INTERNATIONAL
COMMITTEE *on*
ELECTROMAGNETIC
SAFETY

IEEE SCC-28 Subcommittee 4

Unapproved Meeting Minutes

Radisson Riverview Hotel
St. Paul, MN
June 8-9, 2001

1. Call to Order

The meeting was called to order by Co-Chairman D'Andrea at 1:15 PM, June 8, 2001.

2. Introduction of those Present

Each of the attendees introduced him/herself. See Attachment 1 for list of attendees.

3. Approval of Agenda

Upon a motion by M. Meltz and a second by D. Blick, the agenda was approved without modification. (See Attachment 2 for agenda.)

4. Approval of Minutes of November 2000 Meeting

Upon a motion by E. Adair and a second by W. Hurt, the minutes of the November 2000 meeting were approved without modification.

5. Secretary's Report

Petersen reported that the PAR for Project PC95.1expires in December. This means that a "PAR Target Date Extension Request" will have to be approved by the Standards Board at or before the December meeting in order not to have the project administratively withdrawn. Petersen said that he would submit the request this summer in time for it to be considered at the September meeting of the Standards Board. He also reported that the IEEE Standards Association (SA) Board of Governors has resolved the issue of fees for non-SA members who want to vote on ballots before the main committee. Invited experts will not be charged a fee but will have to be approved by the Standards Board on an individual basis, i.e., a list of the non-SA members of the balloting group will have to be submitted to the Standards Board with justification for each as to why it is important that they participate – the same as it was in the past.

6. Chairman's Report

Co-Chairman D'Andrea reviewed the revision process for C95.1-1991. He pointed out that about 500 papers still have to be reviewed and that Tell, Erdreich and Swicord have prepared

an outline with writing assignments listed for each of the sections including the annexes. At the March meeting of the Revision Working Group, Tell agreed to complete the normative section of the revision by August. D'Andrea noted that once again the timelines set last year seem to be slipping. He explained that in order to keep on schedule D. Sena would try to organize and manage the process by periodically distributing a matrix of action items, writing assignments, etc., to the members of the Revision Working Group. Completion of the matrix by each person with a writing assignment should help keep the process on track by reminding them of their commitments.

Co-Chairman Chou noted that there were eleven action items that resulted from the November meeting in San Antonio – action items 1-4 were resolved and Tell will report on item 5 at this meeting.

7. SCC28 EXCOM Report

SCC28 Chairman J. Osepchuk reported that a detailed report of EXCOM activities would be given at the SCC-28 meeting on Sunday, June 10, 2001. He briefly reviewed the process that led to the adoption of the name "International Committee on Electromagnetic Safety" – ICES. He explained that over the past year the EXCOM had been considering a name change that would reflect the international status of SCC28 and the scope of the committee better than the original title – "Non-Ionizing Radiation." The Standards Board approved the name change in March after the issue was discussed with several members of the Standards Department and a meeting was held with members of EXCOM and H. Epstein of the Standards Board. Epstein has oversight of the SCCs. Osepchuk said that the immediate name change and future plans to develop ICES into an umbrella committee that would include both SCC28 and SCC34 are in alignment with the IEEE global strategy. He then briefly reviewed the plans to work with the IEEE Standards Department to develop a program to raise funds for SCC28 activities. He also reported that the EXCOM has tentatively approved plans to hold the fall 2001 meeting in Luxembourg immediately following an EU/EC EMF meeting.

8. Risk Assessment Working Group Report

R. Tell introduced J. Bushberg who reviewed the definitions of *biological effects, adverse effects,* and *established effects,* which he said represent the consensus of the Revision Working Group (see Attachment 3). Meltz pointed out that "consistency" must be stressed in the definition of established effects – Bushberg agreed and added that "quality" should also be included. Osepchuk stated that "quality" should be addressed in the literature review. Bushberg concluded with the definition of *adverse effects exposure level,* which he said should tie everything together since it will be used as the basis for defining the MPEs.

9. Mechanism Working Group Report

A. Sheppard reviewed the Mechanisms Working Group activities and its membership. He said that the white paper that was started in 1996 is still at about the same level. As soon as it is completed it will be incorporated into Annex B (Mechanisms Literature Review). He said that no papers have been submitted – and none have been reviewed. So far here has been little activity regarding contributions to Annexes B and C.

10. Harmonization with ICNIRP

Osepchuk reported that members of SCC28 leadership met twice with ICNIRP members during the past 12 months. He said that a joint sponsored workshop on thermophysiology is being planned. ICNIRP and SCC28 also agreed to exchange documents and SCC28 recently provided detailed comments on an ICNIRP draft document *General Approach to Protection against Non-Ionizing Radiation.* Osepchuk said that another meeting with the leadership of SCC28 and ICNIRP would probably be held in December if SCC28 meets in Luxembourg. He also briefly discussed the WHO goals for establishing a framework for global standards – he noted that he is chairman of WG-1 (Terms and Definitions).

E. Adair elaborated on the planned SCC28/ICNIRP workshop. She explained that the idea is to bring together world-renowned experts to discuss related aspects of thermophysiology and dosimetry. The goal is to develop a model that could be used to predict the effects on humans exposed to RF fields. J. Elder noted that WHO is sponsoring a workshop that will bring together biologists to address specific organs. The outcome of this meeting, which is scheduled for October, should be a report that discusses the effects on cells, organs and tissues. A list of potential attendees has been submitted, which is now under consideration by WHO.

M. Swicord reported that a workshop sponsored by the Mobile Manufacturers Forum (MMF) was held a few weeks ago. The purpose of this workshop was to examine physical interaction mechanisms. The outcome of the workshop was agreement that in general there is no evidence of any plausible mechanism other than thermal – but there may be plausible mechanisms under certain circumstances of exposure. He said that a number of mechanisms have been ruled out and that FGF will be holding a similar workshop in December to follow up on some of the ideas brought up at the MMF meeting.

11. Literature Evaluation Working Group Reports

a) Literature Surveillance and Database Software

R. Tell provided an update on the status of the database of reviewed papers. He said that he has not yet gotten to the point where members of the Risk Assessment Working Group (RAWG) who want to review individual reports have been able to do so.

L. Heynick reported that the Literature Surveillance Working Group recently sent out citation list number 22, which contains a total of 1521 citations. The list was sent by e-mail and would be posted on the SCC28/SC4 web-site by first author and without the accession numbers. Swicord pointed out that Annex A discusses the literature review process and asked about how the number of papers reviewed by each of the groups, e.g., engineering, *in vivo*, are tracked. Specifically, which studies have been selected by the biological and epidemiology working groups and how many and which ones of those selected have been given passing scores by the engineering working group? C. K. Chou said that everything is done in parallel and that information has not yet been pulled together. Meltz added that each of the working group chairs has a record of the number of papers sent and the number of papers reviewed, etc. D'Andrea recommended tracking the papers as part of the process and suggested that perhaps this could be included in the process management program being set up by D. Sena. Tell concluded by noting that the RAWG would act as a review point for white papers and would provide feedback to their authors regarding the outcome of certain reviews, i.e., the reviews become a tool for the RAWG. Heynick asked if the groups preparing the white papers have seen any of the reviews – D'Andrea replied that some have.

b) Engineering

W. Hurt reported that about 500 critical papers are being targeted. He presented a summary of the status of the engineering reviews and acknowledged the reviewers (see Attachment 4). He noted that a member of the staff at Brooks (H. Sheriff) translated the earlier paper reviews into computer format. Tell asked about the projected completion date for all 1521 papers – Hurt replied that his group is targeting the 500 papers considered critical. Of the 500, about 200 – 300 have yet to be reviewed but these reviews should be completed by the end of the year. Heynick noted that about 200 papers of the 1521 are in the "peripheral" category for which reviews are not necessary.

c) *In Vitro*

M. Meltz reported that there have been about 10 – 12 reviewers in each cycle of the *in vitro* reviews. Out of the total number of papers distributed, 70 have been distributed to 1 reviewer, 76 have been distributed to 2 reviewers and 4 have been distributed to 3 reviewers – a total of 150 papers have been distributed for review. Of the 150, a total of 68 papers have had two reviews and 27 had one review. Of the total of 68 papers with two reviews, 26 had both reviewers score the paper as 1, or 1 and 2, or 2, i.e., 38.2% were scored less than adequate on the biology alone.

d) *In Vivo*

D. Blick acknowledged the *In Vivo* Working Group members and reported the results of the reviews to date (see Attachment 5). He said that out of the 598 papers in the *in vivo* database, 320 have been reviewed by two reviewers and 140 have been reviewed by one reviewer. He added that some of the papers have been out for a very long time.

e) Epidemiology

G. Gorsuch reported that the RAWG has identified about 75 papers that should be reviewed. He pointed out that out of that number, approximately 60 still have to be reviewed. The 60 papers have been scanned and pdf files created for electronic distribution to the reviewers. Three additional reviewers attached to the military have been identified. He noted that additional papers are coming in as the identified papers are being reviewed – the number of non-reviewed papers is remaining somewhat stable. In response to a question from Heynick, D'Andrea replied that the literature cutoff date would be July 1, 2001.

f) Dissemination of Literature Review Results

Petersen reported that the question of potential liability associated with making the review scores public was discussed with Tom Wettach, IEEE legal counsel. Wettach said that he does not see this as being any different from the peer-review process followed by most journal editors and sees no liability risk.

12 Editorial Committee Reports

a) Third Revision Working Group Meeting and Time Schedule

C. K. Chou reported that the 3rd revision Working Group meeting was held in March in Tempe, AZ and that the minutes appear in the *Spring 2001 Mailing*. He said that several of the "white papers" have been completed or partially completed. The next meeting will be held in September in Washington DC and he hopes to have a complete draft for SC4 by then. He pointed out that all of the work is being done in parallel, e.g., reviews, drafting white papers and drafting the normative parts of the standard and the annexes. D. Sena is in the process of developing a project management program, using commercial software, to track progress and

remind section editors and others of their obligations (see Attachment 6). A matrix will be circulated bi-weekly with due dates, etc.

b) Topic Reports

1) Spark Discharge and Induced Current

Before discussing spark discharge and induced current, J. P. Reilly discussed a peripheral issue – a suggested change of the lower (higher) frequency limit of C95.1 (P1555) from 3 kHz to 100 kHz. He said that while this makes sense from a mechanism viewpoint, this is not the time to make the change since SC3 has already balloted on the low-frequency standard and most voters approved the draft. Since SC3 appears to be on a faster track than SC4, changes in frequency limits at this point would unnecessarily delay the low-frequency standard. He recommended proceeding as planned but establishing a mechanism to ensure that SC3 and SC4 are cognizant of each others drafts to ensure that a disconnect does not occur at 3 kHz, e.g., in the contact current limits and field limits.

Reilly then discussed discrepancies in the low frequency range of the C95.1 standard that SC4 should be aware of. For example, at 3 kHz the grasping current limits in the 1991 standard could be painful to more than 50% of the population under touching contact conditions. He also pointed out that there are no limits in the C95.1 standard for spark discharges – only a note that such phenomena may be painful and should be avoided. He said that he and Passour have discussed the issue and are proposing guidelines for spark discharge but relevant MPEs will not be included in the standard.

Reilly then discussed the multiple frequency criteria in the C95.1 standard, i.e., summing the ratios of the exposure (E^2) at each frequency to the corresponding square of the E-field MPE. He said that while this is proper for heating, it is over-permissive for electrostimulation effects – it should be written in terms of peak and duration, i.e., zero crossings. He noted that both thermal effects and electrostimulation effects have to be considered by SC4 since the effects of electrostimulation for pulsed fields can occur up to 5 MHz under certain conditions.

In response to Tell's request to say more about spark discharge, Reilly replied that he is not proposing a change in the MPEs – just a discussion in the rationale of the standard that could be incorporated as a guideline. Osepchuk praised Reilly for his efforts toward developing a reasonable transition between the SC3 and SC4 standards. He said that there are still problems with terminology, however, which seems to be different on either side of 3 kHz. Reilly acknowledge this and added that the issue is being addressed, e.g., acceptability factor versus safety factor.

2) Thermoregulation

E. Adair pointed out that the minutes of the Tempe meeting (see *Spring 2001 Mailing*) contain two papers on thermoregulation and she is working on a third – a review of the physiological effects of exposure to RF fields. The latter, which is now being read and critiqued by D. Black, should be ready in a few weeks as a white paper. She said that she is not aware of any groups "more at risk" to RF fields in the environment.

3) Non-Thermal Effects

L. Heynick reported that he has completed a white paper on calcium efflux and needs help in completing the other sections. He said that he has a list of citations on non-thermal effects considered established that he is willing to distribute. Sheppard stated that the calcium paper is excellent and he has only minor comments. Heynick said that some of the white papers might require review and updating.

4) Definition of Adverse Effects & Selection of an Adverse Effect Level

A. Sheppard pointed out that this topic was addressed earlier by Bushberg. Mantiply asked whether non-thermal effects that are considered established would be considered by this committee; Sheppard responded yes – some of the effects discussed by Reilly. He added that he is not making any judgments right now but would wait until the literature review is completed.

5) Whole Body SAR Limit

E. Adair reported that the outline developed at the Tempe meeting (*In Defense of a Proposal to Base the New Standard on Whole Body SAR* – Attachment 6 of the *Spring 2001 Mailing*) would be used as the basis of the revision. She said that she does not recommend ΔT as a basis for the revision since it has no meaning regarding reconstruction of exposure conditions because there is no baseline – for the whole-body or for specific organs. She said that ΔT depends on a number of other variables, e.g., other heat sources, the sun, whether the person just ate, etc. A range of ΔT – 35-39.5^{O} C whole-body (deep) temperature – covers more than 95% of the population and includes circadian changes, acclimation factors, etc. She said that specifying a range of the thermal environment is recommended but the standard should be based on whole-body-averaged SAR over an extended range – specifically, 1 W/kg. A. Brecher asked about partial-body heating, impaired people, etc. Adair responded that partial-body exposures would be addressed – there is no solid data on sensitive groups in the literature. Tell said that this makes sense. He noted that Reilly speaks of sensation and pain and asked if this could be used here. Adair responded that based on the huge mass of data on people that she is relying on, e.g. the ASHRE charts, the threshold SAR would be approaching discomfort. Cohen agreed that this approach is rational and would eliminate the "uncertainty factor." Adair said that rationale is to plug the RF aspects into the comfort/discomfort index. Sheppard pointed out that an SAR-based standard would not take into account environmental conditions, e.g., the SAR could be higher at low temperatures.

6) Biological Basis for Local SAR Limit

M. Meltz reported that a meeting was held at Brooks AFB to discuss this issue but no conclusions were reached. He pointed out that with ionizing radiation individual organs are important but there seems to be no information on bioeffects and damage relating to organ ΔTs. Studies show a lack of genotoxic effects in tissue, even at SARs of 30 W/kg for extended periods of time and he added that he needs to draft a concise statement regarding direction, i.e., what can be said. Heynick noted the early papers on *in vitro* and *in vivo* effects on the heart. Meltz asked if there is a limit below which temperature is no longer considered important – Adair responded that such a limit is probably near 43^{O} C. In response to a question from Lang, Meltz responded that dosimetry is important and numerical simulations could be used to ensure that the temperature distributions are known everywhere in the body during exposure, e.g., "hot" spots. Swicord asked the following procedural question: How will multiple sources and near- versus far-field exposures be treated? Meltz answered by stating that something will have to be written that addresses that issue.

FOR ACTION

M. Meltz will address the question of how near-field, far-field and multiple source exposures will be handled.

7) Spatial Averaging, Averaging Volume

R. Tell reported that he had sent a questionnaire on spatial averaging to a number of selected individuals and compiled the answers (see Attachments 7 and 8). He said that he has received responses from about 10 – 12 people so far. He briefly reviewed the questions and summarized the responses as follows:

- the 1 g averaging mass could be increased (which would increase the coherence since small volumes are unstable)
- need to set a local SAR limit based on ΔT
- the peak-to-average rationale is probably inappropriate
- need more data to ensure that the whole-body-averaged and peak spatial-average SARs are not exceeded when spatially averaging exposure fields
- not clear if a larger averaging volume would have much impact biologically, i.e., there is no evidence that it would.

Chou said that a small change in the averaging volume could have a large impact on industry, for example on cellular phone manufacturers. He indicated that a realistic low-power device exclusion is needed. Tell noted that the 1991 standard has such an exclusion but virtually no one uses it – Gorsuch pointed out that DoD uses the 1991 low-power device exclusion all the time. Brecher asked Tell to consider whether or not the averaging volume should be frequency dependent and raised the issue of whether 6 GHz might be too high for SAR considerations. Meltz said any potential issues regarding penetration depth versus the size of the exposed individual should be investigated and Chou suggested that unless there are reasons not to the ICNIRP peak spatial-average SAR limits should be considered.

8) Single vs Two Tiers

In the absence of Erdreich and Sena, Swicord briefly reviewed the overheads prepared by Erdreich and Sena (Attachment 9) and the discussions about one versus two tiers that took place at the Tempe meeting (see *Spring 2001 Mailing*). He said that one option is a single tier standard that could be relaxed for certain occupational exposures under certain conditions. McManus pointed out that the report of the Stewart Independent Expert Group on Mobile Phones discredited the NRPB single-tier limits and recommended adoption of the ICNIRP recommendations in the UK – as a precaution. Swicord pointed out that the Stewart report was not a scientific response. In response to a question from Meltz, Swicord said that the paper being prepared by Erdreich and Sena is the framework for a white paper – it essentially describes the choices but needs further discussion and review. Brecher said that IEEE would lose credibility if a single tier is adopted. Adair disagreed pointing that if two tiers were adopted the decision would not be science-based but would be political – the same as was done in 1989.

9) Peak Power Limits

J. D'Andrea reported that so far he sees no reason to change the peak power limits in the 1991 standard – only a need to explain them better.

10) Low Power Device Exclusion, Measurement Distance, Harmonization with ICNIRP

Petersen reported that the measurement distance has been modified and is contained in the 1999 Edition of C95.1-1991 and in the draft of the revision of C95.3-1991. He said that a realistic low-power device exclusion should be included in the revision but the exact values cannot be specified until the averaging volume issue is resolved. The consensus is to move

to a larger averaging volume (see Tell's compilation in Attachment 8) and perhaps higher limits for the peak spatial-average SAR, e.g., adopt the ICNIRP limits.

11) Averaging Time (6 GHz to 300 GHz)

J. Osepchuk reviewed his proposal for new averaging times. He pointed out that the reason for a change is to resolve the issue of the "eyes and testes" caveat in the partial-body relaxation. The current averaging times result in higher MPEs than the IR laser MPEs at wavelengths where the penetration depths would be about the same. He reviewed the joint SCC28/Z136 workshop held at Brooks a few years ago and the thermal modeling of Foster that led to the new averaging times. He pointed out that the new ramps are consistent with the AF work.

Adjournment

At the Chair's discretion, the meeting was adjourned at 5:00 PM – to be continued the following day, June 9, at 8:00 AM.

IEEE SCC-28 Subcommittee 4

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(Continued)

Call to Order

The continuation of the SC4 meeting was called to order by Co-Chairman D'Andrea at 8:05 AM.

Before returning to the agenda, a demonstration of the MMF searchable database was presented by J. Morrissey (see Attachment 10). Morrissey pointed out that the database contains two subsets – IEEE and WHO. He said that the potential exists for including the IEEE review results. The studies are editable and new studies can be added but the site is password protected. The WHO website should be available shortly. The URLs, respectively, for the MMF website and the WHO website are

http://www.mmfai.org

http://www-nt.who.int/peh-emf/database/htm

Meltz pointed out that it would be desirable if the IEEE database could be searchable simultaneously by a number of terms to narrow the results. Heynick complimented Morrissey for his efforts and pointed out the value of the database for standard setting, e.g., for developing the white papers.

12. Literature Evaluation Working Group Reports (Continued)

c) White Paper Reports

1) Cancer

Heynick reported that a draft of the white paper on cancer was distributed to the Revision Working group and asked if it should be distributed further. He pointed out that the paper also covers mutagenesis and includes a number of rather poor papers as well as a number of papers that report negative findings.

2) Organ Toxicity (Dysfunction or Diseases of Major Organs)

D. Black reported that he and J. Elder are preparing a paper addressing this issue and asked for guidance. He noted that these effects are usually associated with chemicals and ionizing radiation. He said that the conclusion so far is that toxicity can fall into a number of groups. Organ toxicity, used in radiation biology, has found its way into the NIR literature. It has to be clearly distinguished from acute toxicity – which is reversible. The term may not have much meaning in NIR – by the time a specific organ is affected other organs may also be affected. He said the question then is "why are we looking into this area"? Heynick asked

if we are also looking into effects to the heart – Black responded that we are not. He added that a number of papers have been found that report effects to the isolated heart but none have been found yet on the intact animal. Meltz asked "what evidence is there that pathology on different organs has been examined"? Black responded that the concern is that if specific organs are effected, e.g., cell death, this could lead to other physiological changes. Sheppard agreed that the term was borrowed from other areas of toxicology. He noted this issue is being pursued because at the Florida meeting, lists of papers on specific topics were identified and there was agreement that these lists would be examined to identify key papers. Black noted that he probably would not include papers that are included in other white papers. Gorsuch said that the reason why this issue was included stems from the categories in the NCRP Report 86 – Elder said that it is a catchall section to include topics/papers not included in all other categories.

3) Reproduction, Growth and Development

Heynick reported that a draft was distributed to a number of people for comment. He said that the paper covers everything from insects to humans and summarized the conclusions (see Attachment 11 for overall conclusions). Heynick noted that the relevant Lai-Singh papers are included as well as the Roti-Roti papers. Sheppard said that he has not yet had a chance to read the paper line by line but he does have some suggestions based on what he read so far – Heynick said that he is waiting for comments from all of the reviewers. Chou pointed out that the process for dealing with the white papers would be discussed later in the meeting.

4) CNS Effects

D'Andrea reported that the CNS paper is about 90% complete and the behavioral and cognitive effects paper is also about 90% complete and should be ready for distribution in a few weeks. Elder asked if an attempt was made to separate CNS effects in humans from animals – D'Andrea replied that it had not but it was a good idea and he will consider it.

5) Behavioral and Cognitive Effects

See above.

6) Non-Thermal Effects

Heynick noted that he referred to the report on calcium efflux earlier. He said that he is not sure how to proceed with other "low-field" effects but pointed out that it is important to proceed because of misplaced criticism and attacks on the IEEE for not including these studies.

7) Life Span

Elder reported that the 1984 EPA report included a section on life span as did Carpenter's book. He said that few papers have "life span" in the title but a number of papers address the issue. He has reviewed earlier papers and other papers that discuss the issue within and should have a draft available in a few weeks.

8) General Discussion (How to Deal with White Papers)

Chou asked for suggestions on how to proceed with the white papers, e.g., should they be published in the peer-reviewed literature? Brecher asked if anything has been found at this point that would lead to a change in the 1991 standard. Meltz said that we should turn the question around. He recommended establishing small groups to review the white papers and indicate whether there is evidence that would support raising or lowering the current MPEs. He said that this question should be asked of each paper. Tell asked about the

number of references from the database that are actually cited in the white papers and suggested comparing the lists of references to find out. He also suggested examining the evaluation results (scores) of studies cited in the white papers. Heynick said that he agrees with Tell and pointed out that the white papers were prepared to speed things up and papers with high scores and papers with low scores will be included. Swicord agreed and added that every relevant paper in the database must be included – the process must ensure that all papers/topic are included in the database to show what has been considered. Adair pointed out that the database was compartmentalized at the Florida meeting and the authors of the white papers are using most of those papers.

S. Johnston said that she sees no problem with preparing white papers before all of the reviews are in. Heynick agreed saying that everything should be done in parallel but it would be useful to see the evaluations while he is preparing the white papers. Tell asked if every paper in the database would be referenced in the white papers, i.e., would each of the 1521 papers be referenced somewhere? Chou responded that most should be – with the possible exception of a number of engineering papers and other irrelevant papers. Meltz said that although lists are available, it is not necessary to include every paper. However, there should be a mechanism to ensure that the papers considered important/relevant are included. In response to Tell's question about ensuring that every paper in the database is included somewhere, the consensus was that it is not necessary. Osepchuk pointed out that some papers are irrelevant, deficient, etc., and there is no need to include every one. Tell disagreed pointing out that some studies may be deficient, e.g., Repacholi's study, but are important and should be included. Morrissey said that it is important to consider all the papers but not all of the papers need to be cited. Cohen said that he thought the process was to either generate new limits or confirm the existing ones. He said that a number of papers have no relevance whatsoever with regard to standard setting – only about 500 papers may be relevant. He said whether or not a paper was considered relevant was based on the title of the paper and, in fact, many of these papers may not be relevant. Chou said that the process is to identify relevant papers – this means that all the papers have to be considered. Heynick said that we seem to be too fragmented. If this were to be done over, it may be more efficient to have just two literature evaluation groups – engineering and bioeffects. Gorsuch aid that it is important to have all of the papers reviewed and a record established as to what was considered in order to avoid future criticism. As long as all of the citations were considered, it is not germane if some of the papers are not included in the white papers. Coghill stated that it is important to consider the cutoff point and asked how major study results would be addressed, e.g., the results of important studies that will not be published for several years. Meltz proposed that Citation List Number 22 should be the cutoff list. He said that if important papers not on the list become available in the next few months, Heynick should update the list and that list will serve as the cutoff.

MOTION

M. Meltz moved to continually update the database and that all new papers will be approved by the working group chairs. All approved papers will appear on a new list for distribution and that list will serve as the cutoff list. As of now, list # 22 is the cutoff list.

L. Heynick seconded the motion.

Discussion:

Bushberg spoke against the motion saying that continually adding papers would delay progress. D'Andrea agreed with Bushberg saying that a cutoff should be decided now and

adhered to. He said he is concerned because of criticism of the 1991 standard process where certain papers published after the cutoff date were let in and others were not. Bodemann asked about the criteria used to determine the importance of a paper. Adair suggested that the cutoff date should be the date the 1st draft is completed. There was consensus that Adair's suggestion was appropriate and the motion was withdrawn.

MOTION

E. Adair moved that the literature cutoff date should be the date that the 1st draft of the revision is submitted to SC4.

M. Ziskin seconded the motion; the motion was approved unanimously.

J. Elder noted that immunology is not specifically covered and asked if it is covered in any of the white papers. Chou agreed that it is not covered specifically and Heynick volunteered to prepare a white paper on immunology/hematology. Although there was no response to Heynick's request for volunteers to help draft the paper, he said that it would get done.

Chou concluded the discussion on process by stating that as soon as all of the white papers are finished, they will be compiled and submitted to a journal for publication.

13. Annex Reports

a) Annex A: Approach to Standard Revision

Swicord reviewed the process that will be described in Annex A, e.g., looking at all the evidence, weighing the evidence, etc. (see Attachment 12 – from *Spring 2001 Mailing*). He described the procedures followed by other organizations and the detailed procedures followed by IEEE, e.g., open process, documentation at every level, balance of disciplines and affiliations, input from stakeholders, etc.

b) Annex B: Selecting an Adverse Effect: Summary of the Literature Evaluation Results

Sheppard discussed the status of Annex B. He said that the challenge has been to address the entire spectrum in a coherent form. He noted that immunology will be added to address concerns discussed earlier and will become a major heading in the outline (see Attachment 13 – from *Spring 2001 Mailing*). Swicord pointed out that the titles in the outline refer to sections of the standard. Summaries of the white papers will be included – the entire papers will not. Bushberg suggested including just the conclusions of the white papers plus some introductory material. Sheppard said that a reasonable amount of progress has been made on this annex. Heynick pointed out that a white paper is needed on the effects on cells and tissues – section f(vi) of the outline – or at least something definitive should be said to address the issue. Meltz said that he would address the issue but will need about 3 months and some assistance. Meltz said that he would also help Heynick with the immunology white paper – Heynick will complete the draft and send it to Meltz.

FOR ACTION

M. Meltz will draft a section on the adverse effects on cells and tissues – to be completed in three months.

L. Heynick will complete a white paper in immunology and send it to Meltz for review.

c) Annex C: Explanation of Maximum Permissible Exposure Values

Tell reported that he should have a draft addressing adverse effects levels completed by August (see Attachment 14 – from the *Spring 2001 Mailing*). Adair noted sensitive tissues such as the eyes and testes would be addressed in her section. Black asked if a rationale for two tiers would be included. He noted that there seems to be no sound rationale for two tiers – ICNIRP and others have used arguments that the public may be exposed 168 h per week while the worker would be exposed for 40 h, there may be a possibility of sensitive groups of individuals, etc. He asked how a number would be chosen to set the lower tier, should it be 5 times lower, 2.5 times lower? Tell responded that the intent was to start out fresh with as few assumptions as possible and see where we wind up – perhaps with a single tier. Cohen pointed out that the word "temperature" in the caption of 1(b) should be changed to "energy absorption." Swicord said that energy absorption is too vague, Johnston said to strike "increased" in the caption, and Reilly suggested adding "internal electric fields" to the caption of 1(b).

FOR ACTION

J. Elder, M. Swicord and R. Tell will revise Section 1 of Annex C.

Gettman asked if multiple sources would be included separately – Sheppard replied that they are already included in a number of sections. Coghill asked about synergism, e.g., cell phone exposure after taking medication, is a 20 minute call the same as 20-one-minute calls, etc. Chou responded that only what is defined in the literature is being considered – if it's not defined it would be difficult to make an informed rational decision.

d) Annex D: Technical Similarities and Differences Between this Standard and other Protection Guides

No report.

e) Annex E: Tables and Figures[1] [To be done later]

No report.

f) Annex F: Papers Subjected to Review

No report.

g) Annex G: Papers Identified as Applicable to the Development of the Standard

No report.

h) Annex H: Examples of Application of the Standard

J. DeFrank reported that several volunteers are working on various sections Annex H and several sections have already been drafted. He said that he supports the use of examples that explain how the standard should be used and he noted that several people in his group at Aberdeen, MD are preparing such examples.

Adair said that she has looked through the drafts and has not seen any references to the exclusions -–Chou assured her that the exclusions are important and will be addressed.

14. Interpretations Working Group

J. Hatfield reported that responses to two requests for interpretation have been prepared recently – one on spatial-averaging, the other on induced current. He said that Osepchuk prepared supplemental letters explaining the interpretations but it was not clear if the explanation of the induced current response satisfied the requester.

15. Other Old Business

a) Biography of Subcommittee Members on the Website

Chou reviewed the idea of posting short biographies and pictures of committee members on the SC4 web page. Heynick said that he was against it since it could lead to inappropriate attacks and questions about individuals based on their training, e.g., why should a physicist be reviewing biology papers? McManus said that he too was against this. He said that it would be useful, however, to see up-to-date lists of committee members with their affiliations and e-mail addresses. Chou said that he would distribute that information.

MOTION

M. Murphy moved to post biographies and pictures of committee members on the SC4 web page.

The motion was seconded by A. Sheppard.

Discussion: K. Gettman spoke against the motion stating that he thought posting pictures and biographies of committee members on a publicly accessible site could be a security issue. Coghill spoke in favor of the motion adding that the disciplines of the members should also be included but access should be restricted.

Anderson said that he was the one who originally proposed the idea – he thought that it would be of interest to new members. He said that he does not consider security an issue – the biographies would be similar to those sent with journal articles. Chou asked Varanelli if sections of the website could be password protected – Varanelli responded that they could. Murphy said that he agrees with Anderson, i.e., the information should be restricted to that which would normally be published with a journal article. This would support the open IEEE process. Tell spoke in favor of the motion – Gorsuch said that there may be legal ramifications for government employees regarding who is being represented, i.e., who are these members speaking for?

The question was called and the motion was approved with one negative vote.

16. New Business

a) Definition of Terms (SC3/SC4 Transition Frequency Working Group)

J. Cohen, R. Coghill and J. Reilly were appointed as an inter-subcommittee working group. The charge of this working group is to ensure that each subcommittee is aware of the other subcommittee's activities to ensure consistency between the two standards in the transition frequency range.

b) Making the Review Scores Public

D. Blick recommended that the review scores be made available to the authors of the white papers by placing them in the searchable database. He made the following motion:

MOTION

D. Blick moved to place the review scores in the IEEE database.

The motion was seconded by M. Swicord.

Discussion: Meltz pointed out that the reviewers are randomly selected but the chairs of the working groups can comment and he recommended that the chair's comments also be included with the review scores. He then made the following amendment to the motion:

AMENDMENT TO MOTION

Comments of the chairs of the literature evaluation working groups should be included in the database with the reviewer's comments.

The amendment was accepted by Blick and Swicord. Meltz noted that so far none of the reviews contain comments from the chair but he intends to comment.

The question was called and the amended motion passed unanimously.

MOTION

L. Heynick moved to provide the RAWG with the actual reviews and the software for searching the reviews.

Blick pointed out that this was already agreed to at an earlier meeting – the motion was withdrawn.

c) SAR in the Pinna

O. Gandhi said that he has been examining the issue of SAR in the pinna. He said that a paper will be coming out soon regarding the pinna proposal. The conclusion of his studies support the ICNIRP peak spatial-average SAR values, namely 10 W/kg averaged over 10 g of tissue for the public. Gandhi made the following motion:

MOTION

Gandhi moved that SC4 consider harmonizing with ICNIRP on the peak spatial-average SAR limits and accept the pinna proposal as a special condition.

The motion was seconded by J. Hatfield.

Discussion: The was a brief discussion on the issue and the consensus of the committee was that the motion should be tabled until more information is obtained. Gandhi accepted this and withdrew his motion. He said that he would provide SC4 with data supporting his position.

17. Date and Place of Next Meeting *D'Andrea/Chou*

a) 4th Revision Working Group

The next meeting of the will be September 13-14, 2001 in Washington DC (FCC Headquarters). Chou noted that SC2 would be meeting September 11-12 at the same location.

b) SCC28/SC4 Meeting

Osepchuk reported that the EXCOM is investigating the possibility of holding the November meetings in Europe – possibly in Luxembourg. The meeting would be held in conjunction with an EU/EC EMF meeting and possibly an ICNIRP meeting. He said that this should be confirmed by late July – if this fails the meeting will be held in San Antonio, TX in November.

18. Adjournment

There being no further business, upon a motion by L. Heynick and a second by K. Jaffa, the meeting was adjourned at 11:30 AM.

ATTACHMENTS

IEEE SCC-28 Subcommittee 4

Radisson Riverview Hotel
St. Paul, MN
June 8-9, 2001

1. List of Attendees
2. Tentative Agenda
3. Definitions of Biological Effect, Adverse Effect,…
4. Copy of Overheads – Engineering Evaluation WG Report
5. Copy of Overheads – *In Vivo* Evaluation WG Report
6. Copy of Overheads – Process Management WG Report
7. Questionnaire - Preliminary Assessment of Opinions
8. Questionnaire – Compilation of Contributed Answers and General Comments
9. Copy of Overheads – Single versus Two Tiers
10. Copy of Overheads – Searchable Database Presentation
11. Conclusions of Reproduction, Growth and Development White Paper
12. Outline – Annex A
13. Outline – Annex B
14. Outline – Annex C

Attendance List

Radisson Riverfront Hotel
St. Paul, Minnesota
June 8, 2001
1:00 PM – 5:00PM
and
June 9, 2001
8:00 AM – Noon

	Name	Affiliation	Status	Country	E-Mail
1.	Adair, E. R	USAF	M	US	eleanor.adair@he.brc
2.	Anderson, V.	Private Consultant	M	AU	vitas@ieee.org
3.	Aslan, E.	NARDA Microwave	M	US	edward.aslan@narda
4.	Baron, D.	Holaday Industries	O	US	baron006@tc.umn.ec
5.	Bellier, P.	Health Canada	O	CA	pascale_bellier@hc-s
6.	Black, D	Enviromedix IT Me	M	NZ	drblack@itmedical.c
7.	Blick, D.	USAF	M	US	dennis.blick@brooks
8.	Bodemann, R	Siemens AG	O	DE	ralf.bodemann@mch
9.	Brecher, A.	DOT/RSPA Volpe Center	M	US	brecher@vople.dot.g
10.	Bushberg, J. T.	Univ of CA – Davis	M	US	jtbushberg@ucdavis.
11.	Chou, C. K.	Motorola	M	US	ECC017@email.mot
12.	Cleveland, R. F.	FCC	M	US	rclevla@fcc.gov
13.	Cohen, J.	Consultant	M	US	jcohen@denny.com
14.	D'Andrea, J. A.	Naval Health Research Det	M	US	john.dandrea@navy.l
15.	DeFrank, J.	US Army – CHPPM	M	US	john.defrank@amedc
16.	Dowdle, J.	3M	O	US	dmdowdle@mmm.c
17.	Elder, J.	Motorola	O	US	
18.	Gettman, K.	NEMA	O	US	ken_gettman@nema.
19.	Gibney, K. B.	Independent	O	CA	kgibne6276@home.c
20.	Gorsuch, G. M.	Dept of Navy – Bur of Medicine	M	US	gmgorsuch@us.med.
21.	Haes, D. L.	MIT	M	US	haes@mit.edu
22.	Hammer, W. C.	Navy – SPAWAR Systems	M	US	hammerw@spawar.n

	Name	Affiliation	Status	Country	E-Mail
23.	Hatfield, J. B.	Hatfield & Dawson	M	US	hatfield@hatdaw.com
24.	Heynick, L. N.	Independent Consultant	M	US	louhey@mindspring.
25.	Hubbard, R.	Technology Services	O	ZA	roy.hubbard@eskom
26.	Hurt, W. D.	USAF	M	US	william.hurt@brooks
27.	Ivans, V.	Medtronic, Inc	M	US	veronica.ivans@med
28.	Jaffa, K. C.	Pacificorp	M	US	kent.jaffa@pacificor
29.	Johnson, S.	Consultant	M	UK	sajohnson@btinterna
30.	Joyner, K.	Motorola	M	AU	C2071@email.mot.c
31.	Kantner, K.	AT&T	O	US	kkantner@att.com
32.	Kuster, N.	IT'IS	O	CH	kuster@it is.ethz.ch
33.	Lang, S.	Nokia	O	FI	sakari.lang@nokia.co
34.	Mantiply, E.	FCC	M	US	emantiply@fcc.gov
35.	Mason, P. A.	USAF	M	US	patrick.mason@broo
36.	Mauer, S.	Consultant	M	US	maueremf.juno.com
37.	McManus, T	Dept of Pub Enterprise	M	IE	tommcmanus@dpe.i
38.	Meltz, M. L.	Univ of Texas	M	US	meltz@utscsa.edu
39.	Mercer, C.	Vodacom	O	ZA	mercer@vodacom.co
40.	Moller, P.	Motorola	O	US	wpm002@email.mot
41.	Morrissey, J.	Motorola	O	US	
42.	Murphy, M	USAF	M	US	michael.murphy@br
43.	Needy, R.	Navy – Surface Warfare Cntr	O	US	needyri@nswc.navy.
44.	Osepchuk, J. M.	Full Spectrum Consulting	M	US	jmosepchuk@cs.com
45.	Pakhomov, A. G.	McKesson Bio Serv	M	US	andrei.pakhomov@a
46.	Petersen, R. C.	Lucent Technologies	M	US	rcpetersen@lucent.co
47.	Quan, G	BC Hydro	O	CA	gregory.quan@bchyd
48.	Reilly, J. P.	Metatec Associates	M	US	jpatrickreilly@erols.c
49.	Roberts, B. J.	US Army – CHPPM	M	US	brad.roberts@apg.am
50.	Scanlon, W. G.	University of Ulster	M	IE	w.scanlon@ulst.ac.ul
51.	Sheppard, A. R.	Asher Sheppard Consulting	M	US	ashersheppard@com
52.	Smith, M.	Pacific NW Nat Labs	O	US	mathew.smith@pnl.g
53.	Sutton, C. H.	Consultant	M	US	doctorchs@aol.com
54.	Swicord, M. L.	Motorola	M	US	EMS029@email.mot
55.	Tell, R. A.	Richard Tell Assoc	M	US	rtell@radhaz.com
56.	van Rongen	Health Council of the Netherlands	O	NL	e.van.rongen@gr.nl
57.	Varanelli, A. G.	Raytheon	M	US	a.g.varanelli@ieee.or

	Name	Affiliation	Status	Country	E-Mail
58.	Wojcik, J. J.	Spec Sciences Inst/APREL Labs	O	CA	jackw@aprel.com
59.	Ziriax, J.	USAF	O	US	john.ziriax@brooks.a
60.	Ziskin, M. C.	Temple Univ	M	US	ziskin@astro.ocis.ten

INTERNATIONAL COMMITTEE *on* ELECTROMAGNETIC SAFETY

ATTACHMENT 2

IEEE/ICES Standards Coordinating Committee 28
Subcommittee 4
(Safety Levels with Respect to Human Exposure, 3 kHz to 300 GHz)

Radisson Riverfront Hotel
St. Paul, Minnesota
June 8, 2001
1:00 PM – 5:00PM
and
June 9, 2001
8:00 AM - Noon
Kellogg Room-I

Preliminary Agenda

1.	**Call to Order**	*D'Andrea/Chou*
2.	**Introduction of those Present**	
3.	**Approval of Agenda**	*D'Andrea/Chou*
4.	**Approval of the Minutes of November 17, 2000 Meeting**	*D'Andrea/Chou*
5.	**Secretary's Report**	*Petersen*
6.	**Chairman's Report**	*D'Andrea/Chou*
7.	**SCC28 EXCOM Report**	*Osepchuk*
8.	**Risk Assessment Working Group Report**	*Tell*
9.	**Mechanism Working Group Report**	*Sheppard*
10.	**Harmonization with ICNIRP**	*Petersen*
11.	**Literature Evaluation Working Group Reports**	
	a) Literature Surveillance and Database Software	*Heynick/Tell*
	b) Engineering	*Hurt*
	c) *In Vitro*	*Meltz*
	d) *In Vivo*	*Blick*
	e) Epidemiology	*Gorsuch*
	f) Dissemination of Literature review results	*Petersen*

12 Editorial Committee Reports

a) Third Revision Working Group meeting and time schedule *Chou*

b) Topic Reports

1) Spark discharge and induced current *Reilly*
2) Thermoregulation *Adair*
3) Non-thermal effects *Heynick*
4) Definition of *adverse effects* & selection of an adverse effect level *Sheppard*
5) Whole body SAR limit *Chou/D'Andrea*
6) Biological basis for local SAR limit *Meltz*
7) Spatial averaging, averaging volume *Tell*
8) Single vs two tiers *Erdreich*
9) Peak power limits *D'Andrea*
10) Low power device exclusion, measurement distance, harmonization with ICNIRP *Petersen*
11) Averaging time 6 GHz to 300 GHz) *Osepchuk/Foster*
12) Replication/validation *Curtis*

c) White Paper Reports

1) Cancer [Heynick*, Meltz]
2) Organ toxicity (dysfunction or diseases of major organs) [Black*, Elder]
3) Reproduction, Growth and development [Heynick]
4) CNS effects [D'Andrea*, Chou, Adair, Lai]
5) Adverse effects on physiological functions [Adair*, Black]
6) Behavioral and cognitive effects [D'Andrea*, Adair, deLorge]
7) Non-thermal effects [Heynick, Sheppard]

d) Annex Reports

1) Annex A: Approach to standard revision [Erdreich,* Swicord*]
2) Annex B: Selecting an adverse effect: summary of the literature evaluation results [Sheppard*, Reilly]
3) Annex C: Explanation of maximum permissible exposure values [Sheppard*, Tell]
4) Annex D: Technical similarities and differences between this standard and other protection guides [Cleveland*]
5) Annex E: Tables and Figures[2] [To be done later]
6) Annex F: Papers subjected to review [Heynick*]
7) Annex G: Papers identified as applicable to the development of the standard [Heynick*]
8) Annex H: Examples of application of the standard [DeFrank*]

13. Interpretations Working Group *Hatfield*

19. Other Old Business

a) **Biography of subcommittee members on the website** *Chou*

20. New Business

21. Date and Place of Next Meeting *D'Andrea/Chou*

a) **4th Revision Working Group meeting – September 13-14, 2001 in DC**

b) **SCC28/SC4 meeting, November 2001**

22. Adjournment

Definitions

I – Biological Effects and Adverse Effects

A **biological effect** is an established effect caused by, or in response to, electromagnetic fields. Biological effects are alterations of the structure functions of the whole organism, its organs, tissues, cells, or molecules. effects can occur without harming health. Biological effects includealte physiological functions and adaptive responses.

An **adverse effect** is a biological effect characterized by a harmful chan example, such changes can include organic disease, impaired mental fu behavioral dysfunction, reduced longevity, and defective or deficient re

Adverse effects do not include:

1. Biological effects without a health effect.
2. Changes in subjective feelings ofwell-being that are the result of anxi effects or impacts of RF infrastructure that are not related to RF emiss
3. Indirect effects caused by electromagnetic interference with electroni indirect effects are covered by other standards.

Definitions Continued

II Established Effect

An effect is normally considered **established** wh
are consistent findings published in the peer-rev
scientific literature from independent laboratori
there is consensus that the effect occurs for the s
exposure conditions.

Definitions Continued

III Adverse Effects Exposure Leve

An **adverse effects exposure level** is the condition or set o
under which an electric, magnetic, or electromagnetic field
adverse effect. Conditions can be a property of the source
strength, power density, frequency, modulation, pulse dura
repetition), a dosimetric quantity (such as current, current d
specific absorption, and specific absorption rate), and an ex
characteristic (such as exposure duration and recurrence int
Adverse effects exposure levels may differ according to wh
and organs are exposed. This standard is based on the lowe
exposure levels for all established adverse effects. The MP
standard are derived from these exposure levels incorporati
appropriate safety factors.

IEEE/ICES—SCC 28, SC IV, RFR Lit. Rev, Eng. WG

24 active reviewers

573 completed evaluations

179 partial evaluations

208 papers in process of being reviewed

110 more papers will be sent out by 1 Jul 01

ATTACHMENT 4

IEEE/ICES –SCC 28, SC IV, RFR Lit. Rev, Eng. WG Membership

	# of Evals	DoE		# of Evals	DoE
V. Anderson*		**12/00**	K. Joyner*		12/99
E. Aslan*	85	8/93	N. Kuster	27	8/93
T. Babij	27	8/93	J. Leonowich*	39	8/94
Q. Balzano	25	7/93	J. Lin	26	9/94
H. Bassen*	78	8/93	E. Mantiply*	66	8/93
R. Biby*		12/00	S. Maurer	24	8/93
P. Chadwick*	10	1/01	M. Moore*	86	12/95
C.K. Chou*	65	7/93	R. Olsen*	86	7/93
J. Cohen*	85	7/93	J. Osepchuk*	54	8/93
J. DeFrank*	59	12/96	R. Peterson*	47	7/93
C. DiNallo*		1/01	R. Tay*		12/00
A. Faraone*	30	4/99	A. Thansandote*		1/01
K. Foster*	92	8/93	A. Varanelli	15	10/96
G. Gajda*	10	3/01	L. Williams, Jr.	67	8/94
D. Hadlock	6	8/93	H. Sheriff	530	6/99
J. Hatfield*	89	7/93			
C. Hicks, Jr.	59	9/94			
W. Hurt*	93	8/93			
M. Israel*	20	1/01			

ATTACHMENT 5

Activity of In Vivo Reviewers by Calendar Year

Sorted alphabetically

NAME	PRE 1998	1998	1999	2000	2001	TOTAL	OUT
Adair, E.	24	16	29	24	40	133	8
Babij, T.		9			8	17	*
Bailey, W.						0	13*
Bellier, P.					8	8	
Blake, D.						0	7
Blick, D.			53	24	16	93	4
Bushberg, J.						0	7
Cobb, B.	1	12	13	2		28	4*
Cook, M.						0	20*
DeLorge, J.			48	18		66	*
Elson, E.		8				8	*
Frei, M.	4					4	*
Jauchem, J.		8	12	4		24	8*
Johnston, S.						0	7
Klauenberg, B. J.						0	5*
Lai, H.	11	1				12	*
Lapin, G.			25	7		32	*
Lotz, G			2			2	*
Lu, S.-T.		4	12	20	8	44	8
Marmaro, G.		7	13			20	*
Mason, P.		4				4	14*
McNamee, J.					2	2	
Merritt, J.			8			8	11*
Miller, S.			28	5		33	13*
Monahan, J.	6					6	*
Morrissey, J.		4	16	19	15	54	9
Murphy, M.	9	2	17	2		30	8
Orr, J.			5			5	*
Ryan, K.			22	1		23	*
Seaman, R.			9	13		22	7
Spiers, D.			8	16		24	*
Tattersall, J.				11		11	8
Utteridge, T.				15	11	26	
Vijay			8	6		14	9
Walters, T.		2	3			5	*
Wenger, C. B.			1			1	*
Ziskin, M.			6	10		16	5
TOTAL	55	77	338	197	108	775	87
* indicates reviewer not currently active.							

Progress (or lack thereof) of In Vivo Review

Dennis W. Blick, discouraged chair

	6/01	11/00
Database total in vivo papers	**598**	**584**
Total number of reviews needed	**~1210**	**~1175**
Sent out to date	**~980**	**~950**
Received back to date	**781**	**685**
Still out (some for a LONG time)	**>200**	**>260**
Completed (≥2 reviewers)	**320**	**270**
Incomplete (only one review in)	**~140**	**~140**

Comments on Project Managem date

- 6 authors/editors replied to first notice
- Subsequent week updates dwindled to 3
- Several key section editors had no reply
- Based upon 7 hours of volunteer work/week
  - 16 weeks remain until October 1
  - Working every week yields 112 hours per each to complete work
- Authors need to access their availability and assignments

Successful Project Management F
Input Data!

- status, some estir
  when, how and v
- Garbage in, garba
- Want to be flexib
  recognize workir
- Goal is to facilita
- Beyond outline,
  needed

Preliminary Assessment of Opinions Expressed in Questionnaire Answers

Prepared June 6, 2001
Richard A. Tell

1. What is the scientific basis for the 1-gram tissue mass averaging specification in the present standard?

   None, based on technical measurement limits at the time.

2. Does the scientific basis for a 1-gram mass for SAR averaging apply equally to small animals and typical sized humans or is there a technical reason why these would/should be different?

   It was based on animal data; extrapolation to humans could imply larger equivalent tissue masses because of physical scaling. This suggests that the use of a 1 gram tissue averaging mass for humans could be substantially more conservative since 1 gram in a small animal represents a larger fraction of the total body mass than it does for a human.

3. The rationale for the present IEEE standard local SAR limit includes the use of a 20:1 ratio between local SAR and whole-body average SAR. The 20:1 value was chosen in 1979 and was related to exposure near body resonance. Today, we have much more and high resolution dosimetry data than we did in 1979, and many of these data suggest that the ratio is higher. ICNIRP, for example, used a ratio of 25:1 in deriving its guidelines for exposure. Is the use of the 20:1 ratio still scientifically justified or should it be changed?

   Probably still reasonable, difference between 20 and 25 not supportable, but SAR limits should be based on controlling thermal injury.

4. What is the uncertainty associated with this ratio? How should the ratio be stated, as $x \pm y$:1?

   Not particularly relevant.

5. What data support the 20:1 ratio of peak SAR to whole-body average SAR at <u>non-resonant frequencies</u> for humans for uniform exposures?

6. What are the ratios of peak SAR to whole-body average SAR for non-uniform exposures for human body sizes?

   Can be greater than 500 but as long as SAR remains under limit, OK.

7. The present standard states that for <u>partial body exposures</u>, the peak field may be as great as 20 times the MPE limit but that this provision may not be applied if the eyes or testes can be exposed.

   a. What are the implications of this provision in terms ofpeak SARs?
   b. What scientific data support this statement?

c. Some have interpreted this statement to imply that spatial averaging of non-uniform fields (to be distinguished from partial body exposures) would not be permitted for almost all exposures since the eyes and testes are generally exposed. Is this technically appropriate?
d. What criteria should be used to identify partial body exposures in light of the fact that the standard specifies that RF fields are to be spatially averaged over the body (the implication of which is that the eyes or testes could be acceptably exposed to RF fields up to 20 times the MPE limit)?

Eyes and testes should not be treated any differently from other body parts relative to present local SAR limits in standard.

8. When does field uniformity become so non-uniform that:
   a. Spatial averaging is no longer valid (i.e., a hazard could occur)?
   b. Non-uniform exposure has become partial body exposure?

   No need to distinguish.

9. Can the present rationale for the low power exclusion rule be strengthened or should the exclusion be changed or deleted?

   It can be strengthened and should be but do not delete it.

10. What evidence supports applying the local SAR limit derived from whole-body exposures to localized exposure to low power devices?

    None really, but, no known injury or adverse effect.

11. What would be the best technical basis for defining a minimum tissue mass for averaging of SAR and what should that that mass be?

    Should be based on a maximum permitted tissue temperature.

12. Do present insights support the use of spatial averaging of exposure fields (i.e., what is our strongest specific support for relating spatially averaged plane wave equivalent power densities to whole body average SAR)?

    Body currents show how body integrates nonuniform fields but more evaluation is needed.

13. When spatially averaging RF field exposures, how should the averaging be accomplished? Provide technical basis for answers.

    a. Over a standardized height of, say, six feet?
    b. Over the actual posture of the body for individuals who may not be standing?
    c. Using some measurement technique other than over a vertical linear axis?

    Any way is ok as long as it is as conservative as using the silhouette profile.

14. How well does limiting the maximum of spatially averaged plane wave equivalent power densities to 20 times the permitted spatial average value, as specified in the

present standard, correlate with a maximum local SAR of 20 times the whole body average SAR?

Believed to limit OK but based on limited analysis.

15. What data exists supporting the belief that spatially averaged exposures that conform to the specified time averaging provisions of the standard are safe? For example, the present standard permits 48 W/kg local SAR for 1 minute in every 6 minutes. If the ratio of peak to whole body average is greater than 20:1, this value could become greater. Are there local, intermittent SAR values that would still comply with the time averaging provisions but would be thermally unsafe?

    There is not a substantial basis for this.

16. The present standard is based on the presumption of uniform exposure of the body with a resulting peak SAR that is 20 times greater than the whole-body average value and that this peak SAR is acceptable. (i.e., 8 W/kg for long term exposure). But as the exposure field becomes non-uniform, the ratio of peak to average SAR will obviously increase significantly, i.e., become much greater than 20:1. How does the local SAR value anywhere in the body change relative to whole body average as a function of non-uniformity of the field?

    It can become very much greater, but must observe local limit at all times. Need additional data to support assumption that local exposure less than 20 times MPE comply at all times.

17. Typical non-uniformity in RF fields can easily be 5-10 times greater than the average over the body for whole body exposure. What does this mean relative to local SAR?

    As long as body average meets standard, local values will not exceed local limit but additional analysis recommended.

18. With localized exposures, there is more body heat sink to help dissipate heat and we can sustain higher incident fields locally but are there local heat dissipation limits that are different than that of the whole body?

    None known.

19. Can we reach a point at which the very high field permitted by time and spatial averaging would result in local SARs that exceed a local tissue's ability to adequately dissipate the heat due to some localized anatomical characteristic that would not exist generally in the body?

    None known but conceivably possible.

20. Are there specific tissues or points within the body that have particularly high susceptibilities to localized heating due to thermal properties in the immediate vicinity of the tissue?

    Eyes > 80 W/kg, maybe metallic implants.

21. Is the averaging time proper for all body parts, regardless of peak SAR that is permitted through spatial and time averaging?

    Could likely be modified to be more correct based on tissue types and frequency. Shorter times for local hot spots ~2 min; greater for whole body ~15 min.

22. If not, wouldn't this mean that we should set criteria on the application of spatial and time averaging? What would be these criteria?

    Don't go beyond present extremity clause. Would get too complicated.

23. While it would seem that a temperature based standard, for both body average and local tissues, would be more directly related to potential injury from RF fields, does the present scientific database provide sufficient support for deriving such a standard?

    Yes and no. No known harm at exposures below present MPEs.

24. RF hot spots are often highly localized manifestations of reradiation and typically exhibit wave impedances that can be substantially different from plane waves (e.g., >>377 ohms or <<377 ohms) and the localized SAR resulting from such exposures can often be very small.

    a. Should such fields be assessed simply by applying the spatial averaging provisions of the standard, or
       Yes, with a minimum distance criteria.
    b. Should some other criteria be applied for assessing such exposures?
    c. What specific basis would be used to support these alternate criteria?
    d. Should such exposures be characterized as partial body exposures?
       Consider ignoring high impedance fields but worry about low impedance fields.

ATTACHMENT 8

Exposure Assessment and Dosimetry Questions Forming a Basis for a Technical Rationale for Revision of IEEE C95.1-1999

Compilation of Contributed Answers and General Comments as of June 2, 2001

The information contained in this document represents a compilation of answers submitted in response to a questionnaire delivered February 22, 2001 to a list of selected experts in the field of radiofrequency dosimetry (see recipient list inside this document) for the purpose of soliciting answers to questions relevant to revision of the IEEE C95.1-1999 standard. It is anticipated that additional input will be received but this documentation has been assembled in preparation for the IEEE committee meetings being held June 8-10, 2001 in St. Paul, Minnesota.

Corrections should be forwarded to the author via e-mail. Please note that the text has not been carefully checked for editorial or grammatical errors.

Prepared by
Richard A. Tell (rtell@radhaz.com)
Chairman, Risk Assessment Working Group

For discussion during the SC-4 meeting
June 8-9, 2001
St. Paul, MN

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Acknowledgment

Prior to sending this questionnaire to the above list of individuals, it was reviewed for relevancy by Jim Hatfield and Jules Cohen.

ATTACHMENT 8

Exposure Assessment and Dosimetry Questions
Forming a Basis for a Technical Rationale for Revision of IEEE C95.1-1999

Prepared by
Richard A. Tell (rtell@radhaz.com)
Chairman, Risk Assessment Working Group
February 22, 2001

The present version of the IEEE standard, C95.1-1999, is going through a revision process. There are significant underlying issues in the present standard that may need to be strengthened and/or changed. In addition to the responsibility of chairing the functions of the Risk Assessment Working Group within IEEE SCC-28, Subcommittee 4, Co-Chairs, Dr. C-K Chou and Dr. John D'Andrea, have tasked me with the development of a paper that addresses certain exposure assessment and dosimetry issues in the standard. I have decided that the best way to provide a balanced and technically supportable document is to seek technical input from those most closely involved with these topics. The following list of tough questions is designed to elicit thoughts, insights and explanations for many of these underlying issues so that the next revised standard will be more internally consistent and technically defensible. It is anticipated that the answers contributed by those asked to respond will help form the basis for new narrative in the revised standard. You have received this questionnaire because of your past direct involvement in the historical development of the present standard and/or your technical expertise related to the key issues targeted for discussion, regardless of whether or not you are a member of the IEEE SCC-28 Subcommittee 4.

Please carefully consider each of the following questions and provide as much comment as you like. Try to create helpful comments that address as critically and exactly as possible the questions posed. Some of these questions may appear to be similar; for such questions, this is a result of the complexity of the subject matter and the difficulty in trying to express different technical concerns that may be only slightly different. In others, it may be the result of an inability on the part of the author to properly capture the essence of what he deems important in simple narrative statements. Your answers will be used to prepare an overview statement for submittal to Subcommittee 4 of SCC-28 for use in writing the next revision of C95.1. If you feel unable to provide meaningful commentary on any particular questions, please skip those questions and go on the next one. If you believe that a relevant question has not been posed here, please include it along with your recommended answers. Keep in mind that any explanations that we prepare must be supportable by reference to published reports and papers. Hence, an important aspect of your answers is inclusion of specific citations from the published literature or technical reports supporting your answers. This will be especially helpful in our revision effort.

ATTACHMENT 8

I realize that this questionnaire represents yet another drain on your time; nonetheless, your efforts will be greatly appreciated and will be a valuable input to the next revised standard. Our objective is to develop the best, supportable standard that we can at the present time. I thank you in advance for any time and effort that you are willing to give to this task. If at all possible, please email back your answers by February 28 to rtell@radhaz.com. I would very much like to take any ideas you have to share with me to the upcoming standards revision meeting in Arizona on March 1 and 2. However, I realize that this is too short of a time for most but your answers will be appreciated and useful at any time, even if you cannot meet this rather stringent deadline (remember that immediate thoughts generated in a short period of time can often be more to the point than comments developed over a long period). Input from those of you who are located outside the United States is just as important to us as that from individuals within the US who may be directly participating in the IEEE standards process. Your viewpoint can provide useful insight to this revision process. The following questions are, naturally, based on the IEEE standard but I would appreciate your attempt to provide answers even if your background is principally with other, non-IEEE standards or guidelines.

It would be helpful if you can develop your answers to these questions as a Microsoft Word document, with your text following the stated question(s). Saving your document as **'Dosimetry question answers from XXXXXXX.doc'** would be most helpful in my collection and organization of the various responses, where XXXXXXX represents your name. Following the collection of all comments, I will distribute any output that comes from the analysis of the various answers to all recipients of this document. Thanks again for your help.

1. What is the scientific basis for the 1-gram tissue mass averaging specification in the present standard?

2. Does the scientific basis for a 1-gram mass for SAR averaging apply equally to small animals and typical sized humans or is there a technical reason why these would/should be different?

3. The rationale for the present IEEE standard local SAR limit includes the use of a 20:1 ratio between local SAR and whole-body average SAR. The 20:1 value was chosen in 1979 and was related to exposure near body resonance. Today, we have much more and high resolution dosimetry data than we did in 1979, and many of these data suggest that the ratio is higher. ICNIRP, for example, used a ratio of 25:1 in deriving its guidelines for exposure. Is the use of the 20:1 ratio still scientifically justified or should it be changed?

4. What is the uncertainty associated with this ratio? How should the ratio be stated, as $x \pm y$:1?

5. What data support the 20:1 ratio of peak SAR to whole-body average SAR at <u>non-resonant frequencies</u> for humans for uniform exposures?

6. What are the ratios of peak SAR to whole-body average SAR for non-uniform exposures for human body sizes?

7. The present standard states that for <u>partial body exposures</u>, the peak field may be as great as 20 times the MPE limit but that this provision may not be applied if the eyes or testes can be exposed.

a) What are the implications of this provision in terms of peak SARs?
b) What scientific data support this statement?
c) Some have interpreted this statement to imply that spatial averaging of non-uniform fields (to be distinguished from partial body exposures) would not be permitted for almost all exposures since the eyes and testes are generally exposed. Is this technically appropriate?
d) What criteria should be used to identify partial body exposures in light of the fact that the standard specifies that RF fields are to be spatially averaged over the body (the implication of which is that the eyes or testes could be acceptably exposed to RF fields up to 20 times the MPE limit)?

8. When does field uniformity become so non-uniform that:
   a) Spatial averaging is no longer valid (i.e., a hazard could occur)?
   b) Non-uniform exposure has become partial body exposure?

9. Can the present rationale for the low power exclusion rule be strengthened or should the exclusion be changed or deleted?

10. What evidence supports applying the local SAR limit derived from whole-body exposures to localized exposure to low power devices?

11. What would be the best technical basis for defining a minimum tissue mass for averaging of SAR and what should that that mass be?

12. Do present insights support the use of spatial averaging of exposure fields (i.e., what is our strongest specific support for relating spatially averaged plane wave equivalent power densities to whole body average SAR)?

13. When spatially averaging RF field exposures, how should the averaging be accomplished? Provide technical basis for answers.

1. Over a standardized height of, say, six feet?
2. Over the actual posture of the body for individuals who may not be standing?
3. Using some measurement technique other than over a vertical linear axis?

14. How well does limiting the maximum of spatially averaged plane wave equivalent power densities to 20 times the permitted spatial average value, as specified in the present standard, correlate with a maximum local SAR of 20 times the whole body average SAR?

15. What data exists supporting the belief that spatially averaged exposures that conform to the specified time averaging provisions of the standard are safe? For example, the present standard permits 48 W/kg local SAR for 1 minute in every 6 minutes. If the ratio of peak to whole body average is greater than 20:1, this value could become greater. Are there local, intermittent SAR values that would still comply with the time averaging provisions but would be thermally unsafe?

16. The present standard is based on the presumption of uniform exposure of the body with a resulting peak SAR that is 20 times greater than the whole-body average value and that this peak SAR is acceptable. (i.e., 8 W/kg for long term exposure). But as the exposure field becomes non-uniform, the ratio of peak to average SAR will obviously increase significantly,

i.e., become much greater than 20:1. How does the local SAR value anywhere in the body change relative to whole body average as a function of non-uniformity of the field?

17. Typical non-uniformity in RF fields can easily be 5-10 times greater than the average over the body for whole body exposure. What does this mean relative to local SAR?

18. With localized exposures, there is more body heat sink to help dissipate heat and we can sustain higher incident fields locally but are there local heat dissipation limits that are different than that of the whole body?

19. Can we reach a point at which the very high field permitted by time and spatial averaging would result in local SARs that exceed a local tissue's ability to adequately dissipate the heat due to some localized anatomical characteristic that would not exist generally in the body?

20. Are there specific tissues or points within the body that have particularly high susceptibilities to localized heating due to thermal properties in the immediate vicinity of the tissue?

21. Is the averaging time proper for all body parts, regardless of peak SAR that is permitted through spatial and time averaging?

22. If not, wouldn't this mean that we should set criteria on the application of spatial and time averaging? What would be these criteria?

23. While it would seem that a temperature based standard, for both body average and local tissues, would be more directly related to potential injury from RF fields, does the present scientific database provide sufficient support for deriving such a standard?

24. RF hot spots are often highly localized manifestations of reradiation and typically exhibit wave impedances that can be substantially different from plane waves (e.g., >>377 ohms or <<377 ohms) and the localized SAR resulting from such exposures can often be very small.

    a) Should such fields be assessed simply by applying the spatial averaging provisions of the standard, or
    b) Should some other criteria be applied for assessing such exposures?
    c) What specific basis would be used to support these alternate criteria?
    d) Should such exposures be characterized as partial body exposures?

Individuals Providing Answers to Questionnaire and/or Comments as of June 2, 2001

Vitas Anderson
Q. Balzano
C-K Chou
John D'Andrea
Peter Dimbylow
Kenneth Foster

ATTACHMENT 8

Om Gandhi
A. W. Guy
Kari Jokela
Maria Stuchly
Mays Swicord

Compilation of Responses Submitted by June 2, 2001

Question 1: What is the scientific basis for the 1-gram tissue mass averaging specification in the present standard?

Anderson:

The fundamental reason for having an averaging mass is to recognise two facts:

1. Localized SAR limits are ultimately intended to protect against excessive local temperature rises, sustained over sufficient time and;
2. SAR induced tissue temperature rises will naturally spread out in accordance with the heat conduction and mass diffusion terms in Penne's bioheat equation:

$$\nabla \cdot (k_t \nabla T) - w_b c_b (T - T_b) + \rho_t SAR = \rho_t c_t \frac{dT}{dt}$$

where the subscripts t and b refer to tissue and blood respectively. Thus, even if the SAR heat load was concentrated at a single point, the resulting temperature rise would still be spread out over a larger volume over time.

The important question to consider is whether the mass averaging of the SAR would significantly affect the temperature distribution. This will depend on a number of factors including:

1. The thermal diffusivity, a_t (m^2/s), of the tissue :
   $a_t = k_t/(\rho_t c_t)$
   A higher a_t will increase the rate and extent of the temperature spread. The thermal diffusivity will vary between tissues.
2. The local specific blood perfusion rate, w_b (W/m°C), of the tissue
   w_b = $mass_{blood}$ per sec per $volume_{tissue}$
   A greater w_b will increase the rate and extent of temperature spread. Local blood perfusion can vary substantially between tissues, and will generally increase when local tissue temperature is elevated by more than 1°C due to vasodilatory mechanisms.
3. The distribution of SAR in the tissue
   If SAR is uniformly distributed then the size of the averaging mass will have no impact. The other extreme is a point SAR source, though this is not theoretically possible. Probably the most extreme variations in SAR will occur for exposure to a nearby RF source, where SAR will decay exponentially with distance from the source. This rate of decline can be determined from the skin depth of absorption, as calculated in the attached TISSUE5.XLS spreadsheet. Skin depth decreases with increasing frequency, so the worst case will occur at 6 GHz.
4. The way SAR is applied with time
   The most homogeneous temperature distributions will occur at steady state conditions. Conversely, the sudden application of SAR will initially cause tissue temperatures to rise in the same distribution as the SAR deposition, i.e.:

$$c_t \frac{dT}{dt} = SAR$$

For pulsed exposures, the periodicity of the application of SAR will also affect the tendency of temperature rises to mimic SAR distribution during the application of the pulse. If the pulse period is shorter than the time constant for thermal diffusion processes, then the pulsed SAR will produce temperature distributions similar to continuously applied SAR.

It is probably worth noting that *mass* averaging and *time* averaging are two interrelated aspects of the same problem. In order to develop appropriate numbers for mass and time averaging, it is not only necessary to know the maximum tolerable temperature rise for prolonged exposures, but also to know how long intermittent excursions of higher temperatures can be safely tolerated.

Balzano:

I do not think that there is a specific scientific basis for the 1g mass average shaped like a cube. The reason for this specification must be traced to the computational and measurement instrumentation limits at the time of the standard formulation. If I remember correctly by 1979 1 cm^3 computations over the human body were the projected upper limit for most computers and by 1989 we could make reliable SAR measurements over 1 cm^3 with the probes then available. Any further refinement would have been wishful thinking at that time.

Chou:

This is related to the thermal diffusion of tissue and the volume of measurement with the available methods.

D'Andrea:

The FCC specified in OET65 that the averaging volume be 1 gram of tissue in the shape of a cube. For occupational exposures the limit in the 1 gram cube is 8 W/kg and 1.6 W/kg for public exposures. The 1 gram mass could be overly restrictive compared to 10 grams. Much lower SAR values will be derived when averaged over the larger volume. On the other hand higher overall temperatures may be seen in the10 gram mass. While there may be a rationale based on thermal redistribution of absorbed energy for a cube smaller than 10 grams over which to average the SAR, I believe that the physical limitations in fitting the 10 gram mass in the shape of a cube within the body is the overriding factor for choosing a 1 gram averaging volume. It is much easier to fit the cube in various parts of the anatomical models used for FDTD calculations.

Foster:

There is no scientific basis, as far as I can tell. Bill Guy told me a year or two ago that the 1 gram number came from the technical ability to measure SAR at the time the standard was developed that first incorporated spatial averaging (late 1980s?)

Gandhi:

It has been well known that the SAR distribution is highly non-uniform, hence the need to look at local SARs. The 1-g mass in the shape of a cube was prescribed to avoid very high SARs if averaged only for the skin or the surface of the body. The metabolic rates of various tissues in the human body vary from 1-8 W/kg. Thus the prescribed SARs are comparable to the metabolic rates of the various tissues.

Guy:

At the time that the data relating to the whole body exposure of test animals were being analysed in terms of the whole body averaged (WBA) SAR that could cause biological harm it was noted from SAR measurements that peak SARs associated with the WBA could be approximately 20 times higher. Thus if a standard for safe exposure was set equal to the WBA SAR threshold for harm, reduced by a safety factor of F, it could be assumed that the same safety factor or greater would apply to the level of hot spots associated with the reduced WBA SAR. As a result of the limitations in probe and thermograph resolution at the time the precision of measured SAR hot spots at the time of adopting the standard was estimated to be no better than the average over a gram of tissue. New animal studies with improved precision of dosimetry would not change the safety factor. For example if we find with more precision that the peak SAR is actually 40 times higher than the WBA based on an average over $1/8^{th}$-gram of tissue the degree of safety isn't changed by specifying a new hot spot limit of 40 times the WBA as averaged over $1/8^{th}$-gram of tissue. Exposure to new mm wavelength sources where the energy absorption in a gram of tissue may be localized in a very small fraction of its entire mass may require special treatment based on data from additional research using these shorter wavelengths.

Jokela:

The basis of 1 g mass is not clear to me although thermodynamically it still looks reasonable. Anyway it is better than 10 g used by ICNIRP. Probably some explanations can be found from the shadows of the EMF standardization history.

I have been informed that the Mobile Manufacturing Forum has intentions to fund studies to improve the scientific basis of spatial and time averaging.

Swicord:

This was the approximate limitation of the theoretical calculation ability of the time at which this was selected. It is not a scientifically based number. Further consideration should be based on a meaningful value related to a possible temperature rise. Such theoretical projects are being proposed and will hopefully be underway.

Question 2: Does the scientific basis for a 1-gram mass for SAR averaging apply equally to small animals and typical sized humans or is there a technical reason why these would/should be different?

Anderson:

I suspect they would be different, though I couldn't quantify it without further analysis. There would be fairly minor differences between animals and humans in the thermal diffusivity and blood perfusion of tissues, though the different scales of bodies and organs could be expected to make a difference in temperature distributions. More importantly, I would expect that SAR induced in small animals would be much more homogeneous compared to humans, though this could be partly compensated by frequency scaling of the RF exposure.

Balzano:

I do not know that the 1g mass averaging was ever applied to small animals or any animals. The limits of C95.1-19xx have been always derived on the basis of whole body averaged SAR of animals exposed in toto. There cannot possibly be a technical-scientific reason for the same gram averaging if the organs of different species are substantially different in weight, volume and their heat metabolism has different tolerances for environmental conditions.

Chou:

This standard is designed for humans. It is not easy to protect animals with the same standard, because the access to RF sources can be different, for example birds. The thermophysiology of birds is also different from humans.

D'Andrea:

In the calculation of SAR distribution in the anatomical model it should be based on the size of voxels used in each model so that the averaging of absorbed energy follows the resolution provided by the model.

Gandhi:

The safety standards pertain to human exposure and are not relevant for animals.

Guy:

Since the SAR measurements at thresholds of harm were done on animals much smaller than man and the 1-gram of tissue for the animal is a much larger portion of its whole body mass than that for man the actual safety factor in applying the 1-gram averaging to man is greater for man than for the animal in tracking the allowed peak SAR with the allowed WBA SAR. If a lot more research were done to better quantitate the extrapolation of thermal consequences of RF heating from animal to man the allowed peak SARs would most likely increase.

Jokela:

Generally no because for small animals the biothermodynamics is different compared to humans and the relative volume of 1 g mass to the body mass is much larger in small animals. Maybe some scaling according to the size of body is needed also for the averaging mass ?.

Swicord:

I do not see the relevance of this question. Standards are for humans. Dose questions for animals should be considered on an individual basis.

Question 3: The rationale for the present IEEE standard local SAR limit includes the use of a 20:1 ratio between local SAR and whole-body average SAR. The 20:1 value was chosen in 1979 and was related to exposure near body resonance. Today, we have much more and high resolution dosimetry data than we did in 1979, and many of these data suggest that the ratio is higher. ICNIRP, for example, used a ratio of 25:1 in deriving its guidelines for exposure. Is the use of the 20:1 ratio still scientifically justified or should it be changed?

Anderson:

Note that the peak:WBA SAR ratios of 20:1 or 25:1 are also only applicable to whole body exposures. Of course, for exposures from nearby sources much greater ratios could be expected. For example peak SAR in the head from a mobile phone would be far greater than SAR induced in the feet. Even in the head, there is at least a variation of 5 orders of magnitude in mobile induced SAR from one side to the other. A typical peak SAR from a mobile phone is ~1 W/kg. We know that about half of the radiated energy from the phone (125 mW) is absorbed by the body, giving a WBA SAR of 0.0018 W/kg for a 70 kg person. This leaves us with a peak:WBA SAR ratio of 560:1.

Balzano:

I think you are formulating your answer. Keep 20:1 given the uncertainty over the human size and constitution, an uncertainty of ±11% is just wishful thinking.

Chou:

The ratio was chosen based on the available data at that time, and can be changed based on newer dosimetry data.

D'Andrea:

I think it is still justified. Some of the highSARs calculated in the models do not seem to be realistic.

Foster:

In my experience, the spatial averaging stuff comes into the picture mostly in context of partial body exposure. In that case, it is a complete nonsequiter to talk about the 20 to 1 ratio of SAR in whole body exposure.

Moreover, the limits for whole body exposure seem designed to protect against excessive total thermal load to the body, whereas those for partial body exposure should probably be designed to protect against excessive local heating (local temperature rise). That would call for a different rationale for the spatial averaging limits entirely.

Gandhi:

Either of the 2 ratios can be defended and may be scientifically justified.

Guy:

The answer to this question is contained in the answer and discussion provided in 1.

Jokela:

This is still a relatively good choice at about 100 MHz. In Dimbylow's article (1997) the peak SAR seems to be equal or less than $20*SAR_{wba}$ in the resonant region.

At 900 MHz for non-uniform and uniform exposures near mobile phone masts the ratio from wba to 1 g peak seems to be about 30 (Bernardi et al. 2000). However, more data is needed. Maybe the ratio could be 30 from 300 to 3000 MHz ?.

At the surface absorption range above 3 GHz, simple planar model calculations indicate that the 1 g peak to average ratio is not exceed 20. However, local SAR is not a good exposure indicator above 6 GHz.

Below 100 MHz the ratio exceeds 20 at the ankle. Several dosimetric studies from Dimbylow (1991), Gandhi (Chen and Gandhi 1989) and our group (unpublished results) suggest that at the ankle the ratio may be as much as 100 when the feet are in contact with the ground. This is a well known thing.

As far as I know the ICNIRP:s ratio is not based on any detailed dosimetric analysis.

Swicord:

This is the wrong question. The ratio is irrelevant and leads to a non- science based conclusion. The question is what is the local temperature rise in tissue. This can be determined by current theoretical means.

Question 4: What is the uncertainty associated with this ratio? How should the ratio be stated, as x ± y:1?

Anderson:

The answer to the first question depends very much on the type of exposure (uniformity, frequency, polarization, etc).

The ratio should be expressed as a dB estimate and ± dB error, since, as with most RF estimates, the errors would be expected to be multiplicative rather than additive.

Balzano:

Keep 20:1 given the uncertainty over the human size and constitution an uncertainty of ±11% is just wishful thinking.

Chou:

There is a large uncertainty associated with this ratio, The question is how much?

D'Andrea:

An answer to this question depends on thevoxel size used in the anatomical model. A range of 20-25:1 may still be appropriate.

Guy:

The uncertainty is probably large and on the conservative side due to the extrapolation from a small lower species to man. Tightening up the precision of the of the uncertainty would require a lot of work and most likely would result in demonstrating that the assumed 10 or 50 to one safety factors for the standard are actually much higher.

Swicord:

See above.

Question 5: What data support the 20:1 ratio of peak SAR to whole-body average SAR at <u>non-resonant frequencies</u> for humans for uniform exposures?

Anderson:

It seems fairly clear that at high frequencies, say 6 GHz, the skin depth of absorption is so small (~8 mm for skin, ~7 mm for muscle) that the 20:1 or 25:1 ratios will be easily exceeded. Likewise, at low frequencies one would expect a low level of SAR homogeneity, and hence higherpeak:WBA ratios.

Balzano:

I do not know that there are any. Given the fact that different bodies anddifferent body parts resonate at different frequencies only the resonant ratio for whole body was used.

Chou:

Guy, A.W., C.K. Chou, and B. Neuhaus. Average SAR and SAR Distributions in Man Exposed to 450 MHz Radiofrequency Radiation. IEEE Transactions on MTT Vol. MTT-32(8):752-763, 1984.

D'Andrea:

Data from human shaped models, rats rabbits etc. are the prime source for this information near resonant frequencies and can be found in the publications listed below. For nonresonant frequencies the ratio is closer to 5-7:1. One study that we made was predictions of eye resonance of near 900 MHz for man and near 2 GHz for the rhesus monkey model. The resonant eyeSARs are 7.7 and 4.5 times the whole-head average for man and monkey models, respectively.

Guy, A. W., Quantitation of Induced Electromagnetic Field Patterns in Tissue and Associated Biological Effects, in *Biologic Effects and Health Hazards of Microwave Radiation* (Czerski, P., Ed.; Polish Medical Publishers, Warsaw), pp. 203-216, 1974.

Gandhi, O. P., K. Sedigh, G. S. Beck, and E. L. Hunt, Distribution of Electromagnetic Energy Deposition in Models of Man with Frequencies near Resonance, in *Biological Effects of Electromagnetic Waves* (Johnson, C. C. and Shore, M. L., Eds.), DHEW Publications (FDA) 77-8011, vol. 2, pp. 44-67, 1976.

D'Andrea, J.A., Ziriax, J.M., Hurt, W.D., Mason, P.M., and Chalfin, S. Modeling microwave absorption in the eye. In Conference Proceedings: Millennium Conference, Herkulenium, Crete, Oct 2000.

Gandhi:

The ratios of peak to average SAR are very dependent on exposure conditions. The peak SARs are prescribed only to protect local tissues from high exposures.

Guy:

The 20:1 ratio is not based on resonant frequency exposures. Most of the exposures of laboratory animals were done at non-resonant frequencies. Previous editions of the standard contain references to the data from which the 20:1 ratios were estimated.

Jokela:

Below 100 MHz the ratio exceeds 20 at the ankle. Several dosimetric studies from Dimbylow (1991), Gandhi (Chen and Gandhi 1989) and our group (unpublished results) suggest that at the ankle the ratio may be as much as 100 when the feet are in contact with the ground. This is a well known thing.

Swicord:

None. This ratio has nothing to do with an adverse health effect. The observed effects used for establishment of past standards (behavioral disruption) are whole body or systemic responses. These have nothing to do with the potential for damage to localized tissue. Thus the ratio is meaningless.

Question 6: What are the ratios of peak SAR to whole-body average SAR for non-uniform exposures for human body sizes?

Anderson:

Depends on frequency and distance from the source. Can be VERY high, as indicated in the response to question 3.

Balzano:

These data have not been collected in large quantity. If you consider that the near field exposure (which is able to give the greatest non-uniformity) depends on frequency, distance

and type of antenna, I do not think that there are enough data even for commonly used antennas to answer this question.

Chou:

Can be very high up to thousands to 1.

D'Andrea:

A good question.

Gandhi:

Highly dependent on exposure conditions (nature of incident fields, how localised, frequency, polarization, etc.)

Guy:

These ratios vary all over the map from near 1 to short of infinity depending on the source. For a cellular phone, the ratio of 200:1 to 500:1 would be common. For an application of an RF cauterizing device or for a finger touching the tip of an energized antenna the ratio would be considerably higher.

Jokela:

At the surface absorption range we might assume as a first approximation that the ratio increases by the same factor as the peak power density (S) to whole body average.

Below 30 MHz the situation is complicated. Our measurements of the whole body current in front of a simulated HF-sealer suggests that the difference of non-uniform and uniform exposure may not be very large (Jokela and Puranen 1999). The grounding conditions are much more important because most of the wba SAR originates from the legs due to the concentration of the current.

From the 30 MHz to 3 GHz range I have no good general idea.

Swicord:

I do not know.

Question 7: The present standard states that for <u>partial body exposures</u>, the peak field may be as great as 20 times the MPE limit but that this provision may not be applied if the eyes or testes can be exposed.

(a) What are the implications of this provision in terms of peak SARs?

Anderson:

Depends on the relative size of the person or body part to the RF wavelength, the proximity of the source, and the impedance of the field. Niels developed a formula that calculates

SAR from the incident H-field from a nearby source. The formula is included in the CENELEC measurement standard for mobile phones. It seems that proximity to surface currents (which generates the H) is the main consideration. I suspect that exposure to a localized capacitive E-field would be less effective in inducing SAR compared to an inductive H field.

Balzano:

We must first define what is partial body exposure and non-uniform whole body exposure. Obviously, uniform incident body exposure exists only in ananechoic chamber. What is the acceptable variation in the incident field amplitude square over the human body? 5dB, 10dB, 13dB (20 times)? Without the parameters of frequency and distance from a source or a scatterer I do not think there is a simple answer. At the low frequency end (f<300 MHz) it is difficult to find steep variations of the field over a large part of the human body, because wavelength is a strong spatial coherence parameter. It is difficult to change the field intensities over much less than $\lambda/2$ unless you are in a very unusual situation. (e.g. right behind a metal slab partially shielding the human body). At the higher end of the frequency spectrum of the applicability of the concept of SAR (f>1-2 GHz, then a steep gradient of the exposure over a small section of the body can happen and it is easy to run into partial body exposure cases, especially in the near field of some antennas that are small with respect to the human body, but large enough in terms of wave length ($\geq\lambda/2$) to be very efficient RF sources. We should fix a maximum acceptable ratio of non-uniformity of the incident power density. One could pick 10dB (3:1 variation of the incident field) and a weighted average over the body for the exposure metric. Let us distinguish two cases.

Case 1) The body subtends a small solid angle from RF sources and scatterers nearby. If SxE is your metric (S= human cross sectional area, E= Exposure level limit in mW/cm^2) a weighted average is SxE = Σ Si x Ei where Si is the area of the body exposed to Ei mW/cm^2 with Ei not varying more than 10-13 dB over S. If Σ Si x Ei is larger than S x E, then we are dealing with partial body exposure. For people (standing, crouching or sitting) the vertical dimension of Si is <$\lambda/2$. Certainly we are dealing with excessive partial body exposure if the local SAR is higher than the basic limit of the exposure safety standard, currently 1.6 or 8 W/Kg averaged over 1g of tissue mass shaped like a cube. We come now to the central issues of your letter (questions 9-23). Are the above numbers valid for all parts of the body in all exposure conditions over the time averaging period of the exposure? They (the basic limits) were derived in the manner you describe in body resonance conditions i.e. coherent exposure over the whole body length of a human. Could the limit values of SAR be increased for partial body exposure? Yes, but we do not have the data to make this decision. In the near field of a source, clearly the limit value will depend on frequency (depth of penetration), organ blood supply and tolerance of that organism to sustain a certain rate of temperature increase during the time averaging period and the environmental conditions. If you have to deal with possible pathologies of organs then matters become even more complicated, because you are dealing not only with heat physiology, but also with general pathology, whose books are much thicker than those on physiology.

If all your questions derive from a drive to relax the SAR limits for partial body exposure, then we should say that we do not have enough data to proceed rationally. The SAR limits that we have now have been established with a limited data base, but are rational and apply to the far field conditions, whereby the whole body is loaded by RF energy in the highest

absorption conditions. These have worked well for the last 20 years. Any relaxation of these limits without an adequate database is not advisable.

The eyes (particularly the lens) are able to handle 8W/Kg on the basis of the studies of Dr. Guy and Dr. McAfee. There are similar data for the human testes. Check with C. K. Chou.

Case 2 Near Field of Sources and Scatterers (question 24)

The local exposure to energy with field impedance much larger than 377 ohms results in relatively small SAR; exposure to energy with low field impedance results in much larger SAR's than the far field predictions. (see my papers and Kuster's). You find these fields only within $\lambda/2\pi$ of a source, even an extended one (e.g. acolliner array) or a large scatterer. At this distance from any RF source you should measure SAR, not local fields, because capacitive and inductive coupling phenomena take over the mechanism of RF energy disposition. The human body modifies (by tight coupling) the RF sources and we cannot apply the concepts and procedures of far field (i.e. plane wave) analysis, where the exposed body does not measurably distort the RF sources. A major modification of the RF sources can also happen if the body human body occupies most of the space around the antenna even if the minimum distance is greater than $\lambda/2\pi$.

You have seen this phenomenon in my lab back in 1997. The phantom was loading most of the space around the antenna at 1950 MHz, so there was much reflection back into the radiator. This modifies the currents and the charges on the antenna and can cause changes in SAR which depend on the phase of the reflected energy back on the RF sources. Fig. 2 of your memo to me dated October 1, 1997 shows this effect with great clarity. It is too bad that neither you nor I had the time to publish those data with adequate analytical support. The presence of a strong stationary wave is obvious, which is not there in absence of the exposed body.

In summary, you cannot apply far field metrics

If the body is at $\lambda/2\pi$ distance or less from RF sources or large scatterers.

If the body occupies a substantial part of the solid angle in front of a directional antenna or a large (with respect to λ) scatterer. In this case the energy has nowhere to go, but is reflected back and modifies the RF sources. An educated guess suggests that one 1/4 to 1/2 of the solid angle in front of a directional antenna, should be the limit, before you must perform SAR measurements. For larger solid angles, you end up with a large part of the energy reflected back on the antenna.

Chou:

To protect thermally sensitive tissues.

D'Andrea:

It doesn't exactly match up with the provisions of peak SAR in the rest of the standard. At long wavelengths, in the pre resonance range, I imagine the body doesn't couple well during a partial body exposure so that peak SAR limits may be relaxed also. However, at the shorter wavelengths, in post resonance, this must not be true so that partial body exposures should adhere to the same peak SAR limits as for whole body exposure. My thoughts revolve around the idea of eye resonance predicted by the FDTD modeling. If eye resonance really does occur, then there are frequencies that make limiting eye exposure sensible. If eye resonance is not real then the deciding factor is the ability of the eye to remove heat. Does it handle heat as well as skin exposure? Good questions. We need more data on both eye resonance and, eye heat load capability.

Guy:

The partial body or non-uniform exposure standard is based on the assumption that it is tied to the SAR limitations in such a way that (a) if the exposure as averaged over the silhouette formed by the body doesn't exceed the MPL the WBA SAR MPL will not be exceeded and (b) if an exposure "hot spot" doesn't exceed 20 times the average the peak SAR MPL will not be exceeded. Thus based on this assumption the peakSARs would always remain below the 1-gram averaged peak SAR MPL.

Jokela:

For partial body exposures there are definitively no clear correlation between the field and peak SAR below 3 GHz. That is why the scientific basis of this provision is poor, although it may happen to be reasonable in some situations.

In the surface absorption range the correlation becomes better. However, I would be a little bit hesitant to multiply 100 W/m^2 by 20. We are then very close to the thermal damage range of the eye and testes which seems to be somewhat lower than for other tissues.

Below, say 300 MHz, the relaxation factor 20 is safe for partial body exposures.

Swicord:

See above. The ratio is the wrong approach.

(b) What scientific data support this statement?

Anderson:

I suggest that somebody runs Niels' formulas to see if the head and torso SARs will be exceeded.

Chou:

Eyes do not have good blood circulation and testes have lower than body temperature.

Foster:

None as far as I can tell

Gandhi:

These organs are not well-perfused,hence have been singled out for the exclusion.

Guy:

I have in the past been somewhat opposed to this provision because of the lack of scientific data to support it. During deliberations on making it part of the standard I performed a number of relatively crude calculations compared to today's methodologies. The calculations were based on plane wave exposures of crude geometries representing body

parts such as cylinders for the upper and lower extremities, spheres for the head and flat surfaces for the trunk of the body. In no case for these exposures did I see the peak SAR MPL being exceeded for incident power densities at 20 times the MPL. I therefore did not oppose the addition of the provision to the standard. However in recent years measurements by Ric Tell indicated to him that there could be problems when finer features of the anatomy such as the face were exposed to 20 times the MPL. At his urging, I conducted an FDTD analysis of the face of a human head model locally exposed to a dipole-corner reflector source such as he had used in his measurements. I was surprised as much from my SAR plots as he from his SAR measurements that the peak SAR MPL was significantly exceeded in the region of the nose. My current conclusion is that the provision is it is now written is not supported by all scientific data. Since the ear has recently been classified as an extremity allowing for a higher peak SAR MPL, maybe because it also has the characteristics of an extremity should be classified as such with a higher allowed peak SAR.

Swicord:

See above. The ratio is the wrong approach.

(c) Some have interpreted this statement to imply that spatial averaging of <u>non-uniform fields</u> (to be distinguished from partial body exposures) would not be permitted for almost all exposures since the eyes and testes are generally exposed. Is this technically appropriate?

Anderson:

I think the best way to approach this is to specify the dimensions over which the fields may be averaged, and to retain the x20 allowable peaks so long as the average values don't exceed the MPE's. The scheme that was developed for the ARPANSA Standard is attached to this document. Essentially, it allows spatial averaging, but reduces the averaging area with decreasing length of the RF exposure wavelength. At high frequencies (> 10 GHz) where the RF exposure is essentially surface heating, the averaging area is a 20 cm^2 square. At lower frequencies, the averaging dimensions become larger, as the body tends to integrate the field over larger dimensions, especially below whole body resonance.

Chou:

No. We have to permit both uniform or non-uniform exposure of the body as long as the intensity is low and not to product adverse effects.

D'Andrea:

Only if we find or develop definitive data on the heat load capability of eyes and testes.

Foster:

It does not make any sense technically. If the goal is to limit excessive heating to these organs, there should be a way to do it by employing some sort of spatial averaging over them.

Guy:

No, as long as the peak SAR MPL for the eyes or testes are not shown to be exceededby the partial body or localized exposure they should not arbitrarily be excluded. The scientific literature indicates the threshold for thermal damage to the eyes of rabbits is somewhat above 80 W/kg. The data also shows that the threshold is considerably common exposures of primate eyes due to the effect of shielding by orbital tissue (in fact in this research no eye damage was seen since the time of exposure was limited due to thermal damage occuring in orbital tissue away from the eyes). There is not much data in the open literature that I am aware of that pertains to exposure of the testes at 10 times MPL. Perhaps some of the data from Chinese experiments producing temporary sterilization by microwave exposure of the testes would be helpful in answering this question.

Swicord:

See above. The ratio is the wrong approach.

(d) What criteria should be used to identify partial body exposures in light of the fact that the standard specifies that RF fields are to be spatially averaged over the body (the implication of which is that the eyes or testes could be acceptably exposed to RF fields up to 20 times the MPE limit)?

Anderson:

See ARPANSA approach provided above.

Chou:

Whether whole or partial body exposure, as long as the tissue is within physiological adaptable temperature rise and there is no adverse effect.

D'Andrea:

If the eye resonance concept is a fact and eye absorption is 7-8 times the whole head average then would we want to allow 20 times the MPE limit?

Foster:

From a technical (as opposed to political) point of view, it makes sense to frame the standard explicitly as addressing two hazards: excessive thermal load to the body (which can result in adverse physiological effects in the absence of local temperature rise), and excessive local temperature rise. The present standard is based on a careful analysis of the first of these, chiefly, and makes ad hoc assumptions to try to address the second.

A more rational limit would consider each situation separately: there would be a maximum total heat load permitted to the body, and a maximum SAR allowed to any region of the body. The second of these would be designed to limit the local temp increase and pay no attention to the total thermal load on the body.

Guy:

See above

Swicord:

See above. The ratio is the wrong approach.

Question 8: When does field uniformity become so non-uniform that:

(a) Spatial averaging is no longer valid (i.e., a hazard could occur)?
(b) Non-uniform exposure has become partial body exposure?

Anderson:

For highly localized exposures e.g. from cellular telephones and other personal wireless devices.

Chou:

For near field exposure, it is always non-uniform, either whole orpartial body exposure. One cannot use only spatial averaging, if the peak is too high to cause damage. For example, one cannot immerse one hand in hot water and the other hand in ice water and use average temperature.

D'Andrea:

Good questions. My input is to consider fields above 1 GHz with multiplereradiators that setup a multipath exposure that is very nonuniform.

Foster:

Spatial averaging can always be used, trick is to choose the appropriate averaging distance.It would be different for mm waves than for 100 MHz fields.

Gandhi:

For highly localized exposures e.g. from cellular telephones and other personal wireless devices.

When a substantial fraction of the body surface area is exposed.

Guy:

Whether it is called non-uniform exposure or partial exposure the 20 times spatial average MPL is assumed to limit the peak SAR to the peak SAR MPL. As long as that is the case the spatial averaging should be valid. There may be exceptions such as the case of the exposed face discussed in7-b above.

Jokela:

At a distance of 20 cm or less from a localized (e.g. small dipole) source.

Swicord:

This needs further exploration with current theoretical modeling.

Question 9: Can the present rationale for the low power exclusion rule be strengthened or should the exclusion be changed or deleted?

Anderson:

Given the recent advances and amassing data in the modeling of SAR induced from nearby sources, this is an issue that would benefit from a review. It would be helpful to provide guidance on RF sources that are maintained at distances closer than 2.5 cm to the body, since many new and developing telecommunication devices fall into this category (eg Blue Tooth earpieces). Perhaps a worst case condition of a short dipole located 1 cm away from the body could be used as an appropriate model.

Chou:

The low power exclusion should be strengthened. The current practice to measure SAR of very low power devices is too excessive.

Foster:

It can be strengthened as long as one is concerned with excessive temperature rise – I did it in my paper with Riu in IEEE Trans. Biomed. Eng a couple years ago. As it turns out, the original exclusion was not bad at all.

Gandhi:

The exclusion limit of 1.4 W or 7 W is too high, will result in very high SARs for personal wireless devices and other very localised sources and should therefore be reduced considerably.

Guy:

The exclusion should be maintained but the rationale needs strengthening

Jokela:

For practical reasons, to avoid laborious and costly SAR tests of low power devices, there is a clear need to define better the exclusion rule. It might be possible to define a maximum radiation power for near body devices below which no SAR tests are needed. In Europe CENELEC is adopting 20 mW for the exclusion. It is based on the simple fact that 20 mW/10 g cannot be exceeded in no situations if the total radiated power is less than 20

mW. Without much hesitation it could be increased to 40mW and on the basis of dosimetric studies maybe up to 100 mW ?.

Swicord:

Yes. If one moves to a thermal base for local or partial body protection then one can theoretically determine the limit below which it is impossible to elevate the temperature to a critical level.

Question 10: What evidence supports applying the local SAR limit derived from whole-body exposures to localized exposure to low power devices?

Anderson:

None as far as I can see.

Chou:

How about low power UHF mobile radio mounted on cars?

Foster:

None at all

Guy:

The lack of any credible reports of health effects or damaging tissue temperature rises associated with the use of low power devices.

Jokela:

I have no good answer for that question. We should look for the differences of SAR peaks produced by localized exposures and whole body exposures. In the former case the exposure is superficial (like see e.g. in the case of mobile phone) and the rest of the body is almost free of exposure, while in the latter case there may be thermal load and other hot spots all over the body. It looks to me that hot spots produced by localized exposures are less harmful than those arising from the whole body exposure. It is acceptable to use this kind of conservative thinking for extending the local SAR limits for whole body exposures to localized exposures. One must, of course, be sure that it is indeed a conservative extrapolation.

Swicord:

See above.

Question 11: What would be the best technical basis for defining a minimum tissue mass for averaging of SAR and what should that that mass be?

Anderson:

I think you would need to develop some thermal models to play around with the parameters indicated in the response to question 1, i.e., thermaldiffusivity and blood perfusion of tissues, and the spatial/time distribution of the SAR load.

A simple model that could be constructed to investigate this would be to consider a plane wave that is normally incident on an infinite slab of tissue. The point SAR distribution is easy to calculate for this circumstance, and represents a worst case scenario (i.e. most heterogeneous SAR distribution), at least for frequencies above whole body resonance. In such a one dimensional model, it wouldn't be too hard to also model thebioheat equation, using difference equations. With the model, one could apply the SAR load as progressively averaged over larger masses, until a significant difference (say 10%) from the baseline temperature distribution calculated for the point SAR distribution is observed.

One possible outcome of this modeling is that different sized masses or shapes should be used for different tissues &/or frequencies.

Chou:

For protect human health, the average of 10 g eye ball is a technical sound choice, since the eye balls do not have good circulation and can be the worst case for thermal injury.

D'Andrea:

I suggest looking into the heat removal capability of different tissues. Data must be available from hyperthermia studies. Averaging over a 1 gram mass may be too restrictive, while 10 gram averaging may not be restrictive enough.

Foster:

To limit local temperature rise (if that is the goal) you would need to invoke heat transfer considerations. Also, the spatial averaging distance would be coupled with the time averaging.

One approach is to invoke the similarity between heat conduction and tracer diffusion. The thermal diffusion constant $D = k/\rho C_p$ where k = thermal conductivity, ρ is the mass density, and C_p is heat capacity. Over a period of time T, heat diffuses a distance of (4 D T)^(1/2).

You could link the distance and time scales using the diffusion length. For a 6 minute averaging time, this would correspond to a bit more than 1 cm (1.7 grams). For a 20 minute averaging time the corresponding averaging distance is 2.2 cm (10 grams).

In any event, the present SAR limits are so conservative that it does not matter too much what the averaging distance is.

Guy:

The historical technical basis is the best since it is based on the animal research done up to the time the provision was adopted. See answer to 1.

Jokela:

The best basis is obtained from good studies which are based oncombined electromagnetic and thermodynamic body models which are well validated (see 1). At the moment we have some information only for mobile phone exposures.

Swicord:

Theoretical methods exist and hopefully will be soon put to use to calculate the temperature rise in localized tissue under worst-case exposure conditions. These methods can determine an appropriate averaging volume.

Question 12: Do present insights support the use of spatial averaging of exposure fields (i.e., what is our strongest specific support for relating spatially averaged plane wave equivalent power densities to whole body average SAR)?

Anderson:

I think the ankle current data provides good experimental support for how the body integrates non-uniform fields.

Chou:

Both peak and spatially averaged exposure fields are important for health protection and compliance purpose.

Gandhi:

This concept of spatial averaging has never been tested by using postulated exposure examples.

Guy:

See answers to 7.

Jokela:

For non-uniform but not for localized fields wehave reasonable insight to support the concept of averaging. However, below, say 30 MHz it is the fieldstrength which should be averaged, instead of equivalent power density, because it is associated with the total body current which is the displacement current coming from the electric field or circulating eddy current induced by the magnetic field. Above 300 MHz, the power density averaged over the whole body is a good indicator of the thermal load of the whole body.

Swicord:

Don't know.

Question 13: When spatially averaging RF field exposures, how should the averaging be accomplished? Provide technical basis for answers.

Anderson:

See ARPANSA methodology attached to this document. An important consideration is to make the averaging instructions as clear and simple as possible.

Chou:

Over the area which a person is exposed, the fields are averaged. The current practice is adequate.

Guy:

The same as specified by the provision, over the vertical projection orsiloette of the body. Modifying that to an average over a vertical rectangle incompassing the projection which has been the custom in the field would be permissible if it is clear that the result is more conservative in terms of safety.

Jokela:

I would prefer the b alternative (see 12 for technical basis).

Swicord:

Have not given much thought to this

(a) Over a standardized height of, say, six feet?

Chou:

Should be size dependent

Guy:

OK if it can be demonstrated that the results are conservative compared to performing it over the actual projections. It may have to include a maximum width (horizontal direction).

(b) Over the actual posture of the body for individuals who may not be standing?

Chou:

Yes. Over the area of the body occupying the space.

Guy:

If and only if they won't be standing for any significant time before and after assuming the actual posture where they may be exposed to higher fields or exhibit a larger body projection.

(c) Using some measurement technique other than over a vertical linear axis?

Chou:

Vertical averaging is fine for standing position. For other positions, combined lateral and vertical averaging sounds better.

Guy:

Again what is specified by the provision or a more conservative technique.

Question 14: How well does limiting the maximum of spatially averaged plane wave equivalent power densities to 20 times the permitted spatial average value, as specified in the present standard, correlate with a maximum local SAR of 20 times the whole body average SAR?

Anderson:

Depends on the frequency of exposure. At high frequencies it will have greater correlation, at low frequencies, less.

Chou:

I need to answer this later.

Gandhi:

Answers similar to those given above.

Guy:

Covered in 1.

Jokela:

For the surface absorption range, see 3rd paragraph in 3 and 5.
For the quasistatic range below 30 MHz the question is not relevant.
For the 30 MHz – 3 GHz range I have no good answers.

Swicord:

I think the question is not relevant.

Question 15: What data exists supporting the belief that spatially averaged exposures that conform to the specified time averaging provisions of the standard are safe? For example, the present standard permits 48 W/kg local SAR for 1 minute in every 6 minutes. If the ratio of peak to whole body average is greater than 20:1, this value could become greater. Are there local, intermittent SAR values that would still comply with the time averaging provisions but would be thermally unsafe?

Anderson:

As indicated in Q1, the bioheat equation clearly indicates that *mass* averaging and *time* averaging are interrelated when determining the temperature distribution, i.e., the bioheat equations contains *both* time and spatial derivatives. Thus you can't consider one without referring to the other.

In order to develop appropriate numbers for mass and time averaging, it is not only necessary to know the maximum tolerable temperature rise for prolonged exposures, but also to know how long intermittent excursions of higher temperatures can be safely tolerated.

Chou:

The worst case temperature rise in one minute of 48 W/kg exposure is 0.69 degree Celsius. It can be well regulated by body, even at whole body level. Using the tissue temperature is the ultimate solution for protecting against thermal injury.

Guy:

This all goes back to the animal data base for the standard and the thermodynamics relating to volume heating of tissue. Exposures to very short wavelengths where the the energy might be absorbed in a very short time in a mass much smaller than a gram need to be evaluated.

Jokela:

As a first and very crude approximation, the final temperature increase in the hot spot is the same as for the whole body if the time constant (averaging time) of the hot spot is 20 times less than that for the whole body. For the reduced ratio of the time constant, the temperature increase of a hot spot exceeds that for the whole body. In the case of thermodynamically simulated localized exposure from a mobile phone the time constant seems to be 2. 5 to about 6 min (Leeuwen et al 1999, Joyner and Anderson 1995). For the whole body it may be 15 to 30 min. For the surface absorption range it seems to be less than 2 minutes (Foster et al. 1998). So, the difference is about 5 or less. This implies a possibility for a greater increase of the local temperature than expected by the previous standard makers. However, on the other hand the increased body time constant is an extra safety factor. Also we might ask whether we could allow greater temperature increases for local hot spots than for the whole body. This is not an easy problem.

Swicord:

Again this points to the need for some specific theoretical modeling.

Question 16: The present standard is based on the presumption of uniform exposure of the body with a resulting peak SAR that is 20 times greater than the whole-body average value and that this peak SAR is acceptable. (i.e., 8 W/kg for long term exposure). But as the exposure field becomes non-uniform, the ratio of peak to average SAR will obviously increase significantly, i.e., become much greater than 20:1. How does the local SAR value anywhere in the body change relative to whole body average as a function of non-uniformity of the field?

Chou:

The present practice is to ensure no SAR is higher than the 1.6 or 8 W/kg in body tissue or 4/20 W/kg in extremities, regardless of uniform or non-uniform exposure.

Gandhi:

The local SAR limit is more important to observe for such localized exposures e.g. cellular telephones. In fact this is the justification for local SAR limits since the EM exposures are hardly ever uniform which can result in high local SARs.

Guy:

Even if the peak to average SAR increases well beyond 20:1 (several hundred for handheld transceivers) the peak MPL always remains at 8 W/kg and is not allowed to be exceeded.

Jokela:

See above.

Swicord:

Good question which needs more modeling.

Question 17: Typical non-uniformity in RF fields can easily be 5-10 times greater than the average over the body for whole body exposure. What does this mean relative to local SAR?

Chou:

For example, for cell phones, the head region is exposed to the RF fields and the intensity is higher compared with the whole body average. The same SAR derived from the 20:1 ratio from the whole body exposure is used. This gives a conservative protection.

Guy:

See response to 1.

Jokela:

See above.

Question 18: With localized exposures, there is more body heat sink to help dissipate heat and we can sustain higher incident fields locally but are there local heat dissipation limits that are different than that of the whole body?

Anderson:

Ellie Adair's work seems to indicate that the core body temperature remains quite stable for WBA exposures up to 8 W/kg. Thus it appears the body heat sink capacity should certainly remain the same for exposures up to the allowable 0.4 W/kg, regardless of the local exposure.

I expect that local variations in the ability to handle heat loads will depend mostly on things like the blood perfusion of the tissue, and its proximity to the surface of the body, where surface cooling mechanisms are available.

Chou:

During local or regional hyperthermia treatment, we have learned that local hyperthermia is limited by pain tolerance. The core temperature do go up during regional hyperthermia depends on the size of tissue heated.

D'Andrea:

I suspect that there are. For example the eyes may not transport heat well. For some time the eye has been identified as being thermally sensitive. The thermoregulatory capability of the eye is poor compared to other tissues of the body. This is primarily due to the lack of blood flow in many parts of the eye which has led many investigators to believe that the eye is vulnerable to the heating caused by microwave radiation absorption.

Guy:

Yes, witness the application of diathermy that produces local SAR of from 50 to 100 W/kg for up to 20 minutes of exposure which is safely dissipated by blood flow.

Jokela:

The ability of different tissues to dissipate heat certainly varies. In the brain the efficient blood circulation efficiently removes additional heat.

Question 19: Can we reach a point at which the very high field permitted by time and spatial averaging would result in local SARs that exceed a local tissue's ability to adequately dissipate the heat due to some localized anatomical characteristic that would not exist generally in the body?

Anderson:

Depends on the robustness of the tissue. Substantial proteindenaturation begins to occur at temperatures above 45°C. Mammalian cells begin to die if their temperature rises to 43°C for 23 minutes, and most mammalian cells die immediately after being elevated to 45°C.

However, I have one reference that indicates that a microwave blood warmer can safely heat blood up to a temperature of 49°C. I suspect that most tissues could safely tolerate higher temperatures for a limited period of time, though I don't have enough data to really substantiate this. Perhaps Ellie would know.

Chou:

43°C is the critical temperature. We need to define a volume; 10 g is a reasonable volume.

D'Andrea:

Maybe. How about eye exposures at the eye resonant frequency or high-short exposures in the millimeter wave range? That may be localized enough to satisfy this scenario.

Guy:

Don't know of any.

Question 20: Are there specific tissues or points within the body that have particularly high susceptibilities to localized heating due to thermal properties in the immediate vicinity of the tissue?

Anderson:

Metallic implants are an interesting example for this question. There can be very localised high field concentrations around the tips of long metal structures, in the gaps of wire loops. Of course, these metal devices don't create energy, but can only redistribute it, so the effect is limited to some extent. Also the high thermal conductivity and specific heat capacity make them good thermal sinks for any localized heat sources generated around them.

Chou:

Eye balls are commonly regarded as the critical organ.

D'Andrea:

Two points on this question. First, Brooks FDTD modeling has noted that rapid changes in dielectrics such cerebral spinal fluid in the ventricles of the brain and surrounding brain tissue lead to high calculated SARs. Secondly, exposure of the eye to microwave radiation can lead to an increased temperature that is sufficient to damage tissues. The temperature rise will, of course, depend on the intensity of the irradiation, how well the energy is coupled into tissues, and how well the deposited energy is removed by normal mechanisms such as conduction and bloodflow. Microwaves at the lower frequencies will be deposited deeper in the eye, while at higher frequencies they will be absorbed near the front surface of the eye. The eye does not efficiently remove heat deposited internally by microwave exposure. The main avenue of heat removal is conduction and blood flow through the retina and choroid. The lens has been thought to be the most vulnerable tissue since it has no bloodflow. Other than conduction through the sclera and convection from the surface of the cornea, heat removal is poor compared to other body tissues. Because the lens is avascular it has been thought to be particularly sensitive to the thermal effects of microwave exposure. These facts have led many investigators to postulate that the poor

heat dissipation from within the eye of humans and other animals may lead to heat buildup and subsequent thermal damage [Al-Badwaihy and Youssef 1976].

Guy:

The eye has been commonly thought to be comprised of such a tissue but the threshold for damage is documented as 80 W/kg or greater (more than an order of magnitude above the MPL).

Jokela:

In the range of a few GHz resonances may occur in ball shaped eyes and testes. They are also electrically and thermally partly insulated from other tissues. Additionally these organs or some of their parts (lens) are thermally a little bit more vulnerable than other tissues.

Question 21: Is the averaging time proper for all body parts, regardless of peak SAR that is permitted through spatial and time averaging?

Anderson:

I suspect that different parts of the body will have different optimal averaging times and masses.

As mentioned previously another consideration for averaging time and mass is the frequency, which indirectly affects SAR distribution. This is explicitly recognized at the high frequency end by both the ICNIRP and IEEE standards.

Chou:
Averaging time question should be addressed by thermal modeling studies.

D'Andrea:

My input is that at the high millimeter wave frequencies the time averaging could be reduced.

Guy:

The MPLs are supposed to be conservative enough to take this into account for all tissues. Some are more or less susceptible to damage at high SARs than others but the standard has been adopted to account for the most susceptible. For example I have been able to maintain a HF current through my finger that produces an average SAR of up to 100 W/kg with no heat discomfort.

Jokela:

On the basis of 21 and 15 I would say that for hot spots the averaging time should be, say 2 min, while for the whole body it might be, say 15 min.

Question 22: If not, wouldn't this mean that we should set criteria on the application of spatial and time averaging? What would be these criteria?

Anderson:

Yes – tissue type and frequency.

Chou:

Thermal modeling analysis will help answer these.

Guy:

As mentioned above if you want the same degree of safety for every tissue or anatomical part of the body the criteria would be different for each and the guidelines very complicated. The current extremity criteria that is different from the rest of the body is probably as far as you want to go in order to keep the standard reasonably practical.

Question 23: While it would seem that a temperature based standard, for both body average and local tissues, would be more directly related to potential injury from RF fields, does the present scientific database provide sufficient support for deriving such a standard?

Anderson:

Yes. I agree with Ellie that the field science of protecting against thermal injury is quite mature, and that there is plenty of data around.

It should be noted that there are some established non-thermal mechanisms that require attention, viz. electrostimulation at low frequencies and high energy pulse effects. The time and spatial averaging considerations are different for these phenomena, as the mechanisms of bio-interaction are quite different.

Chou:

ICNIRP clearly indicate that their standard is based on thermal effects. C95.1 does not state it this way, although the animal behavioral effect is thermally related. There is a large database on thermal injury. Setting temperature limit is a practical approach.

D'Andrea:

No, I would think that more information is needed on the localized deposition and removal of heat from tissues during microwave exposure. The kind of work that E. Adair is doing for whole body absorption is superb. Localized heating in tissues needs equal attention. Such data may be available already in hyperthermia or RF ablation studies. If so, then it needs to be incorporated into the standard.

Guy:

There are lots of data out there and I know of no harm or injuries at exposures below current MPLs

Jokela:

This is a question of great importance. It still seems that the assumption of thermally based injury or adverse effect is valid but this is not totally certain. Particularly in well cooled (high blood perfusion) hot spots there is a possibility for non-thermal effects because the internal E-field is high without high temperature increase.

Question 24: RF hot spots are often highly localized manifestations of reradiation and typically exhibit wave impedances that can be substantially different from plane waves (e.g., >>377 ohms or <<377 ohms) and the localized SAR resulting from such exposures can often be very small.

(a) Should such fields be assessed simply by applying the spatial averaging provisions of the standard, or

(b) Should some other criteria be applied for assessing such exposures?

(c) What specific basis would be used to support these alternate criteria?

(d) Should such exposures be characterized as partial body exposures?

Anderson:

I suggest that you simply apply the field spatial averaging rules. Reradiated or scattered fields are generally less of a problem than near fields generated by primary sources, since they are often changed by the presence of the body itself. For example, a standing wave created by a reflection off a wall may disappear when a person approaches it because he scatters or absorbs some of the incident wave. Reradiated fields will change with proximity of a person, due to the coupling of the person's body to the structure, which alters its impedance.

Chou:

If the SAR is low, the temperature increase is low too.

D'Andrea:

My only experience is with large (compared to the body) reflecting surfaces such as flat plate or corner reflectors. In such cases whole body absorption is profoundly enhanced.

Guy:

I think it would be safe to use and be more conservative than that for exposure to a primary source. The degree of conservatism in its use would require a case by case FDTD analysis of the various exposure scenarios

Only if the situation demanded a more precise evaluation (such as FDTD modeling)

Litigation?

I always have trouble trying to distinquish partial body from nonuniform exposures since it is hard to expose part of the body without some exposure to the rest of the body resulting in nonuniform exposure.

Jokela:

Spatial averaging associated with some minimum distance from the radiating structure, say 20 cm, would be a simple solution.

General Comments Submitted Rather than Answers to Specific Questions

From Peter Dimbylow:

I am sorry to ignore your beautifully structured questionnaire. The time scale for response is very short and as, I am not familiar with the IEEE standard or the underlying rationale used in its development, I will just make a few comments on SAR and temperature rise.

Heating is the basis for restrictions on RF exposures. The primary limiting quantity is temperature rise. Whole body and partial body SARs have been used as surrogates for this primary quantity. However SAR is a secondary derived standard, an indicator of temperature rise. The question is then how good an indicator of temperature rise is a particular combination of partial body SAR level, averaging mass and shape, i.e. does it provide as a secondary standard a conservative estimate of the restriction on temperature rise. The difficulty is that the position of the maximumlocalised SAR is not necessarily collocated with the position of the temperature rise you are trying to restrict. The adoption of a small averaging mass, say 1g will not produce such a stable or robust secondary standard as the adoption of a larger mass such as 10 g. E.g. in mobile phone exposures of the head we want to limit the temperature rise in the brain but the maximum SAR averaged over 1 g will occur at the surface of the head, typically in the ear. Its position and magnitude will change significantly with different orientations of the handset whilst the variation in temperature increase in the brain will not be so marked. The SAR average over a larger mass such as 10 g will damp the changes in magnitude and position and will be easier to correlate with temperature rise.

Best wishes

Peter

P.S. I am glad that you are disseminating the results of this questionnaire. I answered a similar request in quite some detail about ELF dosimetry and realistic voxel phantoms for the IEEE committee and did not receive any acknowledgement to my reply and certainly no feedback !

From Maria Stuchly:

The questions you posed are exceptionally important. i have been planning actually to perform some RF dosimetry modeling to answer at least some of the computational issues that you brought, as i don't think the already published papars mostly from Om's group provide all necessary data (that would also appeal to biologists in helping them to understand what those 1 g ratios are as this has to be tissue related). But unfortunately there is no way i can even think seriously about your questions till late May. For

the next revision (or next meeting of your Committee) i may have something to contribute. The questions you formulated are right on the target (and they will help me to write conclusions, if we ever finally get to do the unsponsored modeling that I have wanted to do for at least 4 years, but am just to busy with the sponsored research and my students esotheric innovative research.
Hope you are well. With my somewhat new focus of research I'm missing old BEMS friends (as I'm again not going to make it to the annual meeting)

Best regards

Maria

From Ken Foster:

Tell: If I recall correctly, you are a proponent of the idea that it makes no difference as to the averaging mass. Am I correct?

Foster: Not exactly.

On the basis of the bioheat equation, the maximum steady state temperature increase in a heated region of tissue is (SAR)/((density*blood flow). However, if the SAR pattern varies over small distances the "average" SAR can be taken over a distance that will take into account the effects of heat conduction to smooth out the pattern of temperature rise.

So, one algorithm that would ensure an upper limit of temp increase would be something like:

1. For EXPOSURE FROM LOCALIZED SOURCES, the "low power exclusion" should be retained. It should be possible to avoid having to measure SAR in most such cases in any event.

2. For PARTIAL BODY EXPOSURE

a. The SAR averaged over a "large" (see below) region should be held to less than the amount sufficient to result in a steady state temp increase of 1 C. This will be of the order of 3 W/kg for a low blood flow rate of 4 ml/100 grams of tissue per minute. Maybe it would be possible to keep the present 8 W/kg to avoid perturbing the standards too much.

b. The spatial averaging distance should be the smaller of

i. The length scale characterizing the transition between convection and conduction limited regimes (about 1-3 cm depending on blood flow)

ii The energy penetration depth in tissue (mostly relevant for exposures at 1 GHz or above). It is expected that at these frequencies the major restriction would be in terms of incident power density and the local SAR would not have to be measured in any event.

A simple thermal analysis would support this kind of approach, at least as a first cut. Clearly the science is rather intuitive and not rigorous but it should be OK given the fact that the standards are very conservative against thermal hazards. The big question: is the committee going to go for a thermal basis of this sort?

As I indicated on your questionnaire, I could find no valid scientific justification at all for the 1 gram averaging limit, or for the use of a 20:1 ratio for determining local SAR. And when I write down the reasons that have been given to me in the past for these choices, the logical gaps become very apparent.

IF you are willing to accept the design goal of limiting local temperature rise, then there is a lot that can be said about maximum local SARs and time and spatial averaging times.

Given the delicate political balances on the committee, I do not that C95 would agree to a precise statement of thermal design goals. But at the very least, it should be possible to make a case for a larger averaging mass. The limits are, in any event, very conservative from a thermal point of view and there is no need for high precision in specifying averaging masses or times.

Why do we need spatial averaging at all? What hazards are we protecting

against by spatial averaging, that are not automatically protected against by other provisions (time averaging, partial body exposure)? What is the exposure scenario where these other restrictions would not provide adequate protection?

Wasn't spatial averaging intended to cover things such as near field exposure to antennas? In that case, adequate protection could be ensured by limits on partial body exposure, and maybe peak exposure. Sure would simplify things a lot!

As far as I can tell, the science does not support spatial averaging, at all. Certainly I have seen no quantitative justification for any particular approach to spatial averaging, or for spatial averaging at all. If it is not necessary, lets dump it. If it is necessary for some purpose, then what is it? There is no point to building in limits that are difficult to verify unless there is a need for them.

My main points:

1. Using the ratio of peak to average SAR (20:1) to determine the peak allowable SAR does not make much sense
2. The choice of 1 gram averaging mass has no scientific justification, at least in present edition of the standard. It is probably not too far off from a reasonable value, however.
3. If the goal is to limit the local temperature rise, you can tie the averaging time and averaging distance together by means of concept of thermal diffusion distance. A first cut approach suggests about 2 grams for 6 minute averaging time, 10 grams for 20 minutes.

From Q. Balzano:

As a piece of advice, do not let the conclusions of SCC28 depart from solidexperimental facts. We need to collect data about the limits of local SAR's in near field and partial body exposure conditions. Extrapolations should not be permitted without adequate experimental data. There are too many variables coming into play and, at this time, we need to collect the pieces of evidence to draw valid conclusions.

From Vitas Anderson:

Why not VAR and volume averaging, instead of SAR and mass averaging?

As I see it, the principle concern with RF heating is the elevated temperatures in tissues caused by a sustained application of RF power. In particular we have set our limits based on the worst case of an elevated steady state temperature rise. The bioheat equation for steady state conditions are:

$\text{div}(k.\text{div}(T)) + VAR - w(\rho.C)_{blood}.(T - T_{blood}) = 0$

where T is the tissue temperature (°C)
VAR is the volumetric RF absorption rate (W/m^3)
w is the blood perfusion rate (m^3/sec per m^3)
$(\rho.C)_{blood}$ is the density of blood times the specific heat capacity of blood ($J/m^3°C$)

Note how this equation does not require the mass density of tissue, and uses VAR instead of SAR.

It is also worth noting that VAR is more simply calculated from electromagnetic analyses than SAR, i.e.:

$VAR = \sigma.|E|^2$
$SAR = \sigma.|E|^2/\rho$

Thus it would appear that one obtains a much cleaner coupling between the electromagnetic and SS bioheat equations by using VAR instead of SAR, as they both work in a volume space, rather than a mass space. The imposition of mass density to obtain SAR only introduces an additional unnecessary source of variablity.

The use of SAR and mass averages also generates some tedious evaluation problems. Since density varies from tissue to tissue, it becomes necessary to evaluate the mass average cube over different volumes in order to maintain the same averaging mass. Indeed, for a 1 gram average cube that straddles more than one tissue, you would have to adjust the size of the cube according to the weightings of the different tissues.

The use of VAR and, say, a 1 cm^3 cube is much easier to evaluate. One cm^3 is one cm^3 no matter where you are in the body!

I also think VAR would be a better metric for researchers investigatingathermal effects, since it is more closely related to E (or J) than SAR.

Lastly, as I understand it, the original choice of SAR as a metric (back in the mists of time) was not made for physical reasons, but rather because mass averaging was used in other areas such as ionising and drug exposures, and it was considered convenient to keep consistency with these other types of exposure. However, it seems to me a much weaker rationale than the physical arguments I have outlined above, especially as RF exposures and bioeffects mechanisms have very little in common with drug and ionising radiation absorption patterns and mechanisms of bioeffects.

Sumittted by Om Gandhi:

Members of the 1-g SAR Averaging Group;

The following approach was suggested by the Dosimetry Working Group of WTR back in 1995 and may be useful. Incidently this is the approach that has been followed at the University of Utah to determine 1-g SARs for cellular telephones where we must contend with curved shape of pina including air in the crevices of the ear lobe, the ear canal etc.

The tissue subvolume in the shape of a cube should be taken such as not to extend beyond the exterior surfaces of the body i.e. each of the cube's faces must have some tissue. The cubicle subvolume may have body-dictated pockets of air in it (e.g. air in the crevices of the ear or the navel). Also the weight of the subvolume may not be smaller than 1-g but preferably as close to it as possible. This may be done by expanding slightly the volume of the cube if necessary to get a weight as close to 1-g as possible.

I would like to get the opinion of the Group on this suggestion which was originally suggested by the Dosimetry Working Group of WTR consisting of the following:

A. W. Guy (Chairman), C. K. Chou, Gabriel, O. P. Gandhi, N. Kuster, R. Petersen, P. Polson, V. Santomaa, Q. Balzano, and A. Talove.

I agree with Ken Foster that we ought to keep the two items separate. Spatial averaging is needed because of the realities of scattered or standing wave fields which result in a high degree of non-uniformity of the incident fields. I have no problem with the spatial averaging provisions presently in the standard even though the factors (20 both for E and H) are not as well justified as I would like to see. In my previously-sent comments I was only addressing the issue of Spatial Peak (1-g or 10-g) provisions of the standard. This is crucial for highly localised radiators such as personal wireless devices (e.g. cellular telephones).

Submitted by Kari Jokela:

Anderson V., Joyner KH. Specific absorption rate levels measured in a phantom head exposed to radio frequency transmissions from analog hand held mobile phones. Biolelectromagnetics 16: 60-69, 1995.

Bernardi et al. Human exposure to radio-base-station antennas in urban environment. Microwave Theor. Tech. No. 11, 2000.

Chen J-Y., Gandhi O.P. RF currents induced in an anatomically based model of a human for plane-wave exposures (20-100 MHz). Health Physics. Vol. 57, pp. 89-98, 1989.

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Dimbylow P. J. FDTD calculations of the whole-body averaged SAR in an anatomically realistic voxel model of the human body from 1 MHz to 1 GHz. Phys. Med. Biol. 1997; 42: 479-490.

Dimbylow P.J. Finite-Difference Time-Domain calculations of absorbed power in the ankle for 10 – 100 MHz plane wave exposure. IEEE Transactions on Biomedical Engineering 1991; 38:423- 428.

Foster K.R. et al. Heating of tissues by microwaves, a model analysis. Bioleectromagnetics 19:420-428, 1998.

Jokela K. Puranen L. Occupational RF exposures. Radiation Protection Dosimetry. Nos 1-2: 119-124, 1999.

Leeuwen GMJ Lagendijk JJW et al. Phys Med Biol. 44: 2367-2379, 1999.

AT

One Tier or Two Tiers?
Scientific and Practical Iss

Prepared by
Linda S. Erdreich
Deborah Sena
For IEEE SC4
June 2001

AT

Working toward Consen

This “white paper” reflects information sh
among members of SC4 through interestin
discussions, over several years. This repo
designed to reflect those thoughtful contrib

Standards in General – O
or two?

- Many standards for the general public are on
  - To protect all, the ‘general population’, lifelong e
  - E.g. drinking water concentrations; ambient air
  - Health Canada WHO/IPCS, USEPA
- Many standards for workers are one tier
  - To protect nearly all workers from adverse effec
  - Examples: Threshold Limit Values, Occupationa Limits; OSHA PELs

Practical Issues

- Different exposure guidance for workers and general public is common practice, accepted
- Most RF standards are two-tiered - NRPB is for whole body exposure, two-tiered for cont currents

NOTE: Two sets of exposure guidance exist agents. These are determined by different au in different 'standards' [e.g.inhaled chemica

Scientific validity - one ti

- Of course a valid one- tiered standard c developed. It needs to:
  - Identify the population it is designed to pr
  - Consider the possibility of a range of resp values (i.e.- interindividual variabilty, ra sensitivity
  - Protect ‘nearly everyone’ (95, 99 % ?) in t defined population, under the defined circ of exposure

Drawbacks of One Tier for

Impractical for covering both work situat
protecting ‘nearly everyone’

– May not provide options for working in a
where levels are higher
– Or, may not protect people who have decr
ability to adapt to an increased heat load i
age, obesity, and hypertension …and vari

- Precedent (common practice) is two t

Is there a need for Two Stan
or Two Tiers in the Standa

- General public exposure may be more u
on average, than worker
- Higher levels may occur in the work
environment, including areas where wo
function.
- To work safely in these areas requires
administrative controls

Moving toward Consensu
The standard(s) should….

- provide guidance under most reasonable exp scenarios
- specify who is being protected, and for what of exposure (e.g. lifelong, regular exposure, l access environment)
- communicate clearly to the non-scientist, and using words that can be misinterpreted
  e.g. uncontrolled

AT

A Searchable & On-Line IE
Database of RF Bioeffect St

Joe Morrissey

Motorola Labs

RF Bioeffect Database

- A list of relevant RF studies for risk analysis assembled by SCC 28 SC4
- Information on 1521 studies has been obtai from Lou Heynik on 3/6/01, with an update c and incorporated into a comprehensive and searchable RF bioeffect database
- This database has two parts, an IEEE subse studies and a WHO subset of studies.

  Both subsets are searchable by themselves alone database subsets, and in addition are *process of being*) integrated together allowi reference of information

Comparison of Database Subsets

- **The IEEE database subset is stratified into inc published manuscripts, reviews, and reports.**
- **Efforts are underway to review each paper reg relevance to risk analysis.**
- **The IEEE database subset is searchable on th following criteria:**
  - **Author**
  - **Accession number**
  - **Reference**
  - **Date (or range of dates)**
  - **Study type**

Study subtype

AT

Current Sites for the IEEE / WHO Database

- **http://www. mmfai.org/**
- **http://www-nt.who. int/peh-emf/database.htm**

- ***IEEE Database***
  - ***http://www.IEEE.org***

4 OVERALL CONCLUSIONS

Most of the teratogenic investigations with animals were done with radiofrequency electromagnetic field (RFEMF) levels well in excess of the ANSI/IEEE (1992) and IEEE (1999) [No ANs] maximum exposure guidelines [No ANs]. Taken collectively, those studies indicate that teratogenic effects can occur in both non-mammalian and mammalian subjects from RFEMF exposure only at levels that produce significant internal temperature rises. For mammals, increases in maternal body temperature that exceed specific thresholds (for each species) are necessary for causing teratogenic effects. Such RFEMF thresholds are far above the maximum exposure levels specified in the ANSI/IEEE (1992) and IEEE (1999) [No ANs] guidelines. It is noteworthy that the differences in experimental findings between mice and rats appear to indicate that mice are more susceptible than rats to RFEMF-teratogenic effects, so neither one may be an adequate surrogate for humans in any future investigations of RFEMF teratogenesis.

None of the epidemiologic studies of possible congenital anomalies provide scientifically credible evidence that chronic exposure of mothers during pregnancy or of potential fathers to RFEMF at levels at or below the ANSI/IEEE (1992) and IEEE (1999) [No ANs] maximum exposure guidelines would cause any anomalies in their offspring.

Detailed Outline for Revision of C95.1-1999

Annex A: Approach to standard revision [Linda Erdreich*, Mays Swicord*, Marty Meltz, Ellie Adair, B Jon Klauenberg, Greg Gorsuch, Don Haes, Aviva Brecher, Ewa Czerska, Ken Foster, John Leonowich, Bob Curtis, Russ Owen, John Osepchuk on high frequency time averaging] work on items 1, 2 and 3

1. IEEE process followed for revision of standard [Linda and Mays]
   a. Continuity of the IEEE standards revision process
   b. Open nature of the IEEE standards development process expresses the value of wide participation that balances vested interests of some parties.
   c. Reassessment of technical rationale for the standard rather than endorsement or adjustment of existing exposure limits
2. General scientific concepts for developing human RF exposure limits
   a. Identifying the potential hazard from RF exposure
   b. Underlying concept is to identify the lowest level at which an adverse effect occurs. Exposure limits are developed to protect from occurrence of the adverse effect that has the lowest threshold.
   c. Adverse health effects distinguished from potentially adverse effects and biological changes that are not linked to adverse sequelae.
3. The role of risk assessment in the standard revision process
   a. Hazard identification
   b. Dose rate effect assessment (characterizing how the nature of the effect or severity varies with dose rate)
   c. Exposure assessment
   d. Risk characterization

      NOTE: c and d are not directly relevant in the revision process, as a and b provide the basis for the standard. Practical insights relevant to concerns about realistic exposure scenarios must be kept in mind, as the goal of the standard is to provide the basis for Risk Characterization. (Most people are exposed to very weak fields but some are exposed to very strong fields and these exposures occur in a wide range of environmental conditions and, often, under special circumstances.) (Loosely interpreted, d. is related to compliance.)

   e. Weighing the evidence in judging the hazard of RF energy
      i) The literature surveillance effort [Lou Heynick]
      ii) Critical reviews of individual studies [Marty Meltz]
      iii) Criteria for data assessment [Bob Curtis]
         (1) Study quality
         (2) Plausibility
         (3) Replication
         (4) Consistency

iv) Complementary data from different scientific approaches (laboratory -cells, animals, mechanistic; epidemiology and studies in humans)

f. The IEEE process for assessing the weight of evidence

i) Literature evaluation working groups for:

(1) Engineering aspects [William Hurt]

(2) In vivo studies [Dennis Blick]

(3) In vitro studies [Marty Meltz]

(4) Epidemiological studies [Greg Gorsuch]

(5) Statistical evaluation [John Orr]?

ii) Special working groups for:

(1) Mechanisms [Asher Sheppard]

(2) Spatial averaging (exposure fields and tissue averaging mass) [Ric Tell]

(3) Risk assessment [Ric Tell, Jerry Bushberg]

g. The issue of uncertainty in interpreting risk and setting MPE limits [Linda Erdreich]

i) Uncertainty factors, their meaning

ii) Data uncertainty (e.g., dosimetry considerations, etc.)

iii) Extrapolations from animal to human responses

iv) Extrapolations from sub-chronic to chronic exposures

v) Variability among individuals and potentially sensitive subgroups [Ellie Adair] review

(1) Infants

(2) Persons with limited ability to perspire

(3) Elderly in which blood does not circulate freely to the skin in the extremities or torso

(4) Patients with fevers

(5) Severely dehydrated persons

(6) Others (use of medications, implanted medical devices, etc.)

vi) Evaluating how conservative approaches affect the margin of safety in setting RF exposure limits

vii) Assessing the need for different MPE limits for different population groups or circumstances (two tier issues, matters of awareness, controlled and uncontrolled environments, potential need for exceptions, etc.)

4. Special or unique considerations of RF exposures [Lou Heynick]

a. For many RF exposure conditions, the hazard is primarily understood to be a dose rate phenomenon rather than a dose phenomenon

b. Special considerations of data regarding effects of weak-fields (These are often referred to as nonthermal effects because they are hypothesized to occur below the threshold for thermal or thermally related effects.

i) Definition of weak fields

ii) Concerns about cancer

iii) Concerns about accumulation of weak-field exposures

5. Practical considerations in implementation of RF exposure limits [Ron Pertersen*, Jules Cohen, Bob Cleveland, Greg Lotz, Bob Curtis]

   a. Exposure guidance must be technically feasible

   b. Proper use of exposure controls and training

   c. Importance of providing examples for applying the standard

   d. Established IEEE mechanism for interpretations and clarifications when needed

Outline for Revision of C95.1-1999

Annex B: Selecting an adverse effect - summary of the literature evaluation results

Note: Where appropriate, the following sections should address the stated considerations according to general frequency bands (TBD) (e.g., 3 kHz to 1 MHz, 1 MHz to 3 GHz, 3 GHz to 300 GHz, or whatever other bands are appropriate relative to concerns over currents, whole-body average SAR, surface SAR or organ-specific SAR issues).

1. Adverse effects in the living organism caused by exposure to RF fields (each of these effects is assessed by studies in humans, laboratory studies of animals, cells and tissue preparations) [Asher Sheppard*]
   a. Cancer [Heynick*, Meltz]
   b. Organ toxicity (dysfunction or diseases of major organs) [David Black*]
   c. Reproduction [Heynick]
   d. Growth and development [Heynick]
   e. CNS effects [D'Andrea*, Chou, Adair, Lai]
   f. Adverse effects on physiological function [Ellie Adair*, David Black]
      i) Adverse effects on essential physiological functions and survival
      ii) Thermoregulatory overload from deep heating
      iii) Thermoregulatory overload from surface heating
      iv) Partial body thermal tissue response
      v) Organs with greater thermal sensitivity
      vi) Adverse effects on cells and tissues
   g. Behavioral and cognitive effects [D'Andrea*, John DeLorge]
      i) Adverse effects on feeding, watering, and other essential functions
      ii) Adverse effects on learning and other higher CNS functions
      iii) Potential adverse effects identified by laboratory research
2. Immediate adverse effects caused by currents in the body and transient spark discharge, (through contact, electric induction and magnetic induction) causing shock, tetanus, burns, tissue damage, cardiac excitation, cardiac arrhythmias, involuntary motor responses, seizures and electroporation [Pat Reilly*, Aviva Brecher, Richard Woods]

   a. Shock levels in humans potentially causing involuntary responses; uncomfortable or painful sensations

   b. Potentially hazardous effects identified by animal studies, in vitro studies, or theoretical models

   c. Direct alteration of CNS function

3. Summary of findings [Sheppard*, Ziskin, Sutton]
   a. Cancer
   b. Health and well being

c. Identified hazards (as functions of frequency, field strength, and other dose rate factors).

Outline for Revision of C95.1-1999

Annex C: Explanation of maximum permissible exposure limits

[Asher Sheppard*, Ric Tell, Sakari Lang, Ellie Adair, Vitas Anderson, Joe Elder, John D'Andrea, Pat Reilly]

Note: Where appropriate, the following sections should address the stated considerations according to general frequency bands (TBD) (e.g., 3 kHz to 1 MHz, 1 MHz to 3 GHz, 3 GHz to 300 GHz, or whatever other bands are appropriate relative to concerns over currents, whole-body average SAR, surface SAR or organ-specific SAR issues).

1. Recommended adverse effect levels
   a. Levels at which internal currents, current densities and transient currents cause adverse effects
      i) Whole body exposure
      ii) Partial body exposure
      iii) Sensitive tissues and organs
   b. Levels at which increased temperature causes adverse effects.
      i) Whole body exposure
      ii) Partial body exposure
      iii) Sensitive tissues and organs
      iv) Relevance of information from classical heat stress studies
   c. Levels at which health or a physiological function are adversely affected
   d. Levels at which behavior is adversely affected
   e. Levels associated with uncomfortable or painful sensations, including thermal and electrical stimulation [Dennis Blick]
   f. Levels at which some other effect is adverse (TBD)
2. Relationship of adverse effect levels to dosimetric quantities measured in the laboratory
   a. Relationships among current density, total current, and contact area, or
   b. Relationship of behavioral response to SAR, or
   c. Relationship of health or a physiological function to SAR, or
   d. Relationship of temperature increase to SAR, or
   e. Relationship of sensory effects to SAR and current
   f. Limitations related to knowledge of dosimetric quantities
      i) Near vs. far-field exposures and SAR
      ii) Spatial considerations (peak vs. whole-body average values)
      iii) Tissue averaging mass considerations
      iv) Localized current density
3. Derivation of practical MPE limits

a. Applying the uncertainty factors
b. Dealing with nonuniform exposure fields
c. Dealing with time-variant exposures
d. Derived MPE limits for:
    i) Current
    ii) Current density
    iii) SAR
    iv) Electric field strength
    v) Magnetic field strength
    vi) Pulse energy content
    vii) Electromagnetic flux density (power density)
e. Environmental exposure assessment considerations (near vs. far field exposures, use of far-field SAR values will generally be conservative when applied in near-field exposures)
f. Special concerns or exceptions
    i) Adverse environmental conditions
    ii) High work loads
    iii) Presence of medical devices or metallic implants
    iv) Influences of medications
    v) Pregnancy
    vi) Localized reradiated fields