literature Surveillance WG Chair available to source new/missing papers
    - Joe Elder (joeaelder@gmail.com)

- Interim goal – complete literature selection by June ICES meetings
Topics & Lead Reviewers

Topics numbered per the current C95.1 Annex B

- **B.5.1 Thermoregulation**
  - M. Ziskin

- **B.5.2 Animal behavior, neurochemistry, neuropathology**
  - B. J. Klauenberg

- **B.5.3 Review of 0 Hz to 100 kHz studies**
  - Kavet & Reilly

- **B.6.1 Teratogenicity, reproduction, and development**
  - Bushberg

- **B.6.2 Hematology and endocrinology**
  - Pioli

- **B.6.3 Blood brain barrier (BBB) permeability**
  - Elder

- **B.6.4 Eye pathology**
  - Kojima

- **B.6.5 Auditory pathology and RF hearing**
  - Ravazzani & Parazzini

- **B.6.6 Membrane biochemistry**
  - Sheppard

- **B.6.7 Calcium studies and neuron conduction**
  - Sheppard

- **B.6.8 Other types of animal studies**
  - Faraone

- **B.6.9 Human provocation studies**
  - J. Withmore

- **B.7.1 Animal cancer bioassays**
  - Repacholi

- **B.7.2 Other animal and *in vitro* studies addressing cancer**
  - Vijay

- **B.7.3 Epidemiology studies (cancer and other endpoints)**
  - Erdreich

- **B.8 Mechanisms**
  - Balzano

- **Dosimetry and exposure system quality evaluation**
  - Faraone
Status & issues

- Roughly 50% of literature selection completed
  - Some topic teams more active than others

- WHO “conflict of interest”
  - Vijay’s team review of in-vitro cancer studies delayed to 2016
    - Currently engaged in WHO EMF Project review
    - Will only address RF studies
      - not ELF (2009 meta analysis published by Vijay)

- Review criteria
  - Repacholi 2015 “Determining whether physical agent exposure causes adverse health effects”
  - Meltz & Erwin 1987 “Essential RFR Study Information”

- 140 additional papers to be reviewed by Health Canada
  - Canadian parliament ordered HC to include these papers in their EMF assessment
  - ICES working to include them in database (if they are not)
Determining whether physical agent exposure causes adverse health effects

*Michael H Repacholi, Visiting Professor, Department of Information Engineering, Electronics and Telecommunications, Sapienza University of Rome - Via Eudossiana 18, 00184 Rome Italy. Email: mrepacholi@yahoo.com

* Corresponding author
Concluding remarks

- Review running behind schedule
  - Any suggestion to increase speed, efficiency is welcome

- ELF out of the picture. Or is it?

- Review criteria selection
  - In the past, each topic team would establish its own

- Funding of review articles
  - US Air Force funded BEMS publication in 2005 (~$30k)
Outline

1. The Transition From NATO to Civil Standards Process
2. Selection Of Standards Developmental Organization
3. Lessons Learned
4. Way Ahead
Specific Agreement Between
NATO and IEEE

“New IEEE Military Workplace Standard” signed 30 July 2009

“IEEE shall develop, maintain, revise, and update a new IEEE military workplace standard that will address normative military occupational/workplace-specific exposure limits to electric, magnetic and electromagnetic fields”

Not simply adopting a non-governmental standard in lieu of a military drafted standard, but having civil SDO draft a military standard. This sets a precedent.
• Designated as “Essential STANAG” (GENMED WG June 2001)

• Provides minimal exposure guidance

• USA Custodian 1993-present

• Based on civil standard (IEEE C95.1)

• Last revision 13 Feb 2003

• Triennial review: reaffirm, revise, cancel
Military Exemption from European Union Directive on Electromagnetic Safety Obtained

- Successfully led NATO action for derogation of all military operating in EU
- Directive 2013/35/EU published 29 June 2013

Impact/Importance:
- EU NATO nations can use NATO STANAG 2345
  - Maintains interoperability
  - Removes impacts to operations
• Approved 16 May 2014
• Published 28 May 2014
  Combines C95.1 and C95.6
  - 0 Hz – 300 GHz

• New environmental **zone** concept

• New concept for safety margin
  - Relaxed exposure limit for experts
  - Restricted expert only access zone
  - New technologies facilitated

• New meaningful terminology
  - Personnel protection program
    initiation level vs. action level

• Guidance for treating RFR overexposures
ICES Editorial Working Group (EDWG)

- Ralf Bodemann, Chair ICES
- Ken Gettman, Vice-Chair ICES (host 11 meetings)
- Ron Petersen, Exec Secretary ICES
- C. K. Chou, Chair EDWG
- Ric Tell, SC2 Chair
- Rob Kavet, SC3 Co-Chair
- Thanh Dovan, SC3 Co-Chair
- Art Thansandote, SC4 Co-Chair
- Marv Ziskin, SC4 Co-Chair
- B Jon Klauenberg, NATO representative
- Pat Reilly, Electrostimulation expert
- John Osepchuk, Ex ICES Chair
NATO Standards Transfer Process

• Selection of NATO standardization documents for transfer
• Market survey (1st Jun 08, 2nd Sep 08)
• SDO response (1 Oct 08) and selection of the SDO (22 Jan 09)
• Technical Cooperation Agreement (14 May 2009)
• Specific Agreement for standard (1 August 2009)
• SDO accepts NATO standard
• SDO forms technical group (1st meeting 22-23 July 2009)
• Revise or draft new (expected in 4 months) .......... 4++ years
• IEEE Ballot and Publish
• NATO Force Health Protection WG review 4-5 Sept 14
• NATO adopt civil standard STANAG ratification (6-12 months)
Thank you for your attention!

QUESTIONS?

B. JON KLAUENBERG, Ph.D.,
Air Force Research Laboratory
711th Human Performance Wing
Human Effectiveness Directorate
Bioeffects Division
Radio Frequency Bioeffects Branch
bertram.klauenberg@us.af.mil
210-536-4837

QUESTIONS
• Provides command flexibility with safety

• Meets EU Framework Directive 89/391/EEC Article 6.3.(d) “Only workers who have received adequate instructions may have access”

• Unlike EU Directive 89/391/EEC there is NO access “where there is serious and specific danger.”

• Access is restricted to highly trained EMF workers to carry out necessary activities under strict and explicit guidelines

• Safety procedures are enhanced - expert is closely monitored

• System-specific expertise required
Overexposure Risk

**Safe:** No Access Buffer

**Safe:** Expert Only

**Safe:** Informed Allowed (Worker)

**Safe:** No Restrictions (Public)
How NIOSH can adopt the ICES Basic Restriction as its Recommended Exposure Limit for ELF-EMF

Progress since Pismo Beach

Joe Bowman
National Institute for Occupational Safety & Health

NIOSH has not reviewed or approved this presentation.
Strategies for Managing Workplace Exposures to Lower Frequency Electric and Magnetic Fields (EMF)

CURRENT INTELLIGENCE BULLETIN #__

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
National Institute for Occupational Safety and Health

Project to develop advice on ELF-EMF

Draft contents:

• Recommended Exposure Limits (REL) for adverse nerve stimulation
  — RELs are exposure limits for adoption by OSHA

• Managing electromagnetic interference (EMI) with active medical devices
  — Collaboration with FDA

• Precautionary advice on the cancer possibility
  — Poster PB-15 (Monday 19:00 hr)
Proposal to the Pismo Beach ICES Meeting

• NIOSH adopts the ICES MPE for ELF EMF as its REL
  – One-tier standard needed by OSHA

• Recommend measurement methods in C95.7 (2010) for evaluating compliance

❖ OBJECTION: MPE is excessively conservative without the Basic Restriction
How the ICES BR can become the REL

• NIOSH recommends the BR for the internal E as its exposure limit.
  – Assumes an internal E meter shaped to the BR’s frequency response will be on sale.

• Collaborate with instrument makers to develop “basic restriction meters”

• Determine uncertainties of the BR meter to use in compliance decisions
Progress since Pismo Beach

- Basic restriction meter
- Electromagnetic interference limits
- Review and publication strategy of REL
Design of Basic Restriction Meter

**Internal E-field meter**
- 3-axis induction curve probe measures dB/dt
- Structured dosimetry for target organs
- Algorithm to invert Faraday’s Law
  - Bowman et al (2010)
- **Output**: $E(t)$ in organ

**Solution**: Shaped time-domain filter
### Basic Restriction Meter

**Induction coil probes**

Probe axes aligned with body

**A/D conversion**

- $d{B_x(t)}/dt$
- $d{B_y(t)}/dt$
- $d{B_z(t)}/dt$

- $>6000\,\text{Hz}$

- Magnetic induction model for brain

- STD filter for ICES

- Basic Restriction

- % BR

**Dosimetry data**

- $E_i(t)$

**Output:**
- read-out
- data logger
- warning lights

---

**Digital signal processing chip**

**ATTACHMENT 7**

---

**Joseph D. Bowman, PhD**

Pismo Beach, CA

9/11/2014
Draft EMI Advisory Levels

GENERIC EMI Limits for Active Implantable Medical Devices
The following limits are based on ISO 14117, ISO 14708-3, ISO-14708-4.

by G. Guillaume (Medtronics)
NIOSH Process for Policy Documents

• Reviews
  – Internal scientific review
  – External scientific review
  – Stakeholder review
  – Public comment

• After each review, update document for Director approval of the next step

• Publication planned for 2019
Review and approval strategy

• Review draft
  – One-tier REL based on MPE
  – Research need is a BR meter that can be applied to both REL and EMI limits

• Concurrent R&D
  – Develop a commercial BR meter for sale in US
Summary of tasks

• Develop BR meter
  – NIOSH and instrument company

• Analysis of side-by-side measurements
  – Assistance of ICES members desired

• Expert and stakeholder reviews of NIOSH document
  – Some recruited from ICES members
A Perspective on Stimulus-Response Relationships and Dosimetric Uncertainty

Robert Kavet, ScD
Senior Technical Executive
Electric Power Research Institute

June 12, 2015
SC3-SC4 Meeting
Pacific Grove, California
ICNIRP & IEEE Exposure Limits <100 kHz

- **ICNIRP:** “protection against adverse health effects…including peripheral (PNS) and central nerve stimulation (CNS),…retinal phosphenes and possible effects on some aspects of brain function.”

- **IEEE:** “…based on avoidance of:….a) Aversive or painful stimulation of sensory or motor neurons b) Muscle excitation that may lead to injury while performing potentially hazardous activities c) Excitation of neurons or direct alteration of synaptic activity within the brain.”
Magnetic Field Dosimetry in IEEE and ICNIRP

Dimbylow, 2005
# Magnetic Field Dosimetry in IEEE and ICNIRP: Peripheral Nerve (1)

<table>
<thead>
<tr>
<th>Feature</th>
<th>IEEE</th>
<th>ICNIRP</th>
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<tbody>
<tr>
<td><strong>Model Type</strong></td>
<td>Ellipsoid</td>
<td>Anatomically-correct voxel model</td>
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<tr>
<td><strong>Computation</strong></td>
<td>Closed form analytic solution</td>
<td>Numerical technique (e.g., FDTD, SPFD)</td>
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<tr>
<td><strong>Dose Metric</strong></td>
<td>Induced e-field calculated for site</td>
<td>Tissue-specific 99&lt;sup&gt;th&lt;/sup&gt; percentile e-field approximates the maximum dose</td>
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<tr>
<td></td>
<td>corresponding to excitable tissue (e.g., heart, PN)</td>
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<tr>
<td><strong>PN Equivalent</strong></td>
<td>Outer perimeter of largest circular cross section of ellipsoid (radius 0.17 m with major body axis 0.9 m)</td>
<td>Dose to skin and fat used as surrogate for dose to PN</td>
</tr>
<tr>
<td><strong>PN Stimulation Threshold</strong></td>
<td>6.15 V/m Peak (SENN Model) population median</td>
<td>4 V/m (probably peak) (So et al., 2004); population percentile unspecified</td>
</tr>
<tr>
<td><strong>Basis for GP Basic Restriction in PN</strong></td>
<td>Pain threshold = 1.45x6.15 V/m = 8.92 V/m peak; equivalent to 6.31 V/m RMS</td>
<td>Unspecified, but probably uncorrected stimulation threshold (4V/m peak or 2.83 V/m RMS)</td>
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### Magnetic Field Dosimetry in IEEE and ICNIRP: Peripheral Nerve (2)

<table>
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<tr>
<th>Feature</th>
<th>IEEE</th>
<th>ICNIRP</th>
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<tr>
<td><strong>Basic Restriction for GP</strong></td>
<td>Median pain threshold ÷ 3 (probability multiplier) ÷ 3 (GP safety factor) = 0.701 V/m RMS</td>
<td>Stimulation threshold = 4 V/m ÷ 5 for occupational exposure ÷ 2 (additional factor for GP) = 0.4 V/m RMS (intended reduction factor of 10 for GP, but actual safety factor = 2.83 V/m ÷ 0.4 = 7.1). Peak stimulation threshold applied for reduction factors instead of RMS threshold</td>
</tr>
<tr>
<td><strong>Exposure Limit</strong></td>
<td>759 Hz-100 kHz: B-field producing in situ electric field at PN-equivalent ellipsoid site equal to IEEE’s Basic Restriction</td>
<td>400 Hz-100 kHz: B-field producing in situ electric field at PN-equivalent anatomical site (skin, fat) at least 2.5 times lower than ICNIRP’s Basic Restriction (using PN coupling coefficients from the literature)</td>
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ICNIRP vs IEEE General Public Basic Restrictions for Peripheral Nerve

**Graph:**
- **Label:** PN Basic Restriction (V/m RMS)
- **X-axis:** Frequency (Hz)
- **Y-axis:** PN Basic Restriction (V/m RMS)
- **Graph Lines:**
  - ICNIRP
  - IEEE
- **Legend:**
  - ICNIRP
  - IEEE
- **Note:** The graph shows a comparison between ICNIRP and IEEE standards for peripheral nerve basic restrictions over a range of frequencies. The graph indicates a factor of approximately 1.57 in the restrictions at certain frequencies, as indicated by the notation "x1.57."
ICNIRP vs IEEE General Public Magnetic Field Exposure Limits

“An additional reduction factor of 3 was applied to these calculated values to allow for dosimetric uncertainty”

- IEEE GP MPE
- ICNIRP GP RL
Review: Lognormal Distribution

Geometric Mean, $GM = 10^{\text{Mean Log}(x)}$

Geometric Standard Deviation, $GSD = 10^{\sigma}$
The Source: Nyenhuis et al. Study of Peripheral Nerve Stimulation (PNS) in Human Subjects

2 Health Effects and Safety of Intense Gradient Fields

John A. Nyenhuis, Joe D. Bourland, Alexander V. Kildishev, and Daniel J. Schaefer

2001

Perception

Pain

N=84
MRI pulse study resulted in two follow-on studies

So et al., 2004
“The computed electric fields...corresponding to peripheral nerve stimulation (PNS) thresholds in humans...range from 3.8 to 5.8 V/m...”

Bailey & Nyenhuis, 2005
“...median PNS detection threshold of 47.9±4.4 mT for a uniform 60 Hz magnetic field exposure coronal to the body. The threshold for the most sensitive 1% of the population is about 27.8 mT.”
Converting Nyenhuis et al. to Estimate 60-Hz Perception Thresholds (Bailey & Nyenhuis, 2005)

Coronal Exposure:
- GM = 47.94 mT
- GSD = 1.262
- 99th Pctl = 82.4 mT
- 1st Pctl = 27.9 mT

Sagittal Threshold ≈ 1.75xCoronal
Vertical Threshold ≈ 1.79xCoronal
Coronal Exposure: X Marks the Spot

Coupling Coefficient

\[ C_{Th-PN} \propto \frac{E_{Th-PN(X)}}{B_{Th-PN(X)}} \]

Lowest PNS Threshold for Coronal Exposure
Basic Equation

\[ E_{Th-PN}(X) = B_{Th-PN}(X) \times C_{PN}(X) \times f \]

- \( E_{Th-PN}(X) \), the \textit{in situ} electric field (V/m) at site X in PN at PNS threshold;
- \( B_{Th-PN}(X) \), the external magnetic field (T) that induces \( E_{Th-PN}(X) \);
- \( C_{PN}(X) \), the \textit{coupling coefficient}, quantifies the coupling of the external magnetic field to the \textit{in situ} electric field in PN at X (V/m/(T-Hz)) (source of dosimetric “uncertainty”)
- \( f \), the frequency(Hz) of the external magnetic field
Consider the following ‘Nominal case’…

- $E_{Th-PN}$ is assumed as lognormally distributed (see IEEE Std. 95.6, 2002);

Based on SENN and So et al. (2004):

- Assume a 99% range (0.5th-to-99.5th percentiles) for $E_{Th-PN}$ at $f<f_c$ of 3.50-7.00 V/m peak (2.475-4.950 V/m RMS);
Four Individuals with Unique $C_{PN}$s

<table>
<thead>
<tr>
<th>Subject</th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
</tr>
</thead>
<tbody>
<tr>
<td>$E_{Th-PN}$ (V/m RMS)</td>
<td>4.0</td>
<td>4.0</td>
<td>3.3</td>
<td>3.3</td>
</tr>
<tr>
<td>$B_{Th-PN}$ (mT RMS)</td>
<td>45</td>
<td>60</td>
<td>40</td>
<td>55</td>
</tr>
<tr>
<td>$f$ (Hz)</td>
<td>60</td>
<td>60</td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>$C_{PN}$ (V/m/(T-Hz))</td>
<td>1.48</td>
<td>1.11</td>
<td>1.38</td>
<td>1.00</td>
</tr>
</tbody>
</table>

Subject:

- W
- Y
- Z
- Q
Hypothetical 60-Hz Example: $B_{Th-PN}$ vs $E_{Th-PN}$
($N=1,000$ randomly selected “persons”)

![Graph showing correlation between $B_{Th-PN}$ and $E_{Th-PN}$](image)
Hypothetical 60-Hz Example: $B_{\text{Th-PN}}$ vs $E_{\text{Th-PN}}$ ($N=1,000$ randomly selected “persons”)

$B_{\text{Th-PN}} = 13.513E_{\text{Th-PN}}$
Hypothetical Example: Geometric Mean of Coupling Coefficient, $C_{GM(PN)}$

\[ C_{GM(PN)} = \frac{E_{GM(Th-PN)}}{(B_{GM(Th-PN)} \times f)} = 1.22 \text{ V m}^{-1} (\text{T} - \text{Hz})^{-1} \]

\[ B_{Th-PN} = 13.513 E_{Th-PN}^{1.0085} \]

\[ B_{GM(Th-PN)} = 47.812 \text{ mT} \]

\[ E_{GM(Th-PN)} = 3.501 \text{ V/m} \]
Switching to Log Axes

\[
\frac{d \log(B_{Th-PN})}{d \log(E_{Th-PN})} \approx 1.0 \text{ for large samples}
\]

\[
\log(B) = 1.0085 \log(E) + 1.1307
\]
Residual of Log Regression

\[ \sigma_{\text{Residual}} = \sigma_{\log(C_{PN})} \]

\[
\text{Residual } [ \log(B_{Th-PN}) - \log(B_{Reg}) ]
\]

\[
\text{Log}[E_{Th-PN} \ (V \ m^{-1} \ RMS)]
\]
Math Derivation (Short form)

\[ E_{Th-PN}(X) = B_{Th-PN}(X) \times C_{PN}(X) \times f \]

\[ \log(B_{Th(X)-PN}) = \log(E_{Th(X)-PN}) - \log(C_{PN(X)}) - \log(f) \]

\[ \frac{d \log(B_{Th-PN})}{d \log(E_{Th-PN})} \approx 1.0 \]

\[ \sigma^2_{LogB_{Th-PN}} = \sigma^2_{LogE_{Th-PN}} + \sigma^2_{LogC_{PN}} \]
In words…

- The distribution of exposure thresholds constrains the distributions of dose and coupling coefficients; or

- Neither $\sigma^2_{\log E_{\text{Th} - \text{PN}}}$ nor $\sigma^2_{\log C_{\text{PN}}}$ can exceed $\sigma^2_{\log B_{\text{Th} - \text{PN}}}$;

- Therefore, **dosimetric uncertainty** is limited by the variance of an empirical observation in human subjects, $\sigma^2_{\log B_{\text{Th} - \text{PN}}}$.
GSDs of $E_{Th-PN}$ and $C_{PN}$ are tied to each other

[Graph showing the relationship between GSD($E_{Th-PN}$) and GSD($C_{PN}$) with points marked at (1.07, 1.25), (1.14, 1.21), (1.20, 1.16), and (1.26, 1.00). The point (1.26, 1.00) is labeled as 'Nominal' Case.]
Solve for $C_{GM(Th-PN)}$ and $GSD(C_{Th-PN})$

- For the ‘Nominal’ case (99th percentile range of $E_{Th-PN}$ at $f<f_c$ of 3.50-7.00 V/m peak; 2.475-4.950 V/m RMS),

\[
GSD(C_{PN}) = 10 \sqrt{\sigma^2_{Log B_{Th-PN}} - \sigma^2_{Log E_{Th-PN}}} = 10 \sqrt{0.1012^2 - 0.0584^2} = 1.210
\]

\[
C_{GM(PN)} = \frac{E_{GM(E_{Th-PN})}}{B_{GM(E_{Th-PN})} \times 60} = 1.217 \text{ V m}^{-1} \text{ (T - Hz)}^{-1}
\]
Distribution of Derived $C_{PN}$ (‘Nominal’ Case)

Central Tendency of $C_{PN}$ from Dosimetry Lit*

*based on skin/fat surrogates for PN
What are the coupling coefficients, $C_{PN}$, ‘implicit’ in the ICNIRP guideline and IEEE standard?

- At the corner frequency, $f_c$, for each, calculate: ‘Implicit’ $C_{PN} = BR/(RL$ or $MPE \times f_c)$
- ICNIRP: $C_{PN-ICNIRP} = 0.4 \text{ V/m}/(0.0267 \text{ mT} \times 3,000 \text{ Hz}) = 5.0 \text{ V m}^{-1} (\text{T-Hz})^{-1}$
- IEEE: $C_{PN-IEEE} = 0.701 \text{ V/m}/(0.205 \text{ mT} \times 3,350 \text{ Hz}) = 1.02 \text{ V m}^{-1} (\text{T-Hz})^{-1}$
Where are the ‘Implicit’ $C_{PN}$s relative to the $C_{PN}$ distribution derived for the ‘Nominal’ case?

<table>
<thead>
<tr>
<th>Parameter</th>
<th>GM</th>
<th>GSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>$B_{Th-PN}$</td>
<td>47.94 mT</td>
<td>1.262</td>
</tr>
<tr>
<td>$E_{Th-PN}$</td>
<td>3.50 V/m</td>
<td>1.144</td>
</tr>
<tr>
<td>$C_{PN}$</td>
<td>$1.217 \text{ V m}^{-1} (\text{T-Hz})^{-1}$</td>
<td>1.210</td>
</tr>
</tbody>
</table>
# Review of Key Parameters for General Public

<table>
<thead>
<tr>
<th>Parameter</th>
<th>ICNIRP</th>
<th>IEEE</th>
<th>IEEE/ICNIRP</th>
</tr>
</thead>
<tbody>
<tr>
<td>( f_c ) (kHz)</td>
<td>3.0</td>
<td>3.35</td>
<td>1.117</td>
</tr>
<tr>
<td>Pop Median Rheobase* (V m(^{-1}))</td>
<td>4.0</td>
<td>6.15</td>
<td>1.538</td>
</tr>
<tr>
<td>Adverse Effect Multiplier</td>
<td>1.0 (Perception)</td>
<td>1.45 (Pain)</td>
<td>1.450</td>
</tr>
<tr>
<td>Basic Restriction for ( f &lt; f_c ) (V m(^{-1}))</td>
<td>0.40</td>
<td>0.701</td>
<td>1.753</td>
</tr>
<tr>
<td>Exposure limit for ( f_c -100 ) kHz (mT)</td>
<td>0.0267</td>
<td>0.205</td>
<td>7.678</td>
</tr>
</tbody>
</table>

* Rheobase here equals population median threshold for \( f < f_c \), but strictly speaking is the stimulation threshold as \( f \to 0 \) Hz)
Two Questions: Given the constraints on the variability of $E_{Th-PN}$ and $C_{PN}$…

①…what multiple of ICNIRP’s and IEEE’s $BR$ protects all but 1 in $10^6$ and 1 in $10^3$ persons against PNS?

②…what exposure levels between the corner frequency, $f_c$, and 100 kHz protects all but 1 in $10^6$ and 1 in $10^3$ persons against PNS under ICNIRP and IEEE assumptions?
Q1. Multiples of ICNIRP BR ‘Protective’ of Perception at Risk Levels of $10^{-6}$ & $10^{-3}$ Across $GSD(E_{Th-PN})$

<table>
<thead>
<tr>
<th>ICNIRP GP</th>
<th>$GSD(E_{Th-PN})$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of PNS</td>
<td>1.000</td>
</tr>
<tr>
<td>1 in $10^6$</td>
<td>7.071</td>
</tr>
<tr>
<td>1 in $10^3$</td>
<td>7.071</td>
</tr>
</tbody>
</table>

For example, if $GSD(E_{Th-PN})=1.200$, 2.970xICNIRP BR would ‘protect’ all but 1 in $10^6$ persons from perception (i.e., 0.40x2.970=1.188 V/m at $f<f_c$).
ICNIRP Example for $GSD(E_{Th-PN})=1.200$
Basic Restriction Scaling from ICNIRP to IEEE

IEEE Multiplier=ICNIRP Multiplier x
(IEEE/ICNIRP Rheobase) x
(IEEE/ICNIRP Adverse Effect Multiplier) x
(ICNIRP/IEEE BR at $f<f_c$)=
$(6.15/4.0)x(1.45/1.0)x(0.40/0.701)=1.272$
Q1. Multiples of IEEE BR ‘Protective’ of Pain at Risk Levels of $10^{-6}$ & $10^{-3}$ Across $GSD(E_{Th-PN})$

<table>
<thead>
<tr>
<th>IEEE GP</th>
<th>$GSD(E_{Th-PN})$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability of PNS</td>
<td>1.000 1.073 1.144 1.200 1.262</td>
</tr>
<tr>
<td>1 in $10^6$</td>
<td>8.995 6.425 4.745 3.779 2.972</td>
</tr>
<tr>
<td>1 in $10^3$</td>
<td>8.995 7.228 5.935 5.118 4.378</td>
</tr>
</tbody>
</table>

For example, if $GSD(E_{Th-PN})=1.200$, $3.779 \times$IEEE BR would ‘protect’ all but 1 in $10^6$ persons from pain (i.e., $0.701 \times 2.970 = 2.649$ V/m at $f<f_c$).
IEEE Example for $GSD(E_{Th-PN})=1.200$

- $10^{-3}$ Pop 50th, 6.31 V/m
- $10^{-6}$ GP BR, 0.701 V/m
- 3.59 V/m
- 2.65 V/m

in situ Electric Field (V/m)

Frequency (Hz)
ICNIRP: B-Field Exposure Levels (mT) for $f=3-100$ kHz vs Risk Across $GSD(E_{Th-PN})$ and $C_{PN}$

<table>
<thead>
<tr>
<th>ICNIRP GP</th>
<th>Fraction of Population ‘At Risk’</th>
<th>$C_{PN}=1.0$</th>
<th>$C_{PN}=1.25$</th>
<th>$C_{PN}=1.5$</th>
<th>$C_{PN}=2.0$</th>
</tr>
</thead>
<tbody>
<tr>
<td>$GSD(E_{Th-PN})$</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.000</td>
<td>1 in $10^6$</td>
<td>0.943</td>
<td>0.754</td>
<td>0.629</td>
<td>0.471</td>
</tr>
<tr>
<td></td>
<td>1 in $10^3$</td>
<td>0.943</td>
<td>0.754</td>
<td>0.629</td>
<td>0.471</td>
</tr>
<tr>
<td>1.073</td>
<td>1 in $10^6$</td>
<td>0.673</td>
<td>0.539</td>
<td>0.449</td>
<td>0.337</td>
</tr>
<tr>
<td></td>
<td>1 in $10^3$</td>
<td>0.758</td>
<td>0.606</td>
<td>0.505</td>
<td>0.379</td>
</tr>
<tr>
<td>1.144</td>
<td>1 in $10^6$</td>
<td>0.497</td>
<td>0.398</td>
<td>0.332</td>
<td>0.249</td>
</tr>
<tr>
<td></td>
<td>1 in $10^3$</td>
<td>0.622</td>
<td>0.498</td>
<td>0.415</td>
<td>0.311</td>
</tr>
<tr>
<td>1.200</td>
<td>1 in $10^6$</td>
<td>0.306</td>
<td>0.317</td>
<td>0.264</td>
<td>0.198</td>
</tr>
<tr>
<td></td>
<td>1 in $10^3$</td>
<td>0.536</td>
<td>0.429</td>
<td>0.358</td>
<td>0.268</td>
</tr>
<tr>
<td>1.262</td>
<td>1 in $10^6$</td>
<td>0.311</td>
<td>0.249</td>
<td>0.208</td>
<td>0.156</td>
</tr>
<tr>
<td></td>
<td>1 in $10^3$</td>
<td>0.459</td>
<td>0.367</td>
<td>0.306</td>
<td>0.229</td>
</tr>
</tbody>
</table>

For example, if $GSD(E_{Th-PN})=1.200$, and $C_{PN}=1.5$ V m$^{-1}$ (T-Hz)$^{-1}$, 0.264 mT ‘protects’ all but 1 in $10^6$ persons from $B$-field perception (i.e., $9.89 \times RL$ at 3-100 kHz).
ICNIRP Case for $GSD(E_{Th-PN})=1.200$, $C_{PN}=1.50$

![Graph showing magnetic field vs. frequency with notable values: 0.959 mT, 0.358 mT, 0.264 mT, 0.0267 mT at different frequency ranges.](image-url)

**B-N Pop Median**: 0.959 mT, 0.358 mT, 0.264 mT, 0.0267 mT

**GP RL**: 0.0267 mT

*Approved Minutes – 12-13 June 2015 TC95 SC3/SC4 Meeting*
Exposure Scaling from ICNIRP to IEEE

IEEE Exposure (3.35-100 kHz) = ICNIRP Exposure (3.0-100 kHz) x
(IEEE/ICNIRP Rheobase) x
(IEEE/ICNIRP Adverse Effect Multiplier) x

\( \left( \frac{f_c(\text{ICNIRP})}{f_c(\text{IEEE})} \right) = \)

\( (6.15/4.0) \times (1.45/1.0) \times (3.0/3.35) = 1.996 \)
IEEE: B-Field Exposure Levels (mT) for $f=3.35$-$100$ kHz vs Risk Across $GSD(E_{Th-PN})$ and $C_{PN}$

<table>
<thead>
<tr>
<th>IEEE GP</th>
<th>( C_{PN} ) (V m(^{-1}) (T-Hz(^{-1}))</th>
</tr>
</thead>
<tbody>
<tr>
<td>$GSD(E_{Th-PN})$</td>
<td>Fraction of Population ‘At Risk’</td>
</tr>
<tr>
<td>1.000</td>
<td>1 in 10(^6)</td>
</tr>
<tr>
<td></td>
<td>1 in 10(^3)</td>
</tr>
<tr>
<td>1.073</td>
<td>1 in 10(^6)</td>
</tr>
<tr>
<td></td>
<td>1 in 10(^3)</td>
</tr>
<tr>
<td>1.144</td>
<td>1 in 10(^6)</td>
</tr>
<tr>
<td></td>
<td>1 in 10(^3)</td>
</tr>
<tr>
<td>1.200</td>
<td>1 in 10(^6)</td>
</tr>
<tr>
<td></td>
<td>1 in 10(^3)</td>
</tr>
<tr>
<td>1.262</td>
<td>1 in 10(^6)</td>
</tr>
<tr>
<td></td>
<td>1 in 10(^3)</td>
</tr>
</tbody>
</table>

For example, if $GSD(E_{Th-PN})=1.200$, and $C_{PN}=1.5$ V m\(^{-1}\) (T-Hz\(^{-1}\))\), 0.527 mT ‘protects’ all but 1 in 10\(^6\) persons from B-field pain (i.e., 2.57xMPE at 3.35-100 kHz).
IEEE Case for $GSD(E_{Th-PN})=1.200$, $C_{PN}=1.50$
Review (1)

- Despite similar basic restrictions for PNS (IEEE=ICNIRP×1.57), ICNIRP’s general public RL is 7.68 times greater than IEEE’s MPE from ~3 to 100 kHz, partially due to a 3-fold added reduction factor to account for “dosimetric uncertainties”;

- Up to now dosimetric uncertainties concerning peripheral nerve (PN) have been viewed as open-ended using skin and fat as a surrogate for PN;

- An alternative approach is to evaluate stimulus-response relationships and dosimetric uncertainty from the perspective of empirical observations.
Review (2)

- Specifically, data from Bailey & Nyenhuis (2005) reporting on 60-Hz magnetic field PNS thresholds from human subjects were used to show how dosimetric uncertainties can be bounded;

- For PNS, these uncertainties are not open-ended, but are constrained by the dispersion of the external stimulus threshold (the magnetic field).

- Therefore, one can derive the population median coupling coefficient for PN ($C_{GM(PN)}$) and GSD($C_{PN}$) without requiring computational dosimetry, and the associated conductivity values for skin or fat, the two tissues used as PN surrogates in the dosimetry literature.
Protecting “All Persons”

- How is ‘All Persons’ defined: All but one in a thousand, a million, a billion? When does a distribution stop representing actual people, and become a fictitious statistical description?
  - ICNIRP does not provide a definition;
  - IEEE considers the median stimulus ÷ 3 as a value that protects >99% of persons;
  - Note: IEEE uses a parameter, the ‘slope factor’ which equals the median threshold ÷ 1st percentile threshold

- Given analyses in this paper is dividing the median by 3 too conservative for PNS? Yes.
IEEE's General Public $BR$ is Beyond the Range of Probability for PNS (given the analyses here)
Implementing a Guideline or Standard

- ICNIRP, 2010: “…whenever a reference level is exceeded it is necessary to test compliance…”
- ICNIRP’s RLs do not correspond to its BRs, because of an arbitrary reduction factor for “dosimetric uncertainties.”
- Consequently, one knows *a priori* that when an external 3-100 kHz coronally-oriented field is measured at the ICNIRP RL, ICNIRP’s BR has, in fact, *not* been exceeded – by a factor of 2.5 or more.
- Thus, ICNIRP mandates potentially time-consuming and expensive measures when none may be necessary.
- Not so for IEEE: *MPE* exceedance coincides with BR exceedance (though $C_{PN}$ may not be sufficiently conservative).
Harmonization Issues

- What is the population median (and distribution of) *in situ* electric field stimulation threshold(s)?
- What endpoint is appropriate as an ‘adverse’ response (perception, annoyance, pain)?
  - IEEE *in situ* PNS pain threshold (8.9 V/m Peak) = 2.2 x ICNIRP’s stimulation threshold (4V/m)
- Can empirical and dosimetric data together set the basis for appropriate safety factors?
  Yes.
Thank You!!
Together…Shaping the Future of Electricity
Comments on Thermal Averaging

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Department of Bioengineering
University of Pennsylvania
kfoster@seas.upenn.edu
Temporal Averaging

WHENCE 6 MINUTES?

“Our early C-95.4 Committee needed to recommend a time constant. My suggestion was 0.1 h. I was trying to come up with a number with as few significant figures as I could, considering the precision of what we were dealing with. A minute was too short — an hour was too long. But, alas, 0.1 h turned into 6 min, and 6 min implies an accuracy beyond the art…”

### Table 8—MPE for the upper tier (people in controlled environments)
(see Figure 3 for graphical representation)

| Frequency range (MHz) | RMS electric field strength (E)\(^a\) (V/m) | RMS magnetic field strength (H)\(^a\) (A/m) | RMS power density (S) E-field, H-field (W/m\(^2\)) | Averaging time | \(|E|^2, |H|^2\) or S (min) |
|-----------------------|---------------------------------------------|---------------------------------------------|---------------------------------------------------|----------------|--------------------------|
| 0.1–1.0               | 1842                                        | 16.3/\(f_M\)                               | (9000, 100 000/\(f_M\)^2)                         | 6              |                           |
| 1.0–30                | 1842/\(f_M\)                               | 16.3/\(f_M\)                               | (9000/\(f_M\)^2, 100 000/\(f_M\)^2)             | 6              |                           |
| 30–100                | 61.4                                        | 16.3/\(f_M\)                               | (10, 100 000/\(f_M\)^2)                          | 6              |                           |
| 100–300               | 61.4                                        | 0.163                                       | 10                                                | 6              |                           |
| 300–3000              | –                                           | –                                           | \(f_M/30\)                                       | 6              |                           |
| 3000–30 000           | –                                           | –                                           | 100                                               | 19.63/\(f_G\)^{1.079} |                           |
| 30 000–300 000        | –                                           | –                                           | 100                                               | 2.524/\(f_G\)^{0.476} |                           |

**NOTE**—\(f_M\) is the frequency in MHz, \(f_G\) is the frequency in GHz.

\(^{a}\)For exposures that are uniform over the dimensions of the body, such as certain far-field plane-wave exposures, the expression

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**IEEE Std C95.1™-2005**
(Revision of IEEE Std C95.1-1991)
<table>
<thead>
<tr>
<th>F, GHz</th>
<th>t, min</th>
<th>sec??</th>
<th>min??</th>
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</thead>
<tbody>
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<td>3</td>
<td>5.999381</td>
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</tr>
<tr>
<td>10</td>
<td>1.636516</td>
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<tr>
<td>30</td>
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<td>100</td>
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<td></td>
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<tr>
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<td>3000</td>
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<td>10000</td>
<td>0.000948</td>
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<td>0.00029</td>
<td>0.018663</td>
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<td>100000</td>
<td>0.010522</td>
<td>0.000175</td>
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<tr>
<td>300000</td>
<td>0.006237</td>
<td>0.000104</td>
<td></td>
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</tbody>
</table>

### MPE Averaging Time (controlled)

<table>
<thead>
<tr>
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<th>Averaging time</th>
</tr>
</thead>
<tbody>
<tr>
<td>10</td>
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<td>100</td>
<td>1</td>
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<td>1000</td>
<td>0.1</td>
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<tr>
<td>10000</td>
<td>0.01</td>
</tr>
<tr>
<td>300000</td>
<td>0.001</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Frequency Range</th>
<th>t, min</th>
<th>Average Time</th>
<th>Equation</th>
</tr>
</thead>
<tbody>
<tr>
<td>3000–30000</td>
<td>–</td>
<td>100</td>
<td>$19.63/f_G^{1.079}$</td>
</tr>
<tr>
<td>30000–300000</td>
<td>–</td>
<td>100</td>
<td>$2.524/f_G^{0.476}$</td>
</tr>
</tbody>
</table>

**IEEE Std C95.1™-2005**

(Revision of IEEE Std C95.1-1991)
Heating of Tissues by Microwaves: A Model Analysis

Kenneth R. Foster,¹* Albert Lozano-Nieto,² and Pere J. Riu,³
Appendix by Thomas S. Ely⁴

Department of Bioengineering, University of Pennsylvania, Philadelphia, Pennsylvania
²SETCE, Pennsylvania State University at Wilkes-Barre, Lehman, Pennsylvania
³Departament d’Enginyeria Electronica, Universitat Politecnica de Catalunya, Barcelona, Spain
⁴Bloomfield, New York
THERMAL RESPONSE OF TISSUES TO MILLIMETER WAVES: IMPLICATIONS FOR SETTING EXPOSURE GUIDELINES

Kenneth R. Foster,* Harvey Zhang,* and John M. Osepchuk†

Abstract—This Note discusses the implications of a simple model for the thermal response of tissue subject to irradiation with millimeter waves (30–300 GHz) for setting limits for safe exposure to this energy. The estimated thresholds for thermal pain and thermal injury from long-term (minutes) and short-term (seconds) exposures are compared with two major exposure guidelines, IEEE C95.1-2005 and ICNIRP limits. An appendix describes the rationale for setting the “averaging times” in IEEE C95.1-2005.

Health Phys. 99(6):806–810; 2010

Key words: exposure, radiofrequency; microwaves; radiofrequency; standards

C95.1-2005), which two of the present authors (Foster and Osepchuk) helped to develop.

METHODS

Thermal model

The authors consider a one-dimensional slab of skin or muscle, on which plane-wave energy incident with intensity $I_0 \text{ W m}^{-2}$ starting at time $t = 0$ is dissipated using Pennes’ bioheat equation (Pennes 1948):

$$\frac{\partial T(x,t)}{\partial t} = \alpha (x,t) \frac{\partial^2 T(x,t)}{\partial x^2} - \frac{q(x,t)}{c \rho} + \frac{S(x,t)}{c \rho}$$
Pennes’ Bioheat Equation (1948)

\[
k \nabla^2 T - \rho_b \rho_t C_b m_b T + \rho_t SAR = C_t \rho_t \frac{\partial T}{\partial t}
\]

- **T** = tissue temperature
- **k** = thermal conductivity of tissue (0.4 W/m °C)
- **SAR** = microwave power deposition rate (W/kg)
- **C_b** = heat capacity of blood (4000 W sec/kg°C)
- **C_t** = heat capacity of tissue (4000 W sec/kg°C)
- **D_b** = density of blood (1000 kg/m³)
- **D_t** = density of tissue (1000 kg/m³)
- **m_b** = volumetric perfusion rate of blood
  (40 mL/100 g of tissue per min)
Limiting solutions to BHTE

Early transient period (heat storage term dominates)

$$\left. \frac{dT}{dt} \right|_0 = \frac{SAR}{C_t}$$

Steady state (convection term dominates)

$$T_{ss} = \frac{SAR}{\rho m_b C} + \frac{k \nabla^2 T}{\rho_b \rho_t C_b m_b}$$

↑ Usually smaller term
Two Time Scales in Bioheat Equation

\[
\tau_1 = \frac{1}{m_b \rho} \approx 60 \text{ sec (convection)}
\]

\[
\tau_2 = \frac{\rho CL^2}{k} \approx 800 \text{ sec (diffusion, for } L = 1 \text{ cm)}
\]

\[\approx 8 \text{ sec (diffusion, for } L = 1 \text{ mm)}\]

\[m_b = \text{blood flow}\]
\[\rho = \text{tissue density}\]
\[k = \text{thermal conductivity of tissue}\]
\[L = \text{distance scale of heating (SAR)}\]
\[C = \text{specific heat of tissue}\]

Shorter time constant dominates
Two Distance Scales in Bioheat Equation

\[ R_1 = \sqrt{4\alpha t} \approx 0.05\sqrt{t} \text{ cm sec}^{-1/2} \]

\[ R_2 = \frac{1}{\nu} = \frac{\sqrt{k_t}}{\rho \sqrt{m_b c}} \approx 1 - 2 \text{ cm} \]

\[ \alpha = \text{thermal diffusivity} = \frac{k}{\rho C} \]
\[ m_b = \text{blood flow} \]
\[ \rho = \text{tissue density} \]
\[ k = \text{thermal conductivity of tissue} \]
\[ L = \text{distance scale of heating (SAR)} \]
\[ C = \text{specific heat of tissue} \]

Shorter distance scale dominates
$$\tau_{eff} = \frac{T_{ss}}{\left( \frac{dT}{dt} \right)_0} \quad \text{(thermal averaging time)}$$
**Fig. 2.** Fluence sufficient to increase surface temperature by 10°C (solid lines) or at the threshold for thermal injury (broken lines). The numbers indicate frequency in GHz.

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A corresponding thermal averaging time $\tau$ can be defined in terms of the present model as:

$$\tau = \frac{\text{fluence of a brief pulse that will produce a threshold temperature increase (Joule m}^{-2})}{\text{incident power density for continuous exposure to produc the same threshold temperature increase (W m}^{-2})}.$$  

(9)

In the limit of short pulses this becomes:

$$\tau = \frac{L \sqrt{C}}{\sqrt{km_b}}.$$  

(10)

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Setting limits:

- Define averaging time as

\[ \tau = \frac{\text{fluence of a brief pulse that will produce a threshold temperature increase (Joule m}^{-2})}{\text{incident power density for continuous exposure to produce the same threshold temperature increase (W m}^{-2})}. \]

- Estimates from plane wave model
- Determine numerator and denominator by FDTD for realistic geometry
Bottom Line

• Averaging distance is $\approx 1\text{-}2$ cm (steady state heating)
  
  *Thermal conduction is nature’s way of averaging thermal exposure*

• Useful definition of averaging time: maximum allowable steady state temperature increase/ peak SAR

How much precision is needed and at what cost in complexity?
Need more features! Cool ideas and technology

Need more...? Fix problems!

Simple
Fast
Easy to change

Complicated
More problems

Incomprehensible
Unstable and slow
Impossible to change

Kill???
Does ANSI C95.1 Follow Moore’s Law?