



**STANDARDS COORDINATING COMMITTEE 28
(NONIONIZING RADIATION)**

Approved Minutes
Subcommittee 4 Meeting

**Holiday Inn Riverwalk Hotel
215 St. Mary's Street
San Antonio, TX**

**Friday, November 17, 2000
1:00 PM - 5:00 PM**

1. Call to Order

The meeting was called to order by Co-chairman C. K. Chou at 1:00 PM.

2. Introduction of Those Present

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

3. Approval of Agenda

Co-chairman Chou asked for changes to the agenda or a motion to approve. There being no changes, upon a motion by M. Meltz and a second by L. Heynick, the agenda was approved as presented. (See Attachment 2.)

4. Approval of the Minutes of the June 9, 2000 Meeting

There being no corrections to the minutes, upon a motion by M. Zizkin and a second by J. Cohen, the minutes of the June 9, 2000 meeting were approved as presented.

5. Secretary's Report

R. Petersen reported that the PAR for the revision of C95.1-1991 is valid only through December 2001. If the revision is not approved by then the project will either have to be withdrawn or a "Target Extension request" form will have to be submitted and approved by the Standards Board in order to continue. The latter requires details about how the committee expects to complete the project, e.g., timelines, meeting schedules, number of people working on the project, etc. Petersen said that a more detailed report would be given at the SCC-28 meeting the following day.

6. Chairman's Report

Chou reported that many of the items usually covered in the Chairman's report would be deferred until later in the agenda. He noted that the third meeting of the Revision Working group will be held in Tempe, AZ, March 1-2, 2001 and reminded the committee of the importance of completing the literature evaluation. Co-chairman D'Andrea pointed out that the committee is falling behind the timetable proposed earlier (see Attachment 3). He then reviewed the revision process. He pointed out that because the process of evaluating more than 1400 papers became cumbersome, it was decided that the papers should be prioritized and those considered crucial should be subjected to immediate evaluation. He said that he would set up a new timetable later during the meeting to try to get the process back on track.

7. Executive Committee Report

J. Osepchuk noted that a full report would be given at the SCC-28 meeting on Sunday and reported the following:

- a) SCC-28 has been very successful in recruiting new members from outside the US.
- b) A plan is in motion to define an umbrella group for SCC-28 and SCC-34 (product performance standards relative to the safe use of electromagnetic energy). The intent is to provide to people not familiar with IEEE a recognizable name that describes the scope of the committees. A name now under consideration is ICES – International Council on Electromagnetic Safety.
- c) The second informal meeting between ICNIRP and the SCC-28 leadership was held Thursday, November 16th. The purpose of the meeting was to develop a cooperative agreement between ICNIRP and IEEE. In response to a request from M. Swicord for specific details, Osepchuk explained that the intent is to work out plans for exchanging documents. He said that a joint workshop on thermophysiology was discussed. This would be a milestone conference with perhaps twenty invited speakers and would require considerable preparation. One possibility would be to schedule the meeting in conjunction with the September 2001 meeting of the European Bioelectromagnetics Association (EBA). In response to a question from Chou, Osepchuk explained that because of the extensive preparation required it would be impractical to try to hold the meeting earlier. He would, however, make every effort to move the workshop up. M. Murphy noted that this issue will be discussed further with ICNIRP but the intent is meeting with EBA in September.

8. Risk Assessment Working Group Report

R. Tell discussed two overheads showing the cumulative distribution of papers with scores $\geq x$ and a distribution of *in vivo* papers with scores $\geq x$ (see Attachment 4). He pointed out that two reviewers did not necessarily review each of the *in vivo* papers. He said that the RAWG is still struggling with how to make the process move more efficiently and asked for suggestions – there were none at this point.

9. Mechanisms Working Group Report

A. Sheppard reported that the Mechanisms Working Group has not made any significant advances recently. He explained that the task of the group is to deal with the literature that presents evidence supporting non-thermal mechanisms and try to determine how this affects development of the standard. S. Lang noted that in Sweden there are about seven different

definitions of “non-thermal mechanisms.” Sheppard said if one looks carefully through the literature, probably even more than seven different mechanisms could be found. Meltz noted that several lists of mechanisms exist that should be circulated to the members of the mechanisms group for comment in support or against. D. Blick pointed out that the *in vivo* reviewers are asked to comment on mechanisms as part of the review process. Heynick said that he compiled a list of about 99 non-thermal and mechanisms papers – D’Andrea noted that these were sorted and the important papers were identified at the last Revision Working Group meeting. Sheppard pointed out that the sort was by important physiological endpoint – not by mechanism.

M. Swicord said that the mechanics of handling the data needs improvement, e.g., the data should be put into Excel or some other format that would allow more efficient sorting. Heynick noted that with the present database and process, no one except the working group chairs see the reviews and suggested distribution to a wider audience at this point. Meltz pointed out that lists were compiled by effect, e.g., cancer, reproductive effect. At the September Revision Working Group meeting the citations in each of these lists were ranked as “priority” and “non-priority.” He suggested that perhaps this accumulated data could be coded and included in the citation lists that Heynick prepares. In response to a question from Heynick, Meltz explained that the triage process is still being followed. Heynick responded that he had prepared summary charts that might be useful for the triage process – the charts are available from the Air Force (Patrick Mason).

10 Literature Evaluation Working Group Reports

a) Literature Surveillance

L. Heynick reported that there are now 1449 citations in the database. He said that he found a few more in the *Proposals for a Research Programme by a European Commission Expert Group* report included with the last SC-4 mailing. He said that new lists by 1st author, but with the accession numbers removed, have been posted on the SCC-28 website (<http://grouper.ieee.org/groups/scc28/>).

b) Engineering

W. Hurt reported that 188 of the 555 high-priority papers have been reviewed. He said that 156 more are ready to be sent out and copies of an additional 132 papers have been requested for distribution. To date, 394 papers have been reviewed out of which 150 have been completely reviewed by two or more reviewers (see Attachment 5). He said that in addition to a lack of response of some reviewers, there were software problems that have been slowing the process. In response to a question from J. Cohen regarding the software problems, Hurt said he was not sure what the problem was but he will try to reload the software – that seemed to have solved the problem in the past.

c) In Vitro

M. Meltz reported that his group has made little progress because of other commitments and a dwindling number of reviewers. He requested that anyone interested in reviewing *in vitro* papers contact him – he is down to about 5 reliable reviewers. He pointed out that an additional burden is the time it takes the chairs of the working groups to add comments to each of the reviews. In response to a question from Heynick regarding when the reviews will be made public, Meltz deferred on that issue until later in the agenda. It will also be discussed at the SCC-28 meeting the following day. D’Andrea asked how long it would take to get the priority papers reviewed and the reviews submitted to the RAWG. Meltz said

that this would be hard to determine – some of the papers have been out for more than 6 months. He said that he would like to prioritize the reviews of 120 high-priority papers and asked for assistance in defining these papers. Hurt pointed out that in order to finish near schedule, about 100 reviews per month or two will have to be completed – this may not be realistic.

d) *In Vivo*

D. Blick reported that he has more than two-dozen reviewers but many are inactive and only six are reliably responsive. He said that he added three more since the Munich meeting and said that more are needed if the process is to be completed near schedule. He said that he can give 270 summaries and anonymous reviews to the RAWG at any time. (See Attachment 6.) In response to a question from Sheppard, Blick responded that so far only about 5 or 6 of the reviews are discordant. Meltz noted that this also holds for the *in vitro* reviews.

e) *Epidemiology*

L. Erdreich reported that she is in the process of transferring everything to G. Gorsuch who will now serve as chair. She said that the number of completed reviews has not increased since the last meeting. Part of the problem is a lack of participation and a paucity of potential reviewers with RF experience. There are a number of potential reviewers in the Scandinavian countries but she has not reached out to them. The chairman's software is being sent to Blick who will transfer it to Gorsuch.

Gorsuch thanked Erdreich for allowing him to participate in the process and said he hopes that she would remain as co-chairman. Heynick said that some of the papers probably could be reviewed by non-epidemiologists. Erdreich said that she prefers epidemiologists for reviewers – if for no other reason than to maintain credibility with those outside of SCC-28.

f) *General Discussion*

The scoring system was discussed briefly. It was pointed out that the engineering and biology scores are not averaged together – each low score acts as a trigger regardless of the other score. Chou explained that the real problem is a lack of adequate reviewers and responsive reviewers. He extended an invitation for additional reviewers – particularly from outside the US. He said that papers are being added to the citation list quicker than the reviews are coming in. A. Brecher suggested limiting the reviews to only those papers that could have an impact of the present limits. She said that the lack of response of some of the reviewers might be because they see little use in reviewing papers that are obviously irrelevant. Meltz reiterated the need for prioritizing the already prioritized papers. He said that there is also a need to communicate with colleagues in Europe who can identify additional European reviewers. R. Bodemann suggested coordinating SC-4 efforts with other organizations that are carrying out similar reviews. Meltz suggested that perhaps a monetary incentive for the reviewers, through some benefactor, could be considered to help move the process, e.g., \$25/paper. He said that this might encourage reviewers not normally interested in reviewing published papers. T. McManus suggested that the real issue might be a lack of appreciation or recognition. He was also concerned that a monetary incentive might attract superficial reviews. He suggested checking the COST 244 BIS mailing list for leads for additional reviewers. Also, some of these issues could be addressed by postings on the web. He suggested making e-mail and web addresses more accessible.

FOR ACTION

The secretary will include with the minutes of this meeting, lists of names of the reviewers of each working group. (See Attachment 7.)

L. Erdreich recommended considering alternative processes. For example, existing reviews such as the ones Heynick prepares for the Air Force could be used as a basis to work from. Heynick agreed. He said that such reviews could be used as part of the triage process to identify important papers. R. Tell noted that we are now coming up on ten years since the 1991 standard was approved and we seem to be running out of time. He said that he supports prioritizing priority papers for immediate review. Meltz said that he would work with Heynick, Sheppard and Tell to prioritize papers for immediate review and suggested that Blick do the same.

FOR ACTION

M. Meltz will prioritize and select papers for immediate review before December 15, 2000.

11. Editorial Committee Reports

a) Revision Working Group

C. K. Chou reviewed the March and September Revision Working Group meetings. (See the *Fall 2000 Mailing* for the minutes and summaries.) He announced that the next meeting would be held March 1-2, 2000 in Tempe AZ.

b) Topic Reports

***i* Spark Discharge and Induced Current**

J. P. Reilly reported that he has submitted proposals on spark discharge, contact current and peak magnetic field limits. With regard to spark discharge, he said that the issue/concern is erosion of the skin in high fields, i.e., burns, and a startle response that may lead to indirect effects. He said that he has reviewed the literature since the last standard was approved and noted that Passour submitted a statement to the effect that no definitive research leading to quantifiable criteria for spark discharge has been reported since then. Reilly noted that the document used by the Navy is adequate but may be overly conservative and said that an MPE for spark discharge has not been proposed.

Reilly then discussed contact current. He said that the existing standard has criteria for induced current and for contact current, but only associated with grasping contact. He pointed out how the criteria for grasping contact is inadequate with respect to "touch" or contact with small areas of the body and proposed specific limits for touch contacts. These limits will be lower than the limits for grasping contact in the current C95.1 standard but will be consistent with those of NRPB, ICNIRP, the Health Council of the Netherlands, Health Canada and New Zealand. He briefly discussed controlled versus uncontrolled environments pointing out that the limit is based on exposure in uncontrolled environments. He said that the limits could be relaxed under controlled conditions for certain groups and suggested considering different names for the categories, e.g., occupational and general public.

The proposed peak limits for the magnetic field were discussed next. Reilly explained how the limits are based on electrostimulation up to about 100 kHz, above which frequency tissue heating dominates (see Attachment 14 in the *Fall 2000 Mailing*). He said that the rms values would have to be corrected and extended to account for pulsed fields – perhaps up to 3 or 5 MHz. Tell asked about the evidence above 100 kHz – specifically, how solid the evidence is regarding shock. Reilly replied that the evidence in the electrostimulation literature is very solid and follows theory at least up to 1 MHz. R. Curtis asked whether the basis for the proposed criteria is different from that of ICNIRP and suggested just harmonizing with ICNIRP, e.g., extending the criteria up to 10 MHz. Reilly said that he agrees with the ICNIRP formulas for summarizing the frequency components and also agrees with the philosophy but not with particular numbers. He pointed out that in some frequency regimes the ICNIRP values differ from his by more than an order of magnitude.

ii Thermoregulation

E. Adair explained that she was suffering from laryngitis and deferred to her sections in the *Fall 2000 Mailing*.

iii Non-Thermal Effects

L. Heynick said that he has no report noting that the *Fall 2000 Mailing* contains a statement regarding non-thermal effects. He repeated what he said earlier, namely that there are now about 90 non-thermal/mechanisms citations in the database.

iv Selection of Adverse Effect Level

A. Sheppard showed the overheads from the March revision Working Group Meeting (see *Fall 2000 Mailing* and Attachment 8). He reviewed some definitions including that of “potentially adverse effect,” which led W. Bailey to ask for an explanation of the difference between “potentially adverse effect” and any biological effect. Specifically, is “potentially adverse effect” even needed or could it be decided on a case by case basis? M. Swicord said that in his mind a potentially adverse effect is an established effect that does not result in harm. He also pointed out that the WHO definition contains “well being” and asked if we should consider harmonizing with ICNIRP and consciously include “well being” in the definition of adverse effect. Meltz suggested replacing the phrase “disease through an established model” in the definition of adverse effect with “ill health.” He also suggested as a third category “speculative effects.” Heynick noted that the definition of adverse effect is not much different from the old Soviet definition, i.e., anything that deviates more than 3σ from the norm is considered adverse. Sheppard said that to his way of thinking a potentially adverse effect is an established effect where the steps leading to disease have not been established. Meltz argued that potentially adverse in this sense is incorrect since the effect could be harmful, beneficial or benign and the word “potential” relates to all three. R. Curtis asked whether we need even more definitions, e.g., for precursors that lead to effects.

Sheppard then asked whether or not we even need these definitions as a guide while working on the revision. Heynick suggested that when considering effect versus non-effect consider normal versus compromised effect. McManus said that perhaps we should revisit the basic definition of biological effect and include reference to

effects that are common and benign to help minimize concern over the term “biological effect.” Meltz agreed that that could be useful and suggested developing the definition even further. Bailey agreed that clarification is needed to allow distinguishing between serious versus trivial effects.

Sheppard then discussed Part 1 of Attachment 8 in detail noting suggested changes, e.g., list “painful sensations” in Part 1 Section I as an adverse effect – not as a potentially adverse effect. Meltz argued that the heading “potentially adverse” in the same section should be called “of interest” instead. M. Murphy agreed. He said that he would like to reinforce the position that “potentially adverse” is incorrect for effects that have no known hazard. Swicord agreed adding that “adverse” should not relate to just any physiological change – sweating is an effect that is not adverse.

FOR ACTION

A. Sheppard will revise Attachment 8 to include comments and suggestions and will provide the revised outline to the secretary by January 15, 2001 for distribution with the minutes.

v Whole-Body SAR Limits

C. K. Chou reported that there is no new material to discuss.

vi Biological Basis for Standard

Meltz reported that he would prepare an issue paper on the biological basis for the standard for the March meeting of the Revision Working group. He said that he has established a dialog with Patrick Mason to identify those parts of the body and the organs that may be at risk from a dosimetry perspective. He will do the same from a biological perspective.

FOR ACTION

M. Meltz will prepare an issue paper on the biological basis for the revision of the standard and submit it to C. K. Chou no later than February 15, 2001. He will also examine papers where the SAR is greater than 4 W/kg for three different categories of effect and provide a summary by February 15, 2001.

vii Spatial Averaging/Averaging Volume

R. Tell reported that at the September meeting he pointed out that there were inconclusive discussions and a variety of opinions across the whole spectrum on this issue and nothing has changed since then. He said he would like to hear discussion by this group – specifically on the topics of spatial averaging incident power density, averaging volume for peak-spatial average SAR, and field averaging in general. Chou reviewed the ICNIRP rationale for their peak spatial-average SAR value, i.e., 2 W/kg averaged over 10 g of tissue. He said that it was based on a threshold for lens opacities of approximately 100 W/kg, a safety factor of 50 times for exposure of the public and an approximate mass of the adult eye of 10 grams. He said that the IEEE values are based on the limiting resolution of the numerical models available at the time the 1982 standard was developed and an observed twenty to one ratio between the spatial peak and the whole body averaged SAR in

animal models exposed under plane-wave conditions. Sheppard noted that both seem rather *ad hoc*. He said that ΔT should be key in defining an appropriate averaging volume and added that a quick look suggests that there would not be much difference in terms of ΔT for either volume.

Tell reminded everyone that C95.1 does not permit spatial averaging at frequencies above 6 GHz and is also more stringent than ICNIRP. Reilly pointed out that spatial averaging is also important at the lower frequencies where electrostimulation dominates – 1-gram would probably be adequate. A. Brecher said that the issue of averaging volume not only involves thermophysiology but themophysics as well. She explained that the basis for averaging time is related to the time to reach thermal equilibrium in a radiation field and said that the same argument could be used for averaging volume. Bodemann pointed out that the present data do not support any particular volume. He said that the ICNIRP averaging volume is biologically based while that of IEEE is technically based and suggested that the revision should be biologically based if it is to be accepted. M. Ziskin said that the concern should be biological, e.g., cell death. He said that it is necessary to find the smallest surface area exposed, which means consideration of wavelength and other factors. Bodemann suggested that the life of the human should take precedence over the life of individual cells. Meltz said that it is hard to comprehend a rationale for averaging volume pointing out that it could depend on individual organs.

Swicord said that preliminary calculations indicate that ΔT is not much different over 1 g or 10 g. He explained that one item on the WHO research agenda is dosimetry in support of standards. Debating this issue at this time may not be fruitful. What is needed is the melding of dosimetry modeling with thermophysiology modeling to provide supporting information. He said that it is important to go forward and address this particular issue. Curtis said that he is concerned that the revision will be delayed until data is obtained if we move forward with the melding of the models. He said that since averaging volume appears to be important for certifying certain products, perhaps we should consider vertical standards for products and decide the issue there. A. Varanelli disagreed and recommended going forward with the modeling in order to try to solve the problem.

FOR ACTION

R. Tell will prepare, by February 15, 2001, a recommendation for going forward to resolve the averaging volume issue.

viii Single Tier versus Two Tier

L. Erdreich reported that she has drafted a white paper on the issue that has been circulated to a small group for comment. The rationale for a single tier standard would be to develop criteria that would protect everyone, i.e., the general public. She said that while there is a strong link with the thermoregulation section, it is desirable to present the rationale for one or two tiers as a distinct entity. Issues that come up are human (population) variability and variability in tissue warming. She said she is still looking for feedback on how to deal with environmental factors, exceptions and on how strong a statement can be made on long-term exposure.

FOR ACTION

L. Erdreich will complete the draft paper white paper by February 15, 2001 so that it can be distributed before the March meeting of the Revision Working Group.

R. Owen suggested distributing the existing draft to a wider audience, e.g., the Editorial Working Group, for comment before February 15, 2001. Gorsuch explained that the intent was not to limit distribution and pointed out that the discussion on this issue went on for a long time at the September meeting and only a few individuals were interested in participating on the group that developed the present draft.

The first half of the meeting was adjourned at 5:00 PM.

Subcommittee 4 Meeting

**Holiday Inn Riverwalk Hotel
215 St. Mary's Street
San Antonio, TX**

**Saturday, November 18, 2000
8:00 AM – Noon**

The second half of the meeting was called to order at 8:00 AM

viii Single Tier versus Two Tier (Continued)

R. Tell recommended starting fresh by determining what is most appropriate and not trying to fixate on the existing numbers, etc. Erdreich continued her presentation (see Attachment 9). She noted that work has been in progress for a long time now. The underlying question is “what is the basis of the standard for the general public?” We now have an expanded database – which is an important part of the revision process. She noted that there are established methods for considering non-carcinogens that have been adopted by WHO, e.g., for chemical safety, and recommended that the focus should initially be on criteria for the general public.

Erdreich noted that thermophysiology is an important part of the process. She recommended focusing on dosimetry in an analogous manner to WHO’s approach regarding chemicals. The underlying concept should be to use data rather than compounding safety factors for uncertainty. She pointed out that it is important to re-visit the issue of one tier versus two tiers because we are revising the standard and we should decide now whether the revision should be science-based or sociopolitical. She then discussed how science is used noting that safety factors, e.g., 5 or 10 times, are used worldwide and asked if we should also define a range of environments where the revision will hold. In order to follow the conventional process of establishing a threshold below which no observable adverse effects can be demonstrated and adding uncertainty factors, she said that we must first decide what the hazard is. The consensus is that the lowest threshold is associated with behavioral effects – the threshold for tissue damage being higher. Then there is the question of identifying the most sensitive group of individuals or determining individual variability. She noted that although there is no convincing evidence supporting long-term effects, the question is still open to discussion. She suggested application of the thermophysiological model to the healthy individual and a compromised person to determine any differences. S. Lang asked if she would consider the IARC cancer study – if yes, it could take 3 to 4 years to obtain the data. Erdreich replied that a caveat could be incorporated to address this issue. She said that other studies could be considered, however, for example the Motorola study.

Chou said that it is important to get feedback on the draft white paper from a larger group, adding that these issues were also discussed at the Revision Working Group meetings. P. Mason pointed out that SAR is only a partial answer – information on

ΔT is also important as is the particular tissue and organ. He said that ideally the MPEs should be based on ΔT but that might not be doable for several years. ΔT would also be easier from a communications perspective i.e., to explain the standard.

G. Gorsuch said that he appreciated the fresh look approach but we seem to be going full circle. He asked Mason how compliance would be determined and if a ΔT -based standard would be more complex than one based on SAR. Mason replied that it probably would be more complex and factors such as workload might have to be incorporated into the model. J. Cohen said that he would like to raise a general plea to approach the standard with an open mind and not focus on what minor changes we should incorporate for the revision. The revision should be soundly science-based – the standards are living documents that can be changed in the future to reflect new knowledge.

A. Brecher pointed out what she sees as weaknesses in the conceptual framework. One weakness is that the no observable adverse effect level (NOAEL) is difficult to obtain since most data applies to acute exposures. Moreover, it may not be known which effects are reversible, cumulative, etc. She said that from a worker perspective dual standards are necessary – the worker levels are the NOAEL.

R. Owen stated that issues regarding the means of assuring compliance are important but should be separated from the scientific basis of the standard. Heynick noted that non-ionizing radiation is quite different from ionizing radiation, chemicals, some medications, etc., and must be dealt with differently. Varanelli said that he supports Erdreich's approach as being more rationale than most and agrees that the means for applying the standard can be decided later. W. Scanlon explained that several good bioheat models are available and it should be possible to do a sensitivity analysis to obtain important information. He said that it is also important to be cognizant of the exposure conditions, e.g., near-field, far-field.

E. Adair pointed out that it took almost four years to resolve the one versus two tier issue for the 1991 standard. The committee settled on exposure environments and she said that she still supports that concept. In response to the question of whether the eyes and testes are the most important organs and whether they are susceptible to damage from chronic exposure, Heynick replied that ocular effects have been extensively studied and a threshold has been well-established – it is clearly a threshold phenomenon. Meltz pointed out that the lens of the eye is being considered.

ix Peak-Power Limits

J. D'Andrea explained that without peak-power limits the power density for a single pulse could rise without bound as the pulse width becomes increasingly shorter (see Attachment 10). He pointed out that ICNIRP caps the peak value at 1000 times the average value while IEEE caps the value at 100 kV/m. There is little data in the literature to support the IEEE MPE for pulsed fields and the current value may be overly conservative. He recommended maintaining the current limits and making necessary adjustments based on any forthcoming changes in SAR and averaging time. In response to a question from Heynick regarding the rationale for limiting the peak power to 1/5 the SA over the averaging time, D'Andrea explained that J. Leonowich would be providing the rationale and examples of how the limits are applied.

x Low-Power Device Exclusion

R. Petersen briefly explained the rationale for the low-power device exclusion in the 1991 standard. He said that it would be desirable to maintain the exclusion in the revision. While there is a wealth of dosimetric data available resulting from the requirements to certify wireless handsets, an informed decision as to what the limits should be cannot be made until the issues of the peak spatial-SAR value and the corresponding averaging volume are resolved. He also recommended extending the limits from 1.5 GHz in the 1991 standard to possibly 3 GHz in the revision.

xi Averaging Time

J. Osepchuk explained that the averaging time issue has been studied in detail over the past decade. He pointed out that the averaging time over portions of the spectrum in the 1991 standard are somewhat arbitrary. For example, the ramp in the millimeter-wave region was established to match the 10 s value at 300 GHz (1 mm) found in the laser standards. He said that one problem with this ramp is that it does not follow penetration depth data. K. Foster's modeling led to modified thermal time constants and a two-step ramp is being proposed. This two-step ramp, which follows the functional dependence on frequency from Foster's thermal modeling, is ready to be incorporated into the revision.

xii Replication/Validation

R. Curtis reviewed the material he presented at the September meeting of the Revision Working Group by referring to Attachment 16 of the *Fall 2000 Mailing* (Attachment 11 this mailing). His conclusion is that the wording in the current standard is adequate. Meltz suggested that "adverse effects" in the second quoted paragraph of Attachment 11 should be changed to "possible adverse effects" or "lack of effects." Tell said it would be useful if each study could be tagged "replicated," "carried out in other species," etc. and these tags included in the revision. Cohen agreed with Tell but suggested that only those studies instrumental in defining the standard should be tagged – not the entire database. Swicord asked about the purpose of all of this – is it to select papers of studies that need to be replicated or validated? Curtis replied that it is in response to the IAC letter where concerns were expressed about the inappropriateness of a selection criteria that is too rigid, e.g., some papers may be important and should be considered even if the studies have not been replicated or validated. Meltz said that as priority papers are received he would provide information on associated or related papers. Curtis concluded by stating that it is important that it be made clear in the revision that non-peer reviewed papers have been considered.

c) Ashley Proposal

B. Roberts thanked the members of the *ad hoc* group that reviewed Ashley's proposal for a revision of C95.1-1991. Besides Roberts, the members of the group were A. W. Guy, E. Mantiply, R. Petersen and R. Tell. He said that the proposal was first mentioned at the March meeting of the Revision Working Group. The Chairman of SCC-28, J. Osepchuk, directed distribution of the proposal for comment by SC-4 – the lack of comments led to the establishment of the *ad hoc* group at the September meeting of the Revision Working Group. Roberts proceeded to review the draft (see Attachment

12) and noted that a response will be sent to Ashley. He pointed out that Ashley desires to eliminate spatial averaging altogether. The *ad hoc* group agreed with Ashley that the surface fields would be a reliable indicator but only for homogeneous models, i.e., it does not address potential hot spots. A number of other issues led the *ad hoc* group to conclude that the philosophy of the proposal is not valid. Varanelli pointed out other problems associated with measurement of surface currents such as the emotional state of the individual being monitored – noting the rationale of the polygraph. He pointed out that a calibrated standard human would be required in order to make repeatable measurements. Curtis pointed out that the volunteer issue is common in worker standards, i.e., measurements on human volunteers is permitted. McManus suggested that Ashley is proposing something more like a research proposal. Roberts agreed adding that Ashley went through a great deal of effort and thought in assembling the proposal. Tell also agreed noting that the proposal points out one of the deficiencies in the current standard, i.e., the issue of measurements in perturbed versus unperturbed fields.

12. Revision Timetable

C. K. Chou presented the new timetable (see Attachment 13). Tell suggested moving the March 16, 2001 deadline up to before the Tempe, AZ meeting March 1 and 2. General discussion regarding the outline followed. Sheppard said that he thought that the process was keyed to the outline – D'Andrea agreed and suggested modifying the timetable based on comments from the audience. Meltz suggested February 15, 2001 as the deadline for material for the March meeting, e.g., comments, topic reports, topic report revisions. He recommended that the chairs of the topic working groups identify all high-priority papers, send the list to Heynick and to the appropriate literature evaluation working group chair if they want the paper evaluated. The accession number plus the complete citation should be included.

FOR ACTION

The topic working group chairs should identify, by February 15, 2001, all papers considered high-priority for their working group. A copy of the list should be sent to L. Heynick and to the appropriate literature evaluation working group chair if they want the paper reviewed. The accession number and the complete citation should be included.

M. Swicord asked if the RAWG would be receiving reviews so that they could start drafting the appropriate sections of the revision. He suggested a parallel process, i.e., begin drafting the various sections as if the evaluations have been completed and make any necessary changes later. R. Curtis suggested sending about 5-10 evaluations of high-priority papers to the RAWG so that they could begin. D. Blick said that the RAWG already has a basis to begin pointing out that most of the key papers have already been evaluated by topic and sent to the RAWG. Heynick suggested making the evaluation summaries more generally available in order to expedite the process. Tell stated that if a decision is made to disseminate the evaluation summaries, a better way of doing so is needed. Meltz noted that there are six topic areas in the literature review database and suggested setting up subgroups within the RAWG to address these topics. Heynick suggested starting with the Air Force reviews as strawmen.

Meltz pointed out that until the summaries and comments from the working group chair are received the evaluations are not official. Heynick asked about how the topic group chairs would get the summary disks. Tell said that he would prefer to distribute the information as an Excel spreadsheet to eliminate the need for distributing the software. Swicord said that the next step is

hazard identification, which means that the database must be grouped by subject, e.g., mutation, and decisions made as to their relevance. He proposed providing two lists; one would be the entire list stripped of the evaluations so that it could be sorted – the other would be the database of reviewed papers. Meltz said that an earlier proposal led to the lists prepared at the Revision Working Group meetings in March and September. Heynick asked whether or not the database could be formatted into an Excel file. Blick responded that it could – but not easily. Meltz recommended that Heynick annotate the database according to decisions made at the Revision Working Group meetings.

FOR ACTION

E. Adair, L. Erdreich and A. Sheppard will send the lists developed at the Revision Working Group meetings to L. Heynick.

Heynick said that he still does not see how the reviews will get to the individuals. D'Andrea said that Blick will transmit the reviews in an Excel format. Blick responded that getting the database into an Excel file would be a monumental task. Meltz then proposed that Tell set up working groups within the RAWG to investigate important topic areas. He also proposed that Heynick forward the lists he receives to Tell to be distributed to the topic area subgroups of the RAWG so that they could move forward. Curtis reminded everyone that at yesterday's meeting it was agreed that citations on the lists of priority papers would be prioritized and recommended going forward with those. He suggested that the subgroups of the RAWG meet sometime in January or February, perhaps following the Salt Lake City SC-2 meeting. Heynick recommended that the topic chairs also receive the priority reviews so that the draft revision can be started.

13. Dissemination of Literature Reviews (Originally Listed Under New Business)

C. K. Chou stated that a decision has to be made at this meeting as to whether the evaluations can be distributed at this point to the RAWG members. Tell reviewed the history of this issue. He noted that initially there was only modest interest but interest in receiving reviews has increased along with the increased number of people on the RAWG. He cautioned that if the evaluations are distributed to individual members, it is inevitable that they will go beyond the RAWG. Meltz suggested having the members of the RAWG sign a non-disclosure agreement noting that legal advice from IEEE may be needed. In response to a question from Heynick, Meltz explained that the software is copyrighted by Veridian – but it is not clear if the data is also copyrighted, e.g., by IEEE. He suggested following up with IEEE legal. Curtis said that as a public official, he could not sign a non-disclosure agreement. Meltz pointed out that there are a number of reasons why the initial choice was not to disseminate the reviews early – one reason is possible monetary benefits if everything is released at once at completion. He said that he supports an open process for moving forward and made the following motion:

MOTION

M. Meltz moved that the chairs of sub committee 4 with input from chairs of the RAWG and Editorial Committee select those persons who are involved in drafting the standard who are to receive a copy of the RAWG Chair's program. The program would be provided by Dennis Blick upon receiving authorization from the Co-chairs of subcommittee 4.

Upon approval of this recommendation the chairs of each of the literature review working groups will forward their review and summary disks to Dennis Blick. He will in turn periodically forward the reviews and summary information to the person designated above.

At the present time it is required that those persons receiving the program and review information are obligated not to reveal that information to any party other than those persons who are actively participating in the standards setting process. This participation should be confirmed with Co-chairs of SC4.

The chairs should investigate the appropriateness and legality of requiring nondisclosure agreements, but if it appears that the timeliness would be impaired they should use their best judgment in making the reviews available. As an alternative to a nondisclosure agreement the persons receiving the information would agree to maintain confidentiality of the information.

Note: There is specific interest in making the underlying literature review database publicly available prior to the balloting on the report of SC4 by SCC28.

The motion was seconded by W. Bailey.

Considerable discussion on the motion followed. Bailey suggested a simple caveat might be in order regarding government employees so that they could receive the reviews without having to sign a non-disclosure agreement. There was discussion about others obtaining the reviews that were in the hands of government employees through the Freedom of Information Act. Curtis said that he sees no problem if the reviews are released globally at the time that SC-4 moves the revision up to SCC-28 and asked if all the information could be released at that time.

A. Varanelli asked for a clarification – specifically, what information belongs to the IEEE and what information belongs to the public? At this point J. Osepchuk made the following motion:

MOTION

J. Osepchuk moved that the motion being discussed be tabled and forwarded to IEEE for guidance.

The motion was seconded by E. Adair and was approved unanimously.

FOR ACTION

R. Petersen will present the issue to the IEEE Legal to seek clarification.

FOR ACTION

R. Tell will contact each member of the RAWG to obtain a commitment regarding his or her continued interest.

In response to a question from Tell regarding whether or not the RAWG database could be distributed without the scores, Meltz said that that could be done right now.

14. Pinna Proposal Report

E. Adair explained how it was decided at the Munich meeting to establish a working group to prepare a rationale regarding consideration of the pinna as an extremity subject to the relaxed SAR requirements of the other extremities. The rationale was distributed to SC-4 early in the fall for ballot; 49 approved, 1 disapproved and 3 abstained (see Attachment 13). She explained how there was a problem writing the first draft using language from the current C95.1 standard regarding the definition of extremities. In particular, does the definition include the arms and legs or just the hands, wrists, ankles and feet? Chou said that the issue was raised by G. Lapin. The

minutes of the meetings that led to the 1991 standard were checked for evidence of intent as to exactly how far the definition extended. Petersen said that he could find nothing specific in the minutes and some of the people involved at the time felt the intent was to include more than just the hands, wrists, ankles and feet – others did not. Cohen recalled that the intent was to include the arms and legs since they did not contain sensitive organs. Both Curtis and Tell said that in their opinion the arms and legs should not be included because of the additional heat load to the body at the relaxed limits.

FOR ACTION

C. K. Chou will move the SCC-34 wording regarding the pinna to SC-4 for approval.

R. Petersen will move the rationale approved by SC-4 to SCC-28 for approval.

A. Brecher noted that the concern should not be so much with the pinna but with the underlying tissue.

15. New Business

The presentation by B. Stuck and W. Wolbarsht relating new CO₂ laser data to millimeter waves was deferred since neither was in attendance. (B. Stuck had to leave because of illness.)

16. Next Meeting

The next meeting will held in conjunction with the BEMS meeting in June 2001 in St. Paul, MN.

17. Adjourn

There being no further business, upon a motion by L. Heynick and a second by M. Ziskin, the meeting was adjourned at 12:05 PM.

Subcommittee 4 Meeting,

Holiday Inn Riverwalk Hotel

215 St. Mary's Street

San Antonio, TX

Attachments

- 1. List of Attendees**
- 2. Approved Agenda**
- 3. SC-4 Timetable**
- 4. Cumulative Distribution of Scores of Reviewed Papers (RAWG)**
- 5. Engineering Evaluation WG Report (Hurt)**
- 6. *In Vivo* Evaluation WG Report (Blick)**
- 7. Members of the Literature Evaluation WGs**
- 8. Copy of Overheads – Selection of an Adverse Effect Level (Sheppard)**
- 9. Copy of Overheads – Single versus Two Tiers (Erdreich)**
- 10. Copy of Overheads – Peak Power Limits (D’Andrea)**
- 11. Copy of Overheads – Replication versus Validation (Curtis)**
- 12. Draft of J. R. Ashley Proposal**
- 13. Revised Timetable**
- 14. Pinna Proposal**

Attendance List
Subcommittee 4 Meeting,

Holiday Inn Riverwalk Hotel
215 St. Mary's Street
San Antonio, TX

Friday, November 17, 2000
1:00 PM - 5:00 PM

Saturday, November 18, 2000
8:00 AM - Noon

Name	Affiliation	Country	Status
1. Adair, Eleanor	USAF	US	M
2. Bailey, William	Exponent	US	M
3. Barbin, Mandel	Motorola	Brazil	O
4. Baron, David	Holiday Industries	US	O
5. Biby, Richard	Sitesate, Inc.	US	O
6. Black, David	Enviromedix	NZ	O
7. Blick, Dennis	Veridian	US	M
8. Bodemann, Ralf	Siemens AG	Germany	O
9. Brecher, Aviva	DOT Volpe Center	US	M
10. Cao, Zhaojin	Inst. Env. Health Monitoring	China	O
11. Chadwick, Philip	Microwave Consultants	UK	M
12. Chickamoto, Kazuhiko	Japan NUS Co Ltd	Japan	O
13. Chou, C. K.	Motorola	US	M
14. Clemens, Chris	TNO Physics and Electronics Lab.	The Netherlands	O
15. Cleveland, Robert	FCC/OET	US	M
16. Cohen, Jules	Consultant	US	M
17. Curtis, Robert	OSHA	US	M
18. D'Andrea, John	Naval Health Research	US	M
19. DeFrank, John	US Army CHPPM	US	O
20. Erdreich, Linda	Bailey Research Associates	US	M
21. Ericksen, Dane	Hammett & Edison	US	M
22. Gardner, Robert	MoD D SGF Pol	UK	O
23. Gettman, Ken	NEMA	US	O

Approved SC-4 Minutes (November, 2000 Meeting)

Name	Affiliation	Country	Status
24. Gibney, Kelly	BC Hydro	CA	O
25. Gorsuch, Gregory	Navy, Bur Med & Surgery	US	M
26. Haes, Donald	MIT	US	M
27. Hammer, Wayne	SPAWAR Systems	US	M
28. Heynick, Louis	Consultant	US	M
29. Hopkinson, Philip	Square D	US	O
30. Hurt, William	USAF	US	M
31. Ivans, Veronica	Medtronix, Inc	US	M
32. Jackson, David	USA Wireless	US	O
33. Jaffa, Kent	Pacificorp	US	M
34. Jauchem, James	USAF	US	O
35. Johnson, Sheila	Neuroscience Consultants	UK	O
36. Kandel, Shaiela	SOREQ NRC	Israel	O
37. Klauenberg, B. Jon	USAF	US	M
38. Lang, Sakari	Nokia Research	Finland	O
39. Lathrop, Janet	Consultant	US	O
40. Lotz, Gregory	NIOSH	US	M
41. Mantiplay, Ed	FCC/OET	US	M
42. McManus, Tom	Dept Public Enterprise	Ireland	M
43. Meltz, Martin	University of Texas	US	M
44. Murphy, Michael	AFRL/HEDR	US	M
45. Nghiem, David	USA Wireless	US	O
46. Olsen, Richard	USN NHRC Detachment	US	M
47. Osepchuk, John	Full Spectrum Consulting	US	M
48. Owen, Russell	FDA/CDRH	US	M
49. Pakhomov, Andrei	MsKesson Bio Services	US	M
50. Petersen, Ron	Lucent Technologies	US	M
51. Petin, Vladislav	Res. Inst. Med. Radiology	Russia	O
52. Proctor, Ken	US Army	US	O
53. Quan, Gregory	BC Hydro	CA	O
54. Reilly, J. Patrick	Metatec Assoc	US	M
55. Roberts, Brad	US Army CHPPM	US	M
56. Rubtsova, Nina	RAMS Inst. Occ. Health	Russia	O
57. Scanlon, William	Center for Comm. Eng	UK	O

Approved SC-4 Minutes (November, 2000 Meeting)

Name	Affiliation	Country	Status
58. Scozzafava, Denise	IEEE	US	O
59. Sena, Deborah	Lucent Technologies	US	O
60. Sheppard, Asher	Asher Sheppard Consulting	US	M
61. Swicord, Mays	Motorola	US	M
62. Tattersall, John	DERA	UK	O
63. Tell, Richard	Richard Tell Associates	US	M
64. Thansandote, Art	Health Canada	CA	O
65. Varanelli, Arthur	Raytheon	US	M
66. Van Rongen	Health Council Netherlands	The Netherlands	O
67. Watkins, Cleveland	Consultant	US	O
68. Williams, Louis	Louis Williams Consulting	US	M
69. Ziskin, Marvin	Temple University	US	M

M = Member; O = Observer

IEEE SCC-28 Subcommittee 4
Safety Levels with Respect to Human Exposure to Radio Frequency
Electromagnetic Fields, 3 kHz to 300 GHz

Holiday Inn Riverwalk
217 N. St. Mary's Street
San Antonio, Texas

November 17, 2000
1:00 to 5:00 PM

November 18, 2000
8:00-12:00 AM

Tentative Agenda

- | | |
|---|----------------------|
| 1. Call to Order | <i>D'Andrea/Chou</i> |
| 2. Introduction of those Present | |
| 3. Approval of Agenda | <i>D'Andrea/Chou</i> |
| 4. Approval of the Minutes of June 9, 2000 Meeting | <i>D'Andrea/Chou</i> |
| 5. Secretary's Report | <i>Petersen</i> |
| 6. Chairman's Report | <i>D'Andrea/Chou</i> |
| 7. SCC28 EXCOM Report | <i>Osepchuk</i> |
| 8. Risk Assessment Working Group Report | <i>Tell</i> |
| 9. Mechanism Working Group Report | <i>Sheppard</i> |
| 10. Literature Evaluation Working Group Reports | |
| a) Literature Surveillance | <i>Heynick</i> |
| b) Engineering | <i>Hurt</i> |
| c) In Vitro | <i>Meltz</i> |
| d) In Vivo | <i>Blick</i> |
| e) Epidemiology | <i>Erdreich</i> |
| 11. Editorial Committee Reports | |
| a) Second Revision Working Group meeting | <i>Chou</i> |
| b) Topic Reports | |
| i) Spark discharge and induced current | <i>Reilly</i> |

- | | |
|--|----------------------|
| ii) Thermoregulation | <i>Adair</i> |
| iii) Non-thermal effects | <i>Heynick</i> |
| iv) Selection of an Adverse Effect Level | <i>Sheppard</i> |
| v) Whole body SAR limit | <i>Chou/D'Andrea</i> |
| vi) Biological Basis for Local SAR Limit | <i>Meltz</i> |
| vii) Spatial averaging, averaging volume | <i>Tell</i> |
| viii) Single vs. two tier | <i>Erdreich</i> |
| ix) Peak power limits | <i>D'Andrea</i> |
| x) Low power device exclusion, measurement distance
& harmonization with ICNIRP | <i>Petersen</i> |
| xi) Averaging time 6 GHz to 300 GHz | <i>Foster</i> |
| xii) Replication/Validation | <i>Curtis</i> |
| c) Ashley proposal | <i>Roberts</i> |
| 12. Revision Schedule | <i>D'Andrea</i> |
| 13. Pinna Proposal Report | <i>Adair</i> |
| 14. Interpretations Working Group | <i>Hatfield</i> |
| 15. Other Old Business | |
| 16. New Business | |
| a) Literature review results dissemination | <i>Chou</i> |
| 17. Date and Place of Next Meeting | <i>D'Andrea/Chou</i> |
| 18. Adjournment | |

Literature Evaluation Working Group Members

***In Vivo* Reviewers:**

In the last 18 months, 20 reviewers have provided 450 evaluations, an average of 22.5 per reviewer. The range of reviews per reviewer is from 1 to 77, with 3 reviewers providing at least 55 reviews each.

These contributors are:

Dennis Blick	John Tattersall
John DeLorge	Brenda Cobb
Eleanor Adair	Ronald Seaman
Joe Morrissey	James Jauchem
Greg Lapin	Tammy Utteridge
Don Spiers	Vijayalami
Shin-Tsu Lu	Andrei Pakhomov
Stephanie Miller	Marvin Ziskin
Michael Murphy	Thomas Walters
Kathy Ryan	Jack Monahan

Unfortunately, four of these reviewers are no longer active; replacements and additions are sorely needed.

Additional individuals who have volunteered or have contributed in the past are:

Sheila Johnston	Ed Elson
Jerrold Bushberg	George Marmaro
David Black	Tadeusz Babij
Patrick Mason	John Orr
James Merritt	Don Justesen
B. Jon Klauenberg	William Bailey
Greg Lotz	Michael Cook
Jack Monahan	Bruce Wenger
Paul Heroux	

Engineering Reviewers

Here is list of current Eng WG members.

Mr. Edward Aslan
Mr. Howard Bassen
Dr. C.K. Chou
Dr. Jules Cohen
Dr. John DeFrank
Dr. Kenneth R. Foster
Dr. James B. Hatfield
Mr. Charles Hicks
Mr. William D. Hurt
Dr. John A. Leonowich
Dr. Edwin D. Mantiplay

Dr. Michael R. Moore
Dr. Richard G. Olsen
Dr. John M. Osepchuk
Mr. R. C. Petersen
Dr. Louis A. Williams, Jr.
Dr. Antonio Faraone
Dr. Richard Biby
Dr. Vitas Anderson
Dr. Roger Tay
Dr. Ken Joyner

SELECTION OF AN ADVERSE EFFECTS LEVEL

Definitions:

Adverse Effect—diminished health as manifested by organic disease, tissue damage, impaired mental and behavioral function, reduced longevity, and defective or deficient reproduction; an alteration in a physiological state or function to a degree that is associated with disease through an established model.

Potentially Adverse Effect—physiological change observed in the absence of adverse effects and in the absence of an established model for adverse effects or at a low level where established models are not reliable.

SELECTION OF AN ADVERSE EFFECTS LEVEL

Note on Frequency Dependence: For clarity, frequency dependence of effects is omitted in this outline, but is an essential parameter in treating each topic.

Part One—Identification Of Adverse Effects

I. Adverse and Potentially Adverse Effects

Effects caused by currents introduced into the body by contact, electric induction, and magnetic induction

Adverse: Currents that cause tetanus, burns, tissue damage, cardiac excitation, cardiac arrhythmias, involuntary motor responses, seizures, electroporation.

Potentially Adverse: Currents that may cause involuntary responses, uncomfortable or painful sensations

Potentially Adverse: Currents that cause effects identified only in animal studies, in vitro studies, or theoretical models

Effects caused by increased temperature of the body or certain tissues

Adverse: effects on essential behavioral and physiological functions and survival

Potentially adverse: Non-disruptive behavioral and physiological changes

Potentially adverse: effects on cells and tissues identified by laboratory research

Effects observed as behavioral responses in animals

Adverse: Changes in feeding, watering, reproductive behavior and other essential physiological functions at physiologically significant levels

Adverse: Dysfunctional changes in learning and other higher CNS functions

Potentially Adverse: Changes in learning and other higher CNS functions without dysfunction

Effects observed as physiological responses of whole animals

Adverse: Diminished health, organic disease, tissue damage, reduced longevity, defective or deficient reproduction, defective or deficient essential physiological functions

Potentially adverse: Effects occurring without adverse effects.

Physiological responses in tissue and cell preparations

Potentially Adverse: Changes in hormone and enzyme activity, metabolism, mitosis, meiosis, neoplastic transformation, cell growth, second messengers, DNA properties, chromosomes, gene expression, protein synthesis, free radicals, etc.

II. Modulation-Dependent Physiological Responses

Any adverse or potentially adverse effect as described in I (above). (Most modulation-dependence was reported in studies on tissue and cell preparations.)

III. Temporal Qualities Of Adverse Effects

- a) Occurs acutely during or shortly after exposure
 - b) Occurs with a delay after acute exposure
 - c) Occurs during or after chronic exposure
 - d) Occurs at a lower level or more severely among susceptible subjects

IV. Recommended Adverse Effect Levels

- a) Levels at which internal currents, current densities and transient currents cause adverse effects, including sensations of heat, pain, or shock
 - 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
- c) Levels at which behavior is adversely affected
- d) Levels at which health or a physiological function are adversely affected
- e) Levels at which another effect is adverse

Part Two—Dosimetric Concerns

I. Relationship of Adverse Effect Levels to Dosimetric Quantities Measured in the Laboratory ⁽³⁾

- f) Metrics and parameters for current-related effects—
- | | | |
|-------------------|---|--------------------------------|
| • Current | | • Tetanus |
| • Current density | → | • Burns |
| • Total current | | • Tissue damage |
| • Contact area | | • Cardiac excitation |
| | | • Cardiac arrhythmia |
| | | • Involuntary muscle responses |
| | | • Seizures |
| | | • Electroporation |

SAR as metric for—

- Temperature increase
- Behavioral response
- Effects on health and physiological functions
- Sensory effects
- Other effects

II. Relationship of Metrics for Adverse Effect Levels to Measures of Electromagnetic Fields ⁽¹⁾

g) Relationship (where applicable) of—

- | | | |
|-------------------|---|--------------------------------|
| • Current | → | • Electric field strength |
| • Current density | | • Magnetic field strength |
| • SAR | | • Pulse energy content |
| • Temperature | | • Electromagnetic flux density |

Notes:

¹ This is not a technical discussion with calculational details, but will make the conceptual link between adverse effects and dosimetric quantities.

² This is not a technical discussion, but serves to complete the linkage from adverse effects to the quantities measured by industrial hygienists using field and current meters.

Part Three—Other Factors Affecting an Adverse Effects Level

III. Factors Affecting Determination of Adverse Effects Levels

h) Role of scientific uncertainty

Role of knowledge gaps

**SC-4 November 17, 2000
DRAFT Outline
Topic area:**

BASIS FOR THE GENERAL POPULATION STANDARD

OVERVIEW:

DRAFT APPROACH HIGHLIGHTS THESE ISSUES:

REASSESS THE LITERATURE AS BASIS FOR STANDARD

EXPANDED DATA BASE 2000

**CONSIDER STANDARD SETTING METHODS IN
WIDESPEAD USE**

FOCUS ON GENERAL POPULATION

**THERMAL PHYSIOLOGY AND REFERENCE TO DETAILED
APPENDIX**

Introduction

Purpose: To Protect the general population
Scientific literature
SAR basis of dose
Thermal

Background

Why revisit the two-tiered RF standard?

- **Sociopolitical; Are workers afforded equal protection?**
- **Science;**
 - **Are the safety factors of 10 and 5 appropriate?**
 - **How do additional research data collected affect standard?**

Approach

Risk assessment approaches used world -wide [threshold, corrections for uncertainty]. W.H.O. applies these principles....

Information on Mechanism

Hazard identification, ID the critical effect

[Qualitative, what effects]

Adverse effect at higher RF level includes behavioral disruption, heat stroke, tissue damage

Adaptive and thermoregulatory responses identified

Biological response; RF tissue warming

Lab data to identify the threshold, or no-observed adverse effect level

Lab data, some epidemiology data, mechanistic data, pertinent to long-term exposure

Developing a population standard from scientific data

[Quantitative, dose-response]

- limits**
- Extrapolating animal data to develop human exposure**
 - Short term versus chronic exposure**
 - Interindividual variability in the human population – [range of thermoregulatory ability]**

NOTE: Inadequate data in any of the above areas may suggest need for 'safety' factor.

Basis for the Maximum Permissible Exposure (MPE) for the General Population

NOTE:

This section summarizes the literature VERY briefly; refers to thermoregulatory appendix regarding animal/ human comparisons, and discusses data gaps and need for safety/uncertainty factors.

-Better thermoregulatory capacity of humans

-Evidence consistent with no cumulative or long-term effects

.

-Safety factor for intra-individual variability and known, large population groups of lowered thermoregulatory capacity

HIGHLIGHTED THESE ISSUES:

REASSESS THE LITERATURE AS BASIS FOR STANDARD

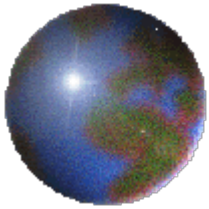
EXPANDED DATA BASE

CONSIDER STANDARD SETTING METHODS IN WIDESPEAD USE

FOCUS ON GENERAL POPULATION

THERMAL PHYSIOLOGY AND REFERENCE TO DETAILED APPENDIX

One Tier or Two Tiers? *Scientific and Practical Issues*



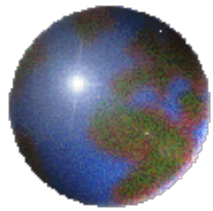
Prepared by

Linda S. Erdreich

Deborah Sena

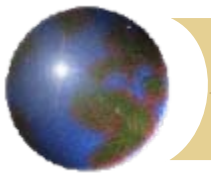
Presented at IEEE SC4 meeting in St. Paul, MN

June 2001



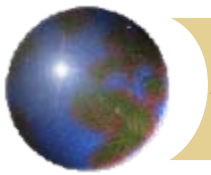
Working toward Consensus

This “white paper” reflects information shared among members of SC4 through interesting discussions, over several years. This report is designed to reflect those thoughtful contributions.



Standards in General – One tier or two?

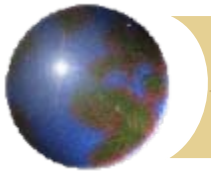
- Many standards for the general public are one tier
 - To protect all, the 'general population', lifelong exposure
 - e.g., drinking water concentrations; ambient air
Health Canada WHO/IPCS, USEPA
- Many standards for workers are one tier
 - To protect nearly all workers from adverse effect
 - Examples: Threshold Limit Values, Occupational Exposure Limits; OSHA



Practical Issues

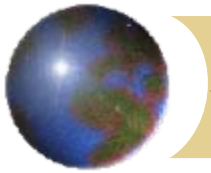
- Different exposure guidance for workers and the general public is common practice, and accepted
- Most RF standards are two-tiered - NRPB is one tier for whole body exposure, two-tiered for contact currents

NOTE: Two sets of exposure guidance exist for many agents. These are determined by different authorities, in different 'standards' [e.g., inhaled chemicals, noise]



Scientific validity - one tier

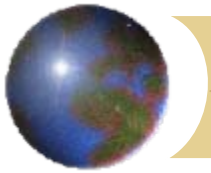
- A valid one- tiered standard can be developed. It needs to:
 - ▣ Identify the population it is designed to protect
 - ▣ Consider the possibility of a range of response values (i.e., inter-individual variability, range of sensitivity)
 - ▣ Protect 'nearly everyone' (95, 99 % ?) in the defined population, under the defined circumstances of exposure



Drawbacks of One Tier for RF

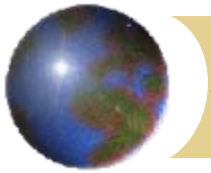
Impractical for covering both work situations, and protecting 'nearly everyone'

- May not provide options for working in areas where levels are higher
- Or, may not protect people who have decreased ability to adapt to an increased heat load include old age, obesity, and hypertension ...and various drugs
- Precedent (common practice) is two tiers



Is there a need for Two Standards or Two Tiers in the Standard?

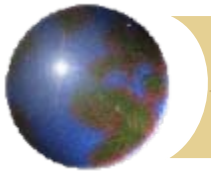
- General public exposure may be more uniform, on average, than worker
- Higher levels may occur in the work environment, including areas where workers function
- To work safely in these areas requires administrative controls



Moving toward Consensus.

The standard(s) should.....

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



Revision Working Group approach

The working group agreed to propose a standard that can protect all members of the population, including children, the sick and the elderly. Time averaging and a safety program (being developed by SC2 and to be included in this standard) will allow occupational group exposures to higher level fields for a shorter time.

Discussion on Peak Power Limits

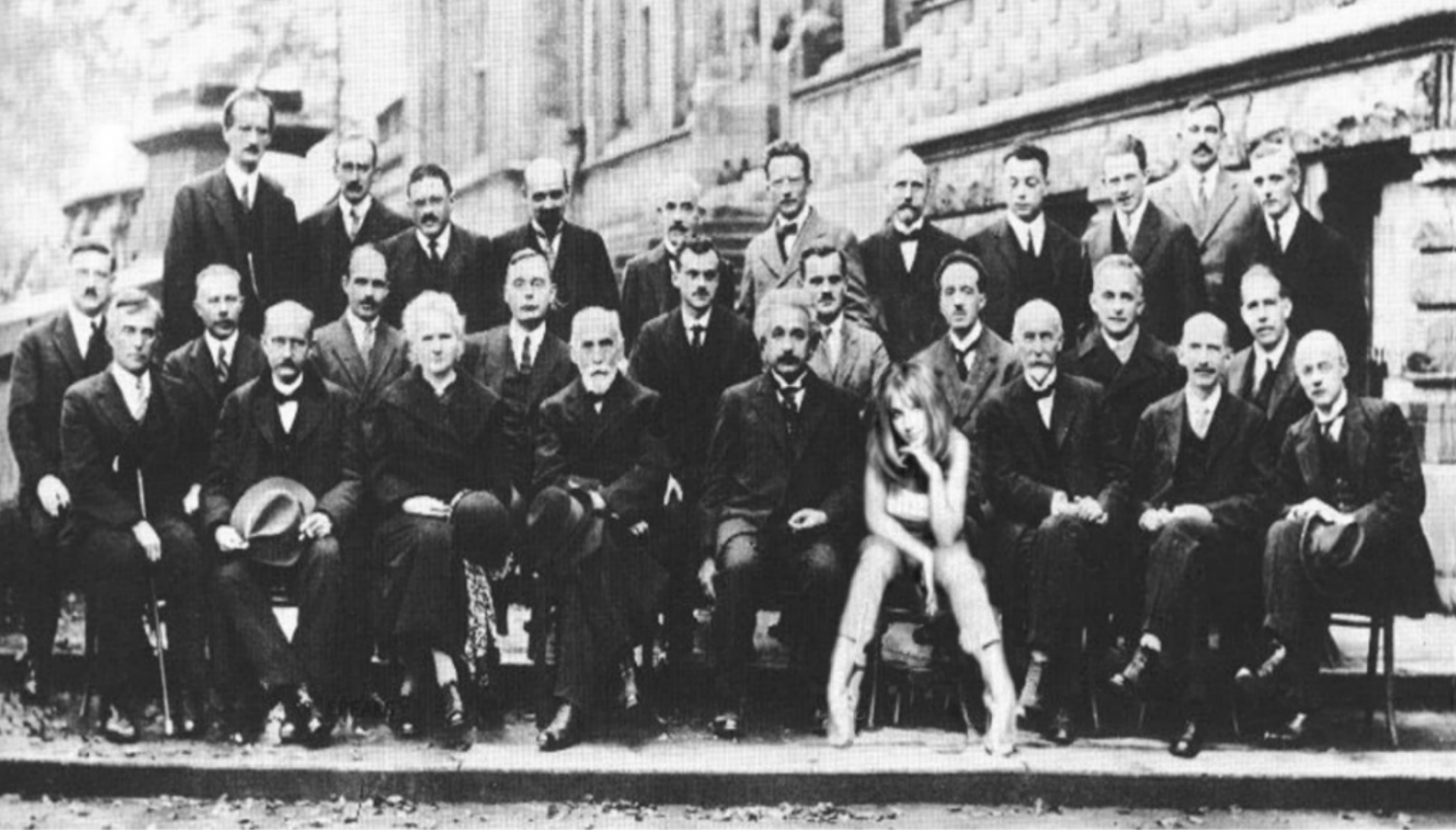
1-2 Dec 2001 – Luxembourg

ICES 2001



Michael R. Murphy, PhD
Chief, RFR Branch
Human Effectiveness Directorate
Air Force Research Laboratory

Peak Limits?



A. PICCARD E. HENRIOT P. EHRENFEST Ed. HERZEN Th. DE DONDER E. SCHRÖDINGER É. VERSCHAFFELT W. PAULI W. HEISENBERG R.H. FOWLER L. BRILLOUIN
P. DEBYE M. KNILSEN W.L. BRAGG H.A. KRAMERS P.A.M. DIRAC A.H. COMPTON L. de BROGLIE M. BORN N. BOHR
I. LANGMUIR M. PLANCK Mme CURIE H.A. LORENTZ A. EINSTEIN B. SPEARS Ch.E. GUYE C.T.R. WILSON O.W. RICHARDSON



Peak Power Limits (microwaves & millimeter waves)



- **Peak SA per Pulse**

- IEEE: 144 J/kg for pulses > 500 ms; based on .4 & .08 W/kg
28.8 J/kg for pulses < 100 ms; limit energy in short pulses
- ICNIRP: 10/2 mJ/kg worker/public to prevent MW hearing
 - head only; averaged over 10 g tissue

- **Peak e- field for pulses**

- IEEE: 100 kV/m (2.65 kW/cm²)
- ICNIRP: none specified in basic restrictions

- **Peak Power Density or Energy Density for mmWaves – needed?**

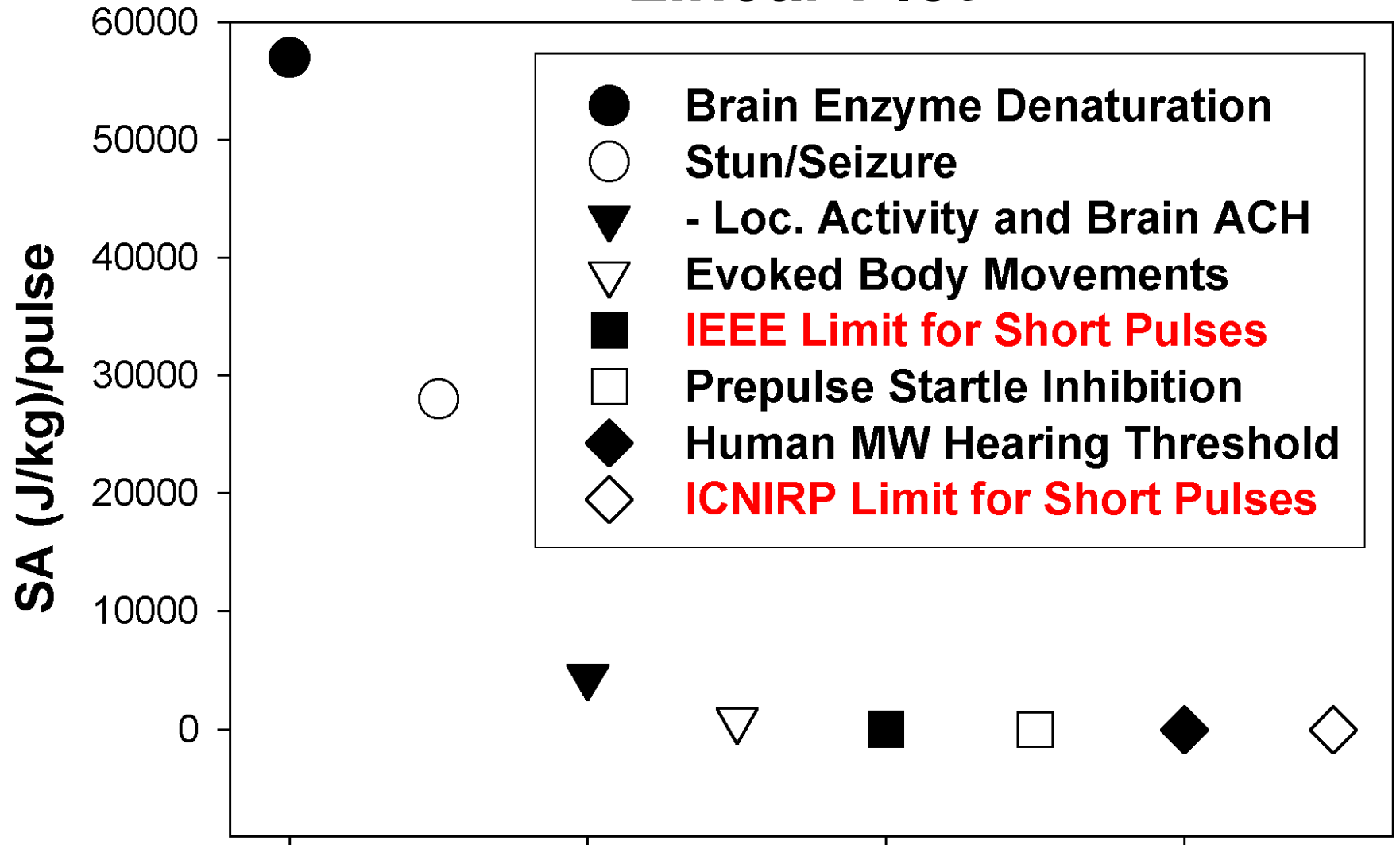
- IEEE: none (all based on time averages for whole or partial body)
- ICNIRP: none (all based on time & spatial averages)
- New IEEE: Discussing moving toward ICNIRP approach but with a peak power density provision added



Biological Effects & Exposure Standards Related to Specific Absorption from 1 Pulse



Linear Plot

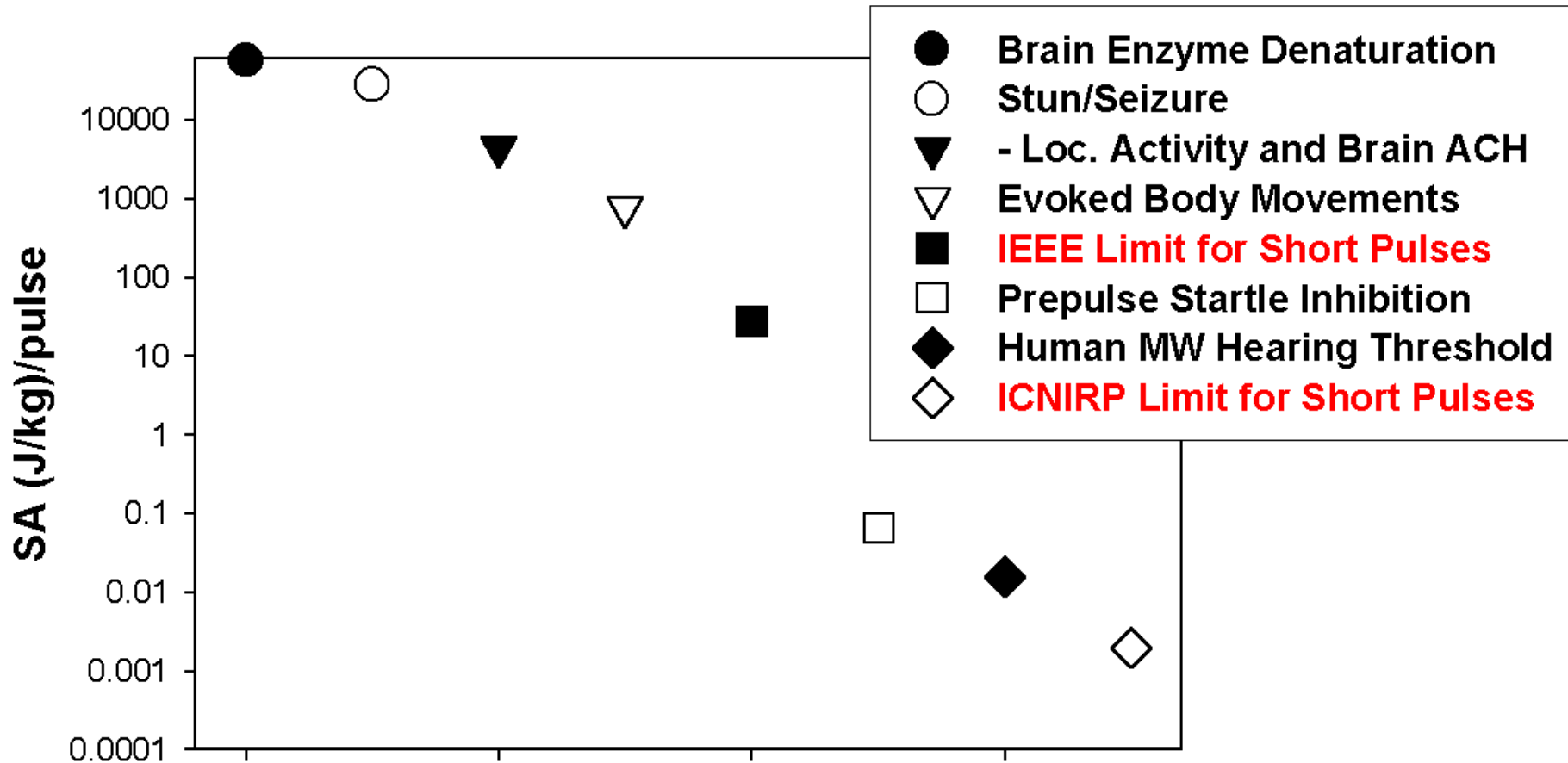




Biological Effects & Exposure Standards Related to Specific Absorption from 1 Pulse



Log Plot

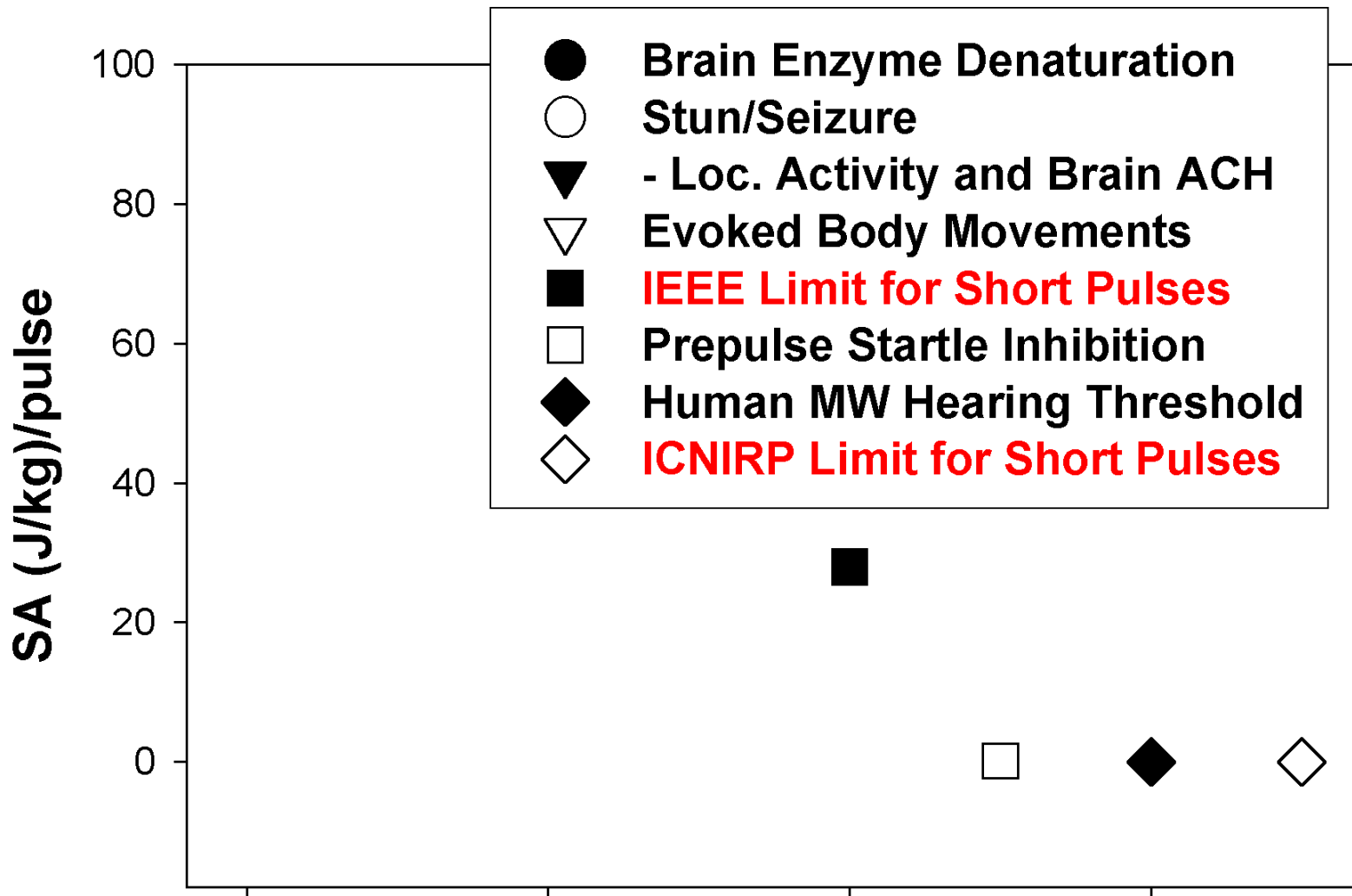




Biological Effects & Exposure Standards Related to Specific Absorption from 1 Pulse



Linear Plot



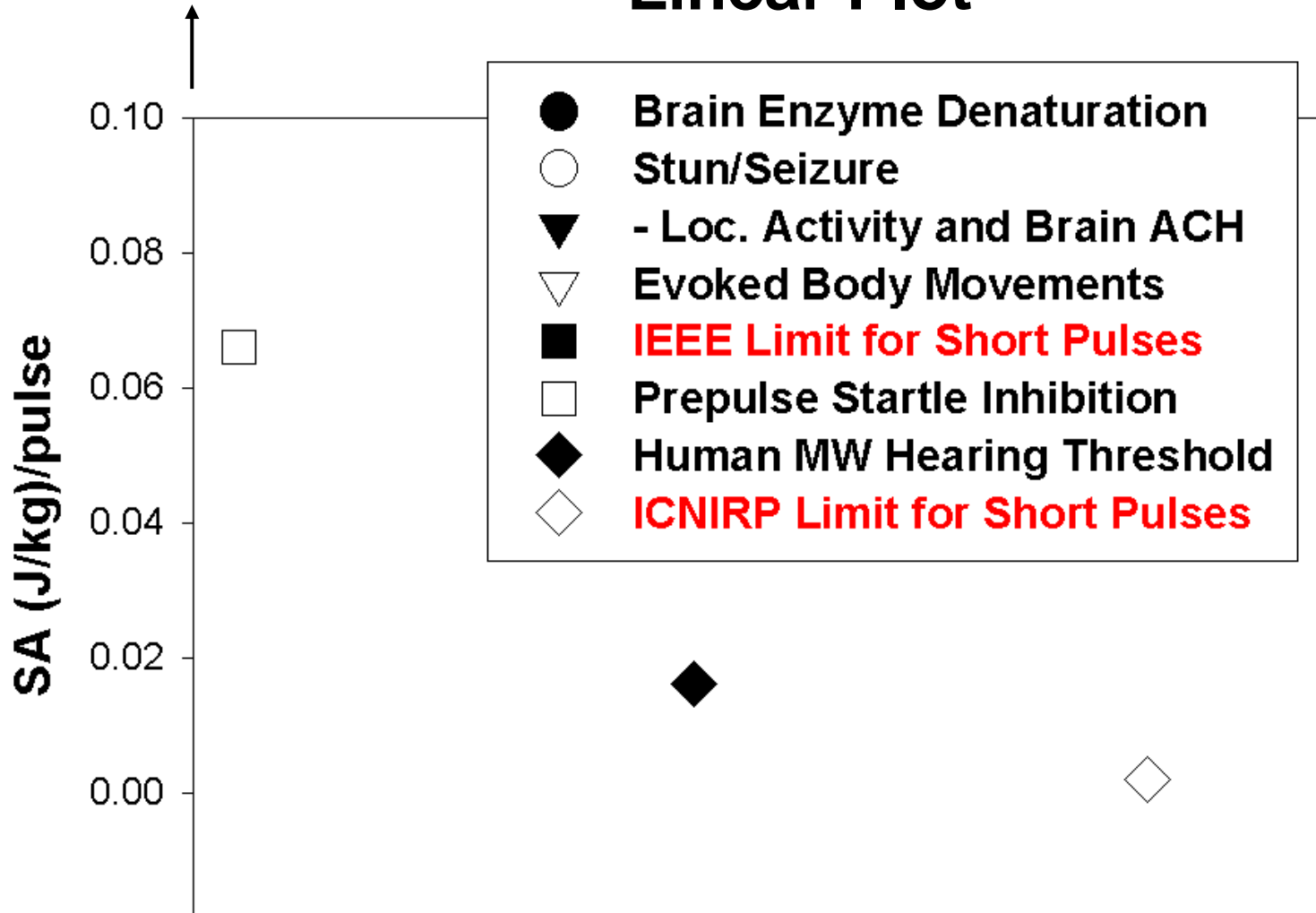


Biological Effects & Exposure Standards Related to Specific Absorption from 1 Pulse



IEEE @ 28.8

Linear Plot





Limits Based on Peak SA & Peak E-field Rational from IEEE Standard



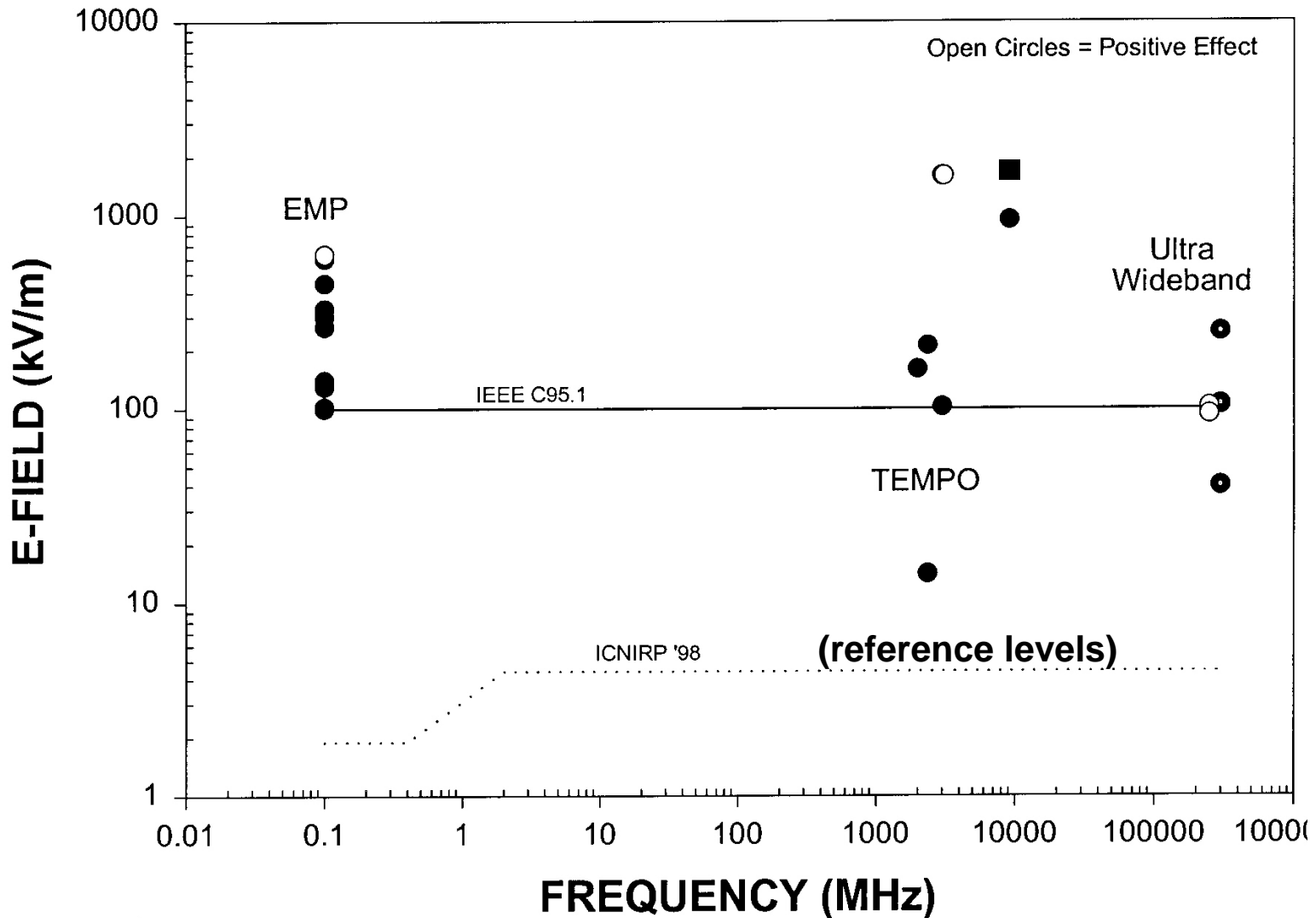
- Preclude high SA for decreasingly short widths of RF pulses
 - Considers the a well- established scientific base of data that includes the auditory effect in humans & RF energy-induced unconsciousness in rats
 - The limit on SA is conservative relative to RF-induced unconsciousness and is well above the threshold for **auditory effect**
 - **The latter (auditory effect) is clearly not deleterious**
- The recommendation for a peak E-field limit of 100 kV/m
 - Based on the necessity to cap the allowable field **below levels at which air breakdown or spark discharges occur**
 - The level chosen is **ultraconservative** in this regard
 - This conservatism is prudent in light of the relative sparseness of studies for very short high-intensity exposures
 - Such studies as do exist are reassuring that this level is indeed far below the threshold or adverse effect.



Limits Based on Peak e-field Biological Data (30 studies)



Plotted without regard to SA, SAR, PRF, duration of exposure, or nature of effect.

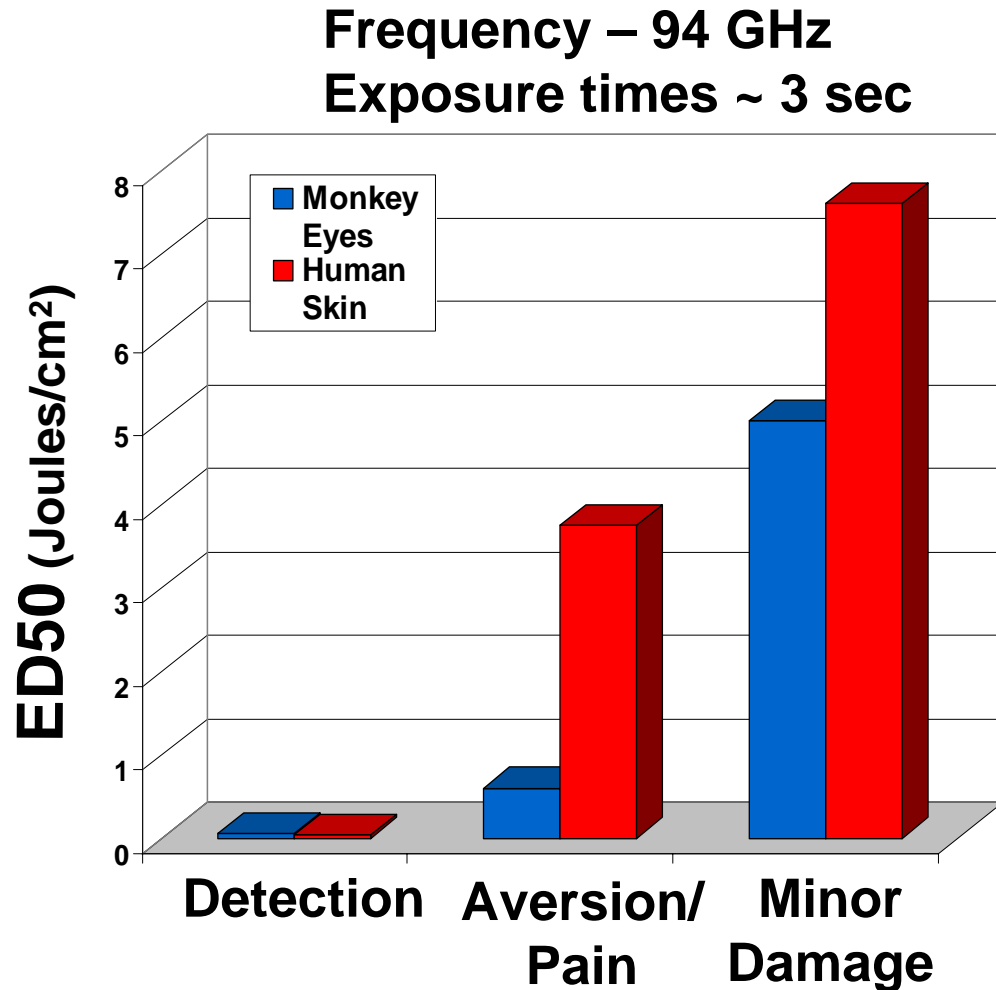




Recent Data on Skin & Eye Response Thresholds to mmWaves



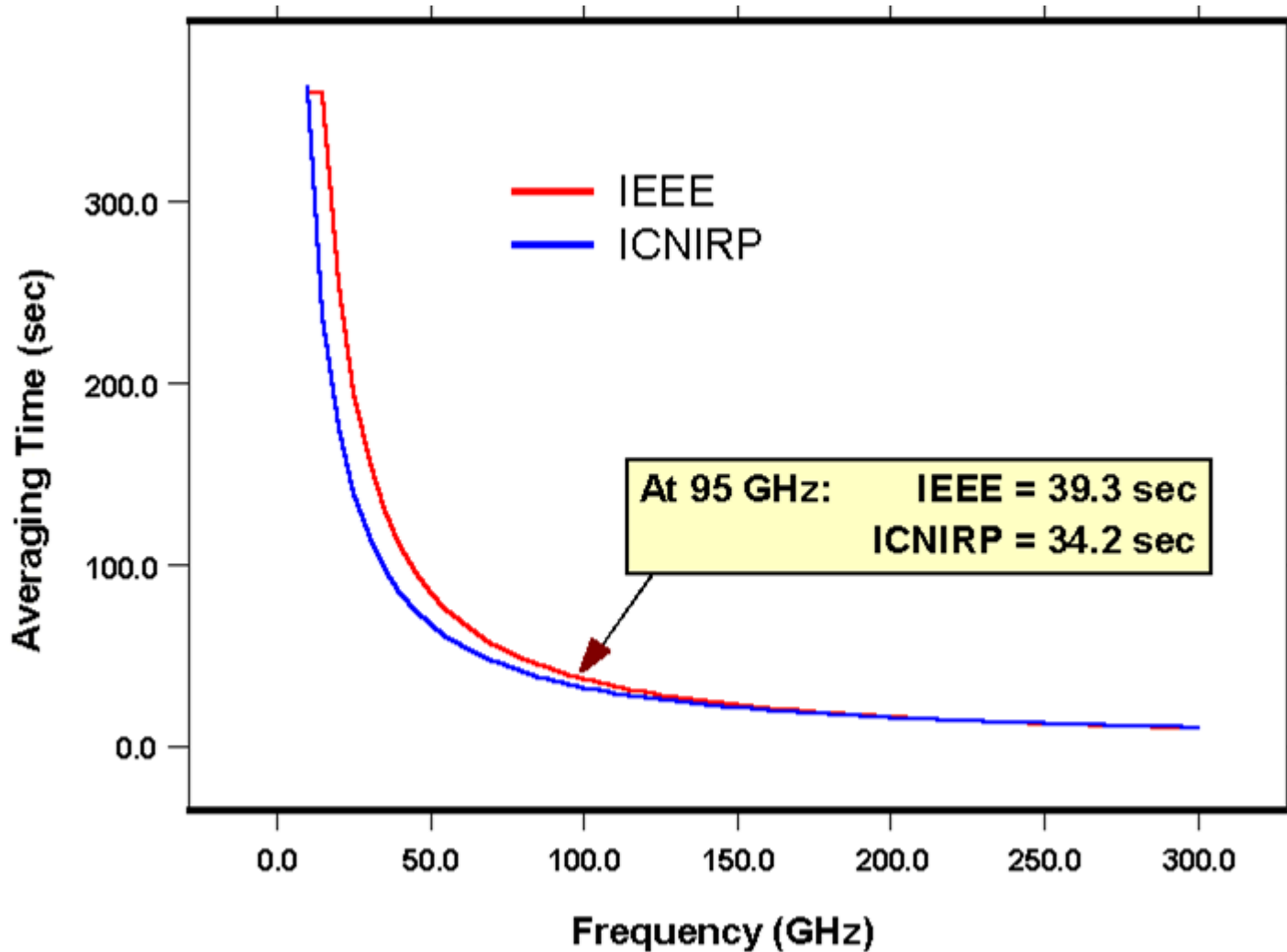
- Mostly based on the research of Blick (skin) & D'Andrea (eyes)
- Detection levels are very low
 - Within IEEE standard
 - Within ICNIRP standard
- Current protection against Aversion/pain
 - Current IEEE – yes
 - ICNIRP - ?
 - New IEEE - ? (needs peak limit?)





ICNIRP & IEEE

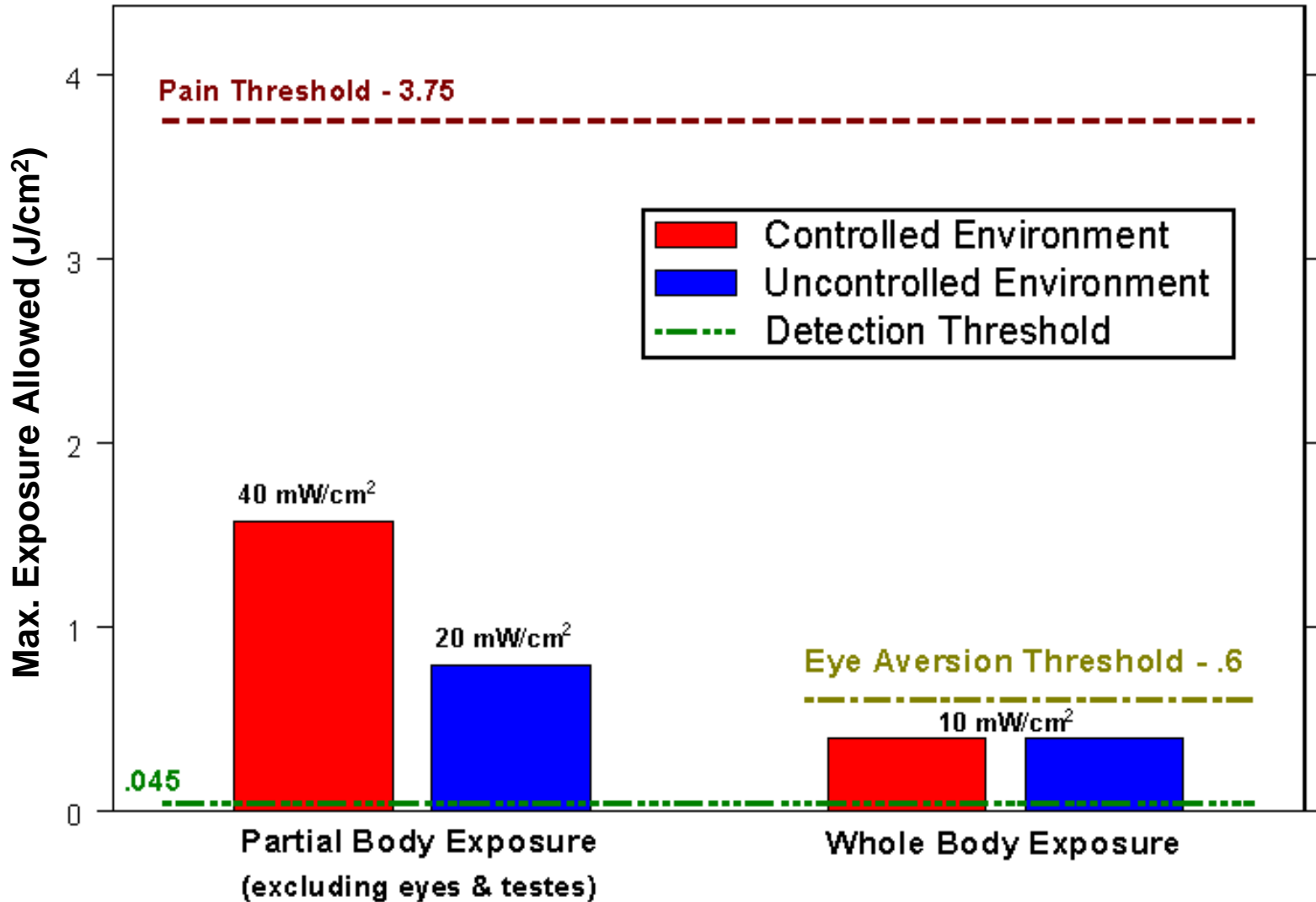
Averaging Time for mmWaves





IEEE Limits for 95 GHz EMF

(averaging time = 39.3 sec)





ICNIRP Limits for mmWaves



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Health Physics

Table 5. Basic restrictions for power density for frequencies between 10 and 300 GHz.^a

Exposure characteristics	Power density (W m^{-2})
Occupational exposure	50
General public	10

^a Note:

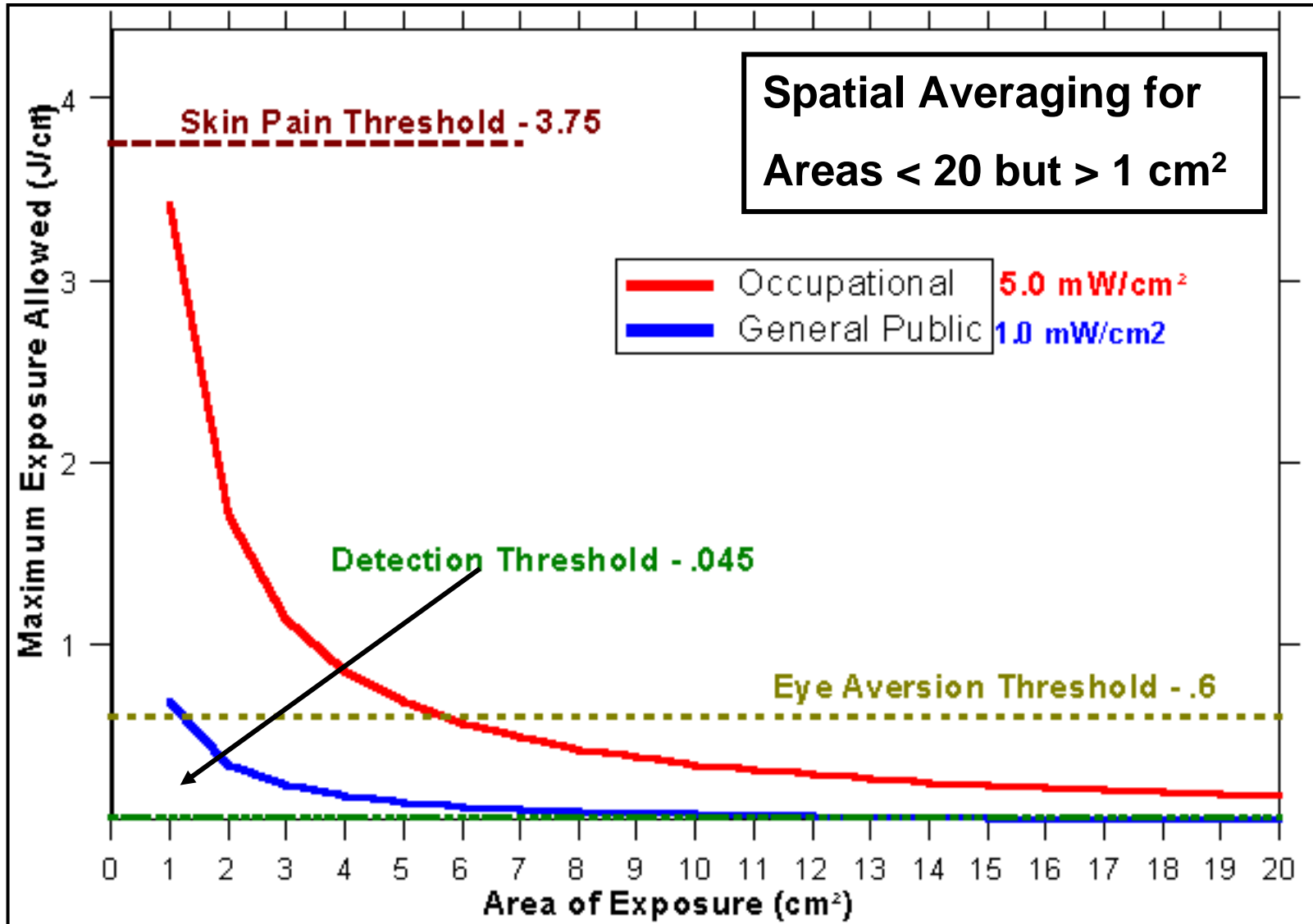
1. Power densities are to be averaged over any 20 cm^2 of exposed area and any $68/f^{1.05}$ -min period (where f is in GHz) to compensate for progressively shorter penetration depth as the frequency increases.
2. Spatial maximum power densities, averaged over 1 cm^2 , should not exceed 20 times the values above.



ICNIRP Limits for 94 GHz EMF



(averaging time = 34.6 sec.)





ICNIRP Limits for mmWaves



510

Health Physics

Table 5. Basic restrictions for power density for frequencies between 10 and 300 GHz.^a

Exposure characteristics	Power density (W m^{-2})
Occupational exposure	50
General public	10

^a Note:

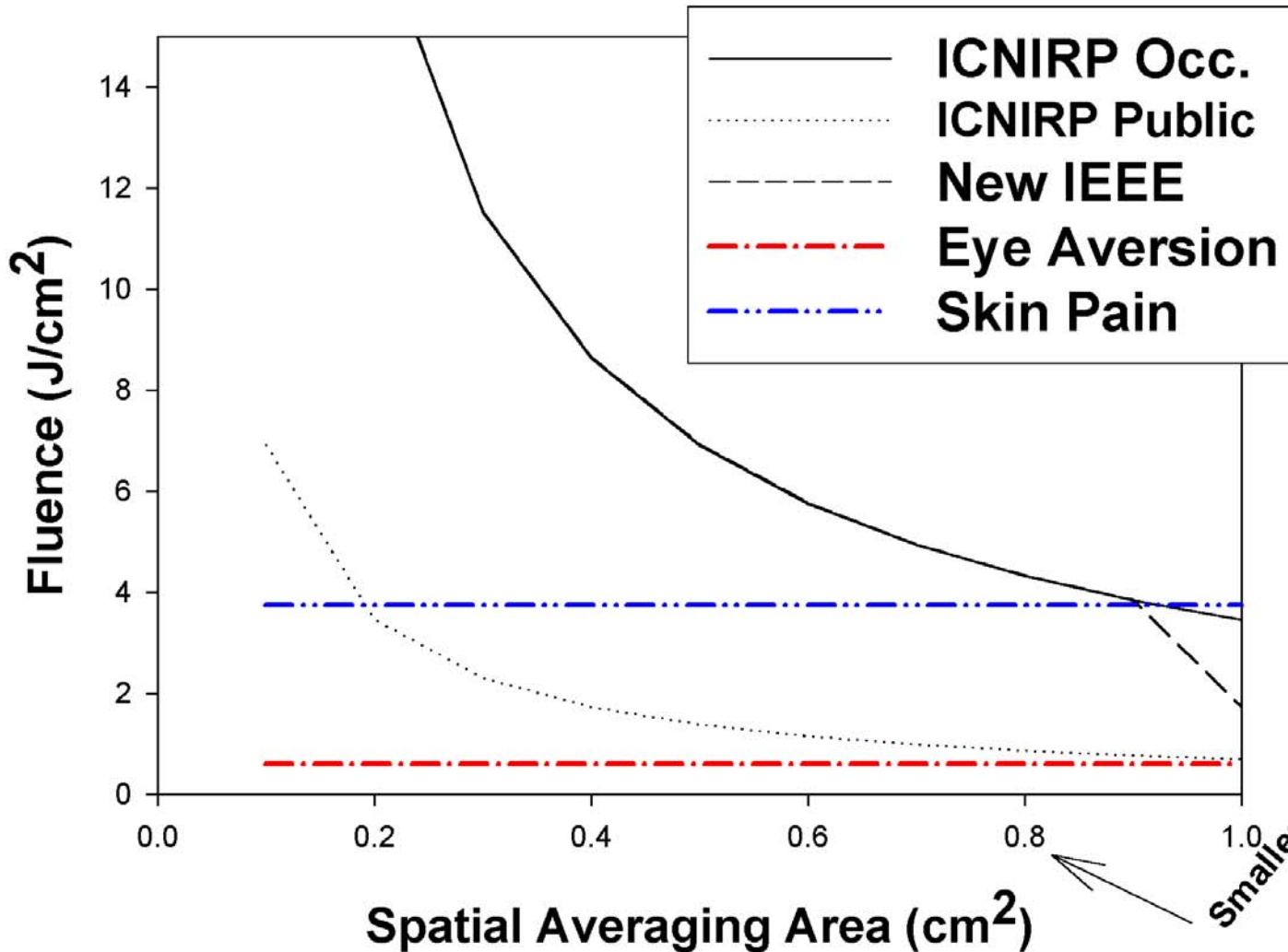
1. Power densities are to be averaged over any 20 cm^2 of exposed area and any $68/f^{1.05}$ -min period (where f is in GHz) to compensate for progressively shorter penetration depth as the frequency increases.
2. Spatial maximum power densities, averaged over 1 cm^2 , should not exceed 20 times the values above.



Limits for mmWaves ICNIRP & “New IEEE”



Spatial Averaging for exposure areas $< 1 \text{ cm}^2$



Smallest spot size for 94GHz ?



Limits for mmWaves

Is there really a problem?



- **Can mmWave exposure spots get that small?**
 - Radiated field?
 - Open ended wave guide?
- **As spots get smaller, heat loss to surrounding area becomes greater**
 - Does mean there is no problem?
 - Or will it still exist as exposure time decreases
- **If a problem exists, how can it be eliminated?**
 - Peak power density that overrides spatial averaging
 - Peak energy density (fluence) for exposure times less than a certain duration (e.g., based on pain threshold)
 - ???

Replication/Validation

Bob Curtis (9-8-00)

The primary issue is whether to establish a criteria of replication/validation for studies used in developing the standard. Meeting the criteria would promote the "scientific bases" and credibility of the standard. Conversely, a rigid adherence to such a criteria may exclude important papers which have not been replicated.

The wording of the current standard (see below) allows for exceptions, and similar wording is appropriate for the new standard.

"A prime criterion governing this first selection was peer review before publication. Presentations at recent scientific symposia or abstracts thereof were excluded from consideration (with few exceptions)..." p. 21.

"Only those reports with adequate dosimetry were judged acceptable. The relevance of each of these reports to standards setting was evaluated, as were the scientific quality and originality of the data, reliability, and evidence of adverse effects. The evaluation stressed thresholds of adverse effects and the extent to which findings had been verified in independent investigations. Reports embodying questionable statistical methods were evaluated further by Statistical Evaluation Working Group. The acceptable reports were then funneled to the Risk Assessment Working Group..." p. 22.

Contrary to the first sentence of the above paragraph, some on the committee have argued that even studies without "adequate dosimetry" could be useful in establishing the existence of "knowledge gaps". Even if these studies can not be used to set quantitative exposure limits, they may be considered in a subjective judgment regarding "safety factors".

The only comments received by the chair on replication/validation are those included in the "federal RF working group letter" (see Fall 1999 mailing). Their comments also argue for variances from a rigid criteria for important studies.

"Published peer-reviewed studies that have been independently replicated/validated should be used to establish the adverse effects level from which exposure guidelines are derived. The definition of "replicated/validated" should not be so restrictive to disallow the use of a set of reports that are scientifically valid but are not an exact replications/validation of specific experimental procedures and results.

Peer-reviewed, published studies that may not be considered to be replicated/validated, but are well done and show potentially important health

impacts provide important information regarding uncertainties in the data base used to set the adverse effect level (e.g., incomplete data base)."
Federal RF Interagency Work Group, (in Fall 1999 mailing).

Finally, it is possible to classify studies based on replication/validation which determines their potential relevancy in developing a standard. For example, in order of decreasing replication/validation:

- Sufficient to establish exposure limits.
- Sufficient for establishing the existence of gaps of knowledge which may be considered subjectively in establishing "safety factors."
- Sufficient for establishing the need for more research, but not relevant for setting standards. We may recommend additional research.
- Not sufficient for our objectives in any way.

As a practical application, any study the committee judges to be important for establishing a standard can and should be used. However, it is important to recognize (and document as appropriate) when we make exceptions to traditional replication/validation criteria.

Dr. Bob Ashley's Proposal

Proposal (basically): Get rid of current standards that rely greatly on “illuminating field” measurements and replace with a standard based on E-Field measurements at the surface of the skin.

Dr. Ashley feels that internal E-fields are maximum at the surface of the skin and that measurements of these E-fields are a better indicator of the “onset” of hazardous conditions than the measurement of Illuminating Fields. By measuring electric fields on the skin surface and using the corresponding tissue conductivity (and permittivity), it can be determined more accurately whether SAR levels have been exceeded.

E-field Level Proposed:

100 V/m throughout frequency range.

Methods for Determining Compliance and Establishing Exposure Boundary:

The induced electric field would be measured on the skin of a volunteer by using a voltmeter equipped with a special 2-pronged probe. The prongs would be 1 cm apart.

A maximum permissible exposure boundary (MPEB) near a radiating structure would be established by making surface E-field readings on the volunteer, determining where if any 100 V/m levels occur. If they are present, this is where the boundary is established. People would be restricted from these areas.

He anticipates that the highest levels would be at the ankles in Spatially Non-uniform fields.

Points of Consideration of Bob Ashley's Proposal:

Internal electric fields and current density can be used for determining SAR in constant tissue density.

Present methods of measuring E and H fields in “unperturbed” near field environments do not always give the same values as those when a person “perturbs” the field – there can be great variations.

Measuring induced E-fields at the skin could be a useful “supplemental” tool.

Problems We Have With the Proposal:

Internal hot spots

Spatial non-uniform field measurement issues would still exist

Ability to have good skin contact over a person's body

Volunteer issue – don't always have one available

E-field measurements at skin will not reduce the total number of measurements

Measuring personnel would have to be educated on different tissue conductivities of the body

Approved SC-4 Minutes (November, 2000 Meeting)

Specialized equipment would have to be developed

No induced current or contact current guidelines/standards are recommended in proposal.

REVISED TIME-TABLE

November - June

Literature Review Task Force will report status of literature review to Chou on 1st day of each month.

Feb 15- All topic leaders provide draft of topic areas to Chou.

Mar 1-2 Third revision Group meeting in Tempe, AZ. Discuss all the topic drafts and list changes needed to finalize each report.

April 1- Chou receives back the revised Topic area drafts (with full references), and emails to SC-4 membership for review and comments.

May 1- Send email comments/reviews to topic leaders for final revision of topic area reports.

May 15- Chou receives final revisions of topic areas and assembles into draft standard.

June 8- The draft standard will be discussed at SC-4 meeting. Other changes to standard can be raised and considered.

Deadlines set for next steps

Pinna Proposal (by SCC34SC2):

(1) Reword the IEEE C95.1-1999 sections on pages 11 and 12.

4.2.1 (a) the exposure conditions can be shown, by appropriate techniques, to produce specific absorption rates (SARs): 1) below 0.4 W/kg as averaged over the whole body, 2) spatial peak SAR values at any location in the body (excluding extremities) shall not exceed 8 W/kg as averaged over a 1 g tissue volume in the shape of a cube, 3) spatial peak SAR at any location in the extremities only (pinna, hands, wrists, feet, and ankles) shall not exceed 20 W/kg, as averaged over a 10 g tissue volume in the shape of a cube. The 1 g or 10 g tissue volumes are defined as cubical volumes containing the appropriate tissue types that are centered at the location. For this purpose, "location" is defined as either the point where the geometric center of the electric field probe sensors are located during an experimental measurement, or the location of the incremental volume (voxel) in a numerical computation.

4.2.2 (a) the exposure conditions can be shown, by appropriate techniques, to produce specific absorption rates (SARs): 1) below 0.08 W/kg as averaged over the whole body, 2) spatial peak SAR values at any location in the body (excluding extremities) shall not exceed 1.6 W/kg as averaged over a 1 g tissue volume in the shape of a cube, 3) spatial peak SAR at any location in the extremities only (pinna, hands, wrists, feet, and ankles) shall not exceed 4 W/kg, as averaged over a 10 g tissue volume in the shape of a cube.

The 1 g or 10 g tissue volumes are defined as cubical volumes containing the appropriate tissue types are centered at the location. For this purpose, "location" is defined as either the point where the geometric center of the electric field probe sensors are located during an experimental measurement, or the location of the incremental volume (voxel) in a numerical computation.

(2) Eliminate the paragraphs immediately following Sections 4.2.1 (b) and 4.2.2 (b) and replace with the following:

When averaging SAR in body tissue or extremity tissue over a 1 g or 10 g volume, respectively, only SAR values from the appropriate tissue type may be considered in the averaging. If both tissue types are found together in any cubic volume, then they must be considered separately. For example, when determining average SAR in a 1 g cube containing body tissue, if any extremity tissue is also present in the cube, it must be treated as air (with mass=0 and SAR=0). Similarly, when determining average SAR in a 10 g cube containing extremity tissue, any body tissue present must be treated as air. The orientations of the cubes used for SAR averaging must align with the coordinate axes used in the experimental measurement or numerical computational procedures.

For details of how to average SAR in the body and extremity tissues,

Please refer to IEEE C95.3-200X.

(3) On page 29, last paragraph:

Add "pinna" before "wrists, ankles, hands and feet".

(4) On Page 30, add the following rationale, which was approved by SC4 in September, 2000:

6.11 Rationale for applying extremity limits to the pinna

For purposes of regulating exposure to RF energy, the pinna or auricle of the external ear is considered an "extremity" of the human body, together with hands, feet, wrists, and ankles. The projecting part of the ear lying outside of the head captures sound pressure waves and guides them into the external auditory meatus. The pinna consists of skin, cartilage, fat, and muscle tissues, a composition similar to that of other extremities, and does not contain cells involved in acoustic or other neural functions. The temperature of the pinna usually lies between room temperature and body core temperature. Under thermoneutral conditions the temperature of human skin usually falls within the range 32.0 - 35.0 °C. However, the pinna, being a thin appendage, will normally have a somewhat cooler surface temperature (e.g., ~30 °C) (Guyton and Hall, 1996).

During use of a handheld mobile phone, a pinna may be pressed against the head and an increase in its surface temperature may occur, largely because surface heat loss by convection is impeded. In addition, thermal conduction of heat generated within the device may raise pinna temperature, but calculations and limited experimental measurements indicate that absorption of RF energy has a minimal effect on pinna temperature. To date, there are no reports on pinna temperature during mobile phone use by humans. The results of such studies would vary significantly from model to model because of differences in heat generated by various devices. The contribution of the phone to an increase in pinna temperature is principally due to thermal conduction from the device, not from RF absorption. Joyner, et al. (1995) reported that cheek temperature near an active mobile phone may increase by 1.7 to 4.5 °C relative to the opposite cheek. Bernardi, et al. (2000) calculated a maximum pinna temperature increase from RF energy absorption of 0.23 °C after 80 minutes and an additional increase of ~1.0 °C after 15 minutes from heat conducted from the phone to the ear. Temperature increases in the pinna from heat generated in the device and from RF absorption cannot be harmful even if imposed on an initial pinna temperature that is close to body core temperature. Thermal tolerance of skin and cartilage is well above that of the brain, for which the critical temperature is 41.8 °C (Bull, et al., 1979). Also, during lengthy telephone use, convective heat transfer by the blood will stabilize pinna temperature. Even in hot environments or after exercise, an additional increase of 1 – 2 °C from use of a mobile phone would result in pinna temperatures that are well below the level (~45.0 °C) at which cellular injury or pain will occur (Hendler and Hardy, 1960).

REFERENCES

Bernardi, P., Cavagnaro, M., Pisa, S., and Piuze, E. (2000): "Specific absorption rate and temperature increases in the head of a cellular-phone user." *IEEE Trans Microwave Theory Tech* 48(7):1118 -1126.

Bull, J.M.C., Lees, D.E., Schuette, W.H., et al., (1979): "Whole body hyperthermia: a phase-1 trial of a potential adjuvant to chemotherapy." *Ann Intern Med* 90:317-323.

Guyton, A.C. and Hall, J.E. (1996): *Textbook of Medical Physiology* (9th Edition)
Philadelphia: W.B. Saunders.

Hendler, E. and Hardy, J.D. (1960): "Infrared and microwave effects on skin heating and temperature sensation." *IRE Trans Med Electron* ME-7:143-152.

Joyner, K.H., Anderson, V., Rowley, J.T., Wood, M.P. (1995): "Mobile phones - Interference and dosimetry issues." *BEMS Abstract Book, 17th Annual Meeting, Boston, Massachusetts*, pp. 26-27.