Approved Meeting Minutes

SCC28 Subcommittee 4 Meeting

Sheraton Gunter Hotel
San Antonio, TX 78205
January 19, 2002

1. Call to Order

The meeting was called to order by Co-chairman D'Andrea at 0810 h.

2. Introduction of those Present

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

3. Approval of Agenda

Following a motion by M. Ziskin that was seconded by L. Heynick, the agenda was unanimously approved without modification. (See Attachment 2 for the agenda.)

4. Approval of the Minutes of the June 2001 Meeting

Upon a motion by M. Ziskin that was seconded by L. Heynick, the minutes of the June 2001 meeting were approved without modification.

5. Secretary's Report

Petersen reported that the IEEE-SA Standards Board approved the extension of the PAR for the revision of C95.1-1991 for four more years. He said that a full report would be given the following day at the meeting of the parent committee.

6. Chairman's Report

Co-chairman D'Andrea reviewed the scope of SC-4 and hi-lighted some of the stumbling blocks that have slowed down the process of revising of the 1991 standard, e.g., the literature review process. He pointed out that the white paper process should help move the process. Four Revision Working Group (RWG) meetings have been held so far – the last one was held in Ft. Lauderdale, FL on January 10-11, 2002. The draft strawman

prepared in August was discussed in detail at the Ft. Lauderdale meeting – the recommendations that resulted form that meeting will be discussed today at this meeting.

7. ICES EXCOM Report

Chairman Adair said that a full report would be given at the parent committee meeting the next day. Adair welcomed the new vice-chairman, Ralf Bodemann, and recognized D'Andrea who recently was elected IEEE Fellow. She briefly reviewed the ERA meeting that took place at the end of November in Luxembourg and noted that the international ICES membership is growing steadily. Adair also reported that SC-3 is about ready to go to ballot on the low-frequency standard and that the EXCOM is working with IEEE staff on funding and a number of other issues. She also said that plans are in the works to draft an article on the ICES standards process for publication in *IEEE Spectrum* and announced that the next ICES meetings would be held in Quebec City in conjunction with the 2002 Annual Meeting of the Bioelectromagnetics Society. The meetings would probably begin at noon on Thursday, June 27th and end at noon on Saturday, June 29th.

8. Risk Assessment Working Group Report

D'Andrea reviewed the scope of the Risk Assessment Working Group (RAWG). Tell, Chairman of the RAWG, pointed out that the task of the group is to render an opinion on "riskiness" after the literature evaluation is complete. He said that a group review of the white papers has not been done yet – but could be. He said that he would need guidance, e.g., the RAWG activity might be to create two papers – each with an opposite viewpoint on various aspects of the revision. He gave as an example the issue of "thermal" versus "non-thermal." The intent would be to see how strong an argument can be made for either position. D'Andrea supported the idea and suggested a mini-debate as a follow-up.

Fichtenberg asked if there were reference papers on the risk assessment methodology – Tell responded that there are several but they are not in the database. Fichtenberg then asked whether or not a section of the revision could be devoted to risk assessment methodology and noted that it is critical to show the approach taken by the committee. The consensus of the group was to follow a suggestion by Heynick and hold off on this discussion until the white papers are discussed.

9. Mechanisms Working Group Report

No Report.

10. Harmonization with ICNIRP

Petersen reported that the Revision Working Group (RWG) is considering adopting the ICNIRP peak-spatial average SAR values and averaging mass, i.e., 2 and 10 W/kg averaged over any 10 g of contiguous tissue. He also said that the leadership of ICES has met several times with members of ICNIRP to discuss harmonization, the exchange of drafts and documents, etc. and would continue with these efforts. Woods pointed out that

the ICNIRP and ICES RF basic restrictions are the same but the MPEs are different. He asked if ICES would address this issue – Petersen responded that this is part of the harmonization process.

11. Literature Evaluation Working Group Reports

D'Andrea briefly reviewed the literature evaluation process pointing out that this has been an Achilles heel regarding meeting timelines.

a) Literature Surveillance

Heynick reported that there are currently 1554 citations in the database and 4 more from the BEMS journal will be added. The literature cutoff will be when the 1st draft is complete. He briefly explained the peripheral file, pointing out that the papers in this file would not go through the evaluation process. In response to a question from Fichtenberg, Heynick pointed out that the peripheral file contains, for example, review papers that do not contain original data. Fichtenberg asked if the database could be searched/sorted by the working group members – Heynick said generally no but it is being done by the authors of the white papers.

b) Engineering

Tell noted that it appears that more than one-half of the papers have gone through engineering evaluation – Blick said that he thought that it was probably more than that. Blick also said that the *in vivo* reviews could probably be completed in one more round if the outstanding reviews are received. In response to a question from Fichtenberg, Blick pointed out that the actual reviews from the 1991 standard are probably not available. Fichtenberg noted that it would be important to know how the review process was handled at that time. Adair responded that the RAWG carried out a thorough review at that time under the leadership Dave Janes of the EPA. She said that she personally re-reviewed many of those same papers for this revision. Meltz pointed out that anyone could ask the working group chairs to review papers deemed important. Blick noted that the first papers that are being reviewed are the new papers – Heynick noted that the old papers are being reviewed for preparation of the white papers. Bodemann asked what "long time" means regarding the statement that some papers have been out for a long time, and asked what can be done to move the reviews of these papers along. Blick suggested sending them to different reviewers – nagging doesn't seem to work.

c) *In Vivo*

Blick reported that if the 120 papers now out for review were returned, the evaluation of the papers judged important could be completed in one more round.

d) *In Vitro*

Meltz reported that 235 papers are in the database, 160 have been reviewed. He said that his own workload and delinquent reviewers have slowed the process. Heynick asked if any of the completed reviews have been sent to the RAWG –

Meltz responded that the summaries have not been completed but probably could be in about six months.

e) Epidemiology

D'Andrea noted that Cmdr. Gorsuch has been reassigned and will be replaced on the committee by J. J. King – Col. Ruscio will replace Cmdr. Gorsuch as chairman of the Epidemiology Working Group.

f) Dissemination of Literature Evaluation Results

Petersen reported that he raised this issue with the IEEE-SA counsel, Tom Wettach, who sees no issue with releasing the summary data. Wettach said that he sees it as being no different from any other peer-review process. McManus asked about the purpose of posting scores and suggested that it might not be appropriate since it could persuade others to discount low-score papers D'Andrea said that he thought it was important – it could alert others about papers that are missing data, etc. Fichtenberg asked if the authors could respond to evaluations of their papers or ask for reconsideration – D'Andrea responded that perhaps they could but only under extraordinary circumstances. Osepchuk pointed out that posting the results of the evaluations is a way of alerting the public to the fact that much of the literature is not useful for standard setting. He said that endless debate about the papers is not within the scope of the committee and posting the summaries will send a valuable message regarding the information that should be included in a paper to make it useful. Vijayalaxmi agreed – she said that it is important that journal editors be informed as to what data is required in order for a paper to be useful.

12. Editorial Committee reports

a) Fourth Revision Working Group Meeting

Chou reviewed the summary statements that arose from the January 10-11, 2002 RWG meeting (see Attachment 3). He noted that the 4th meeting of the RWG was originally scheduled to be held in Washington DC on September 13-14, 2001 but was canceled because of the September 11 incident. He explained that a survey/questionnaire containing 18 questions was sent to the members of the RWG and a teleconference was held November 9 to discuss the results. Twenty-six members of the RWG participated. The results of the survey and discussions at the Ft. Lauderdale meeting led to the summary shown in the attachment. He also pointed out that portions of the draft that were prepared in August to stimulate discussion at the September meeting were published in *Microwave News*, discussed in an article in *RCR Magazine* and put up in its entirety on an activist website – even before it was discussed by the members of the RWG.

Each of the 12 summary statements were reviewed and discussed. Regarding statement 2 (*RF safety standard revision should be derived from peer-reviewed publications and documents that are reviewed by the SC4*), it was pointed out that the database includes reports that have not been peer reviewed. Fichtenberg

asked why papers published before 1986 not being considered – Chou responded that they have already been reviewed and are in fact in the database.

Regarding statement 5 (*Safety factor(s) should consider uncertainties in the biological database, e.g., unknown health consequences, measurements, environmental conditions, exposure duration, individual variability, and other factors*), Woods asked if the current standard recognizes sensitive subgroups – Osepchuk responded that it does. He referred to the database on diathermy and the Air Force human study data and pointed out that the MPEs in the current standard contain a significant factor of safety that should afford protection to all. Bassen pointed out the importance of an appropriate definition for "adverse effect" and the consideration of acute versus chronic exposure. Chou noted that "adverse effect," "biological effect," etc. have been carefully defined. He said that key concepts are "harmful," which includes long- and short-term exposures, "established effect" and "adverse effect." Bodemann asked if there is a definition of the term "unknown health consequences" – Chou replied that there is not. Fichtenberg asked how the definition of "adverse effect" would apply regarding cigarette smoking, where a linkage with disease was not established until recently. Meltz pointed out that establishment of an adverse effect means independent replication. He said that the Environmental Mutagen Society knew about the link between cigarette smoking and lung cancer for years – the issue is a red herring regarding an analogy with RF exposure. McManus pointed out that the task of the committee is to achieve consensus on the issues – which does not mean 100%. In response to a question from Fichtenberg, it was explained that IEEE recognizes consensus as agreement by at least 75% of the participants. Bodemann said that he was still concerned about the uncertainty in the biological database and how unknown health effects are going to be addressed. Chou noted that this issue was also raised by Curtis at the RWG meeting and that the summary statements could be changed to address any concerns.

MOTION

R. Bodemann moved to remove the phrase "unknown health consequences" from statement 5.

Heynick seconded the motion. The motion passed with 24 in favor and 1 abstention.

Fichtenberg pointed out that health and safety, e.g., a secondary effect caused by a transient health effect, are different concepts and he recommended including "safety" in the definitions.

Fichtenberg asked for an explanation of the rationale that led to statements 6 (*Non-thermal RF biological effects have not been established and none of the reported non-thermal effects are proven adverse to health – does not apply to electro-stimulation. Thermal effect is the only established adverse effect*) and 7 (*The microwave hearing effect is not adverse and should not be used for setting the peak power limit*). Regarding statement 7, Chou pointed out that microwave hearing is a very weak effect and is only discernible under extraordinary circumstances, e.g., in an anechoic chamber. Fichtenberg said that he knows

people who live near an airport and cannot sleep because they hear the radars. Chou said that it is unlikely that the evoked auditory response is the culprit – the airplane take off noise is orders of magnitude louder. Adair reminded everyone that the committee is focused on science – not anecdotal evidence.

Regarding statement 8 (*The shape and size of the averaging volume and the peak SAR limit will be determined after the WHO temperature workshop in March. The important end point is the temperature change*), Varanelli expressed concern about the workshop – specifically that the workshop is not open, it's not clear what their rationale may be, it's also not clear why reference to the WHO workshop is included in the statement. D'Andrea pointed out that the WG is not bound to the results of the workshop – the resulting papers would be put into the SC-4 review process.

MOTION

A. Varanelli moved to strike reference to the WHO workshop from statement 8.

Murphy seconded the motion.

Discussion. Bodemann said that although he did not know whether statement 8 resulted from pressure by the federal agencies, but he would be concerned if it had.

AMENDMENT TO THE MOTION

T. McManus moved to amend the motion to retain statement 8 but strike everything after "… peak SAR limit…" and add "are still to be determined."

Varanelli and Murphy accepted the amendment to the motion. The question was called and the motion passed unanimously with 24 in favor, 0 against and 0 abstentions.

Statement 8 now reads:

The shape and size of the averaging volume and the peak SAR limit are still to be determined.

Regarding statements 9, 10 and 11, i.e., *RF standard should be harmonized with other international standards to the extent where scientifically defensible*; *Rationales must be documented for all changes relative to the current standard*; and *Will add a section dealing with potentially sensitive subpopulations, such as children*, respectively, Varanelli pointed out that use of the word "potentially" in statement 11 raises the issue of whether or not the revision can be science-based. Chou explained that a section would be added in the revision to address the issue and Adair pointed out that the current standard contains a similar discussion.

MOTION

L. Heynick moved to rewrite statement 11 as follows: "The editorial committee will add in the informative section a paragraph dealing with potentially sensitive subpopulations, such as children."

R. Weller seconded the motion. The motion passed unanimously with 24 in favor, 0 against and 0 abstentions.

Regarding statement 12, i.e., *Keep the two-tier approach (whole body average SAR 0.4 and 0.08 W/kg) and leave the peak SAR value and averaging volume blank, which are to be decided after the WHO temperature workshop results become available,* Meltz asked about where the scientific discussions supporting two tiers would appear in the revision. Chou explained that so far there has been no extensive debate or discussions on the issue – only a paper supporting a single tier. Blick noted that the RWG has not been able to achieve consensus on a single tier.

MOTION

A. Varanelli moved that everything in statement 12 following "… averaging volume blank" be struck.

L. Heynick/ seconded the motion

Discussion. Reilly noted that there seems to be some confusion about the use of the term "two-tier." He pointed out that SC-3 first established a level that protected everyone and then asked if certain populations could be exposed to higher levels and then raised the MPEs for those populations accordingly. Chou said the same issue was addressed at previous SC-4 meetings where there was agreement that the level should be set for protection of 100% of the population but could be raised for certain exposure conditions or populations. Osepchuk suggested that we keep what we now have, two tiers, but only in the resonance region – and asked if this is what we are considering. Chou said that it is and that is all that was discussed.

AMENDMENT TO THE MOTION

T. McManus moved to amend the motion and change statement 12 to "Reconsider the two-tier approach (whole body average SAR 0.4 and 0.08 W/kg), the peak SAR value and the averaging volume."

Varanelli and Heynick accepted the amendment, the question was called and the amended motion passed unanimously with 24 in favor, 0 opposed and 0 abstentions.

The revision of the 12 statements is shown in Attachment 4.

b) Time Schedule (See Attachment 5)

The proposed time schedule was reviewed. In response to a question from Woods, Chou replied that an ad hoc SC-3/SC-4 task group is addressing the MPEs based on electrostimulation. He said that the focus right now is on resolving issues in the SAR region but the entire region will be addressed and changes from the 1991 standard explained. Chou also said that he suggests retaining the 1991 standard except for those parts where change can be soundly supported, and asked for comments. Fichtenberg pointed out that there seems to be different opinions on risk assessment, e.g., thermal versus non-thermal, and

asked if the subcommittee would be flexible for change – Chou responded that it would.

c) Topic Reports

D'Andrea said that he asked the editors for updates – he said that he would have his completed in a few months. Heynick pointed out that some of the information in the white papers is also available on the Air Force's website, i.e., the Heynick/Polson reviews.

1) **Teratogenesis** – The table of contents and overall conclusions of the July 28, 2001 draft were briefly discussed. The conclusion is that there is no scientifically credible evidence that chronic exposure of mothers during pregnancy or of potential fathers to RF EMF at levels at or below the MPEs of the 1991 standard would cause any anomalies in their offspring.

2) **Mutagenesis** – The latest draft of the mutagenesis white paper has been posted on the ICES website.

3) **Non-thermal effects** – A suitable definition for the term "non-thermal effect" was discussed. Meltz suggested that the term not be used since it is not clearly defined. Fichtenberg supported Meltz pointing out that the term means different things to different people. Murphy agreed with Meltz and Fichtenberg adding that the term "non-thermal" is misleading and emotionally charged. There was consensus that "low-level" should be used instead of "non-thermal" with 4 W/kg as a threshold and all papers reporting effects below this threshold should be examined. Heynick suggested looking at the white papers since this had in effect already been done.

4) **Thermoregulation –** Adair briefly discussed the white papers on thermoregulatory response. She pointed out that early recommendations suggested some form of thermal stress as a basis for the revision. One of the white papers supports 1 W/kg as a basic restriction. She is now completing another white paper with David Black – but has not yet heard from him on the revised draft.

5) **Life span –** Elder reported that he is looking for associations reported in the literature. He noted that recently the results of a number of long-term studies have been reported which suggest that there is no association with cancer and lifespan (see Attachment 6). He noted that the Chou, et al., Air Force study reported an increase in the number of tumors but no significant change in lifespan. Fichtenberg asked how associations with cancer could possibly be found in animal studies since the life of rodents is shorter than the latency period for cancer. Elder pointed out that the animals are exposed throughout their life and McManus noted that the rate of cell division is approximately inversely proportional to age of the animal compared with their normal lifespan.

   Elder pointed out that evidence is accumulating that there is no association with RF exposure and cancer or longevity. Vijayalaxmi noted that most recent studies used either cancer-prone animals or animals promoted with

chemicals to initiate cancer. Elder summarized by saying that the weight of evidence supports no association. In response to a question from Fichtenberg regarding the Szmigielski study, Elder replied that that particular study had problems with the procedure – recent work does not support Szmigielski's conclusions.

6) **Ocular effects.** Elder reviewed the tables shown in Attachment 7. He pointed out that the threshold for cataracts is about 100 W/kg in rabbits but the effect has not occurred in primates even at higher exposure levels. He explained that this might have to do with less efficient coupling to the primate eye but perhaps the threshold for primates would be comparable with that of rabbits if the same energy could be transferred. He said that the data show that the subject animals are significantly thermally stressed when exposed to levels that produce opacities. He said that he also disagrees with the early work by Carpenter that suggested cumulative effects and noted that the work by Kues has not been replicated using non-anesthetized animals. He said that the bottom line regarding Kues' work is that the results are not useful at this time. Fichtenberg asked if eyewear had been taken into account – Elder replied that it had not. Chou pointed out that a study done at cellular and PCS frequencies by Joyner, et al., showed a maximum increase in the peak-spatial average SAR in the head of about 29% when eyewear was worn but this is irrelevant because of the high threshold associated with the production of lens opacities.

7) **Evoked auditory response.** Elder reported that he is preparing a paper on the evoked auditory response (RF hearing) but the data is at least 15 years old.

8) **Behavioral effects.** D'Andrea reported that a paper on behavioral effects is being prepared and there is nothing new to report. In response to a question from Fichtenberg, D'Andrea explained that some studies report thresholds for behavioral disruption that are below 4 W/Kg and this is discussed in the paper.

9) **Immunological and hematological effects.** Chou reported that it is unclear whether Heynick or Bushberg, is drafting a white paper on immunological and hematological effects. Heynick said he will not. Chou will check with Bushberg. Heynick noted that the results of earlier work on the subject are posted on the Air Force website.

10) **In vitro effect papers:** Meltz briefly reviewed the content of the proposed paper. In response to a question by Heynick, Meltz said that the paper should be completed by June.

11) **Single versus two-tier**. Chou reported that Erdreich is preparing a white paper on one versus two tiers.

12) **Special topics**. Chou reported that Reilly is addressing the issue of spark-discharge.

d) Discussion of Preliminary Draft

Tell reviewed the history of the draft revision of C95.1-1991 pointing out that discussions at the 3rd RWG meeting in March 2001 led to a decision to develop a

strawman for discussion at the planned September 2001 meeting. He said that he helped draft the normative sections of the draft – others are drafting the informative sections. The document was made available to the RWG in August and was apparently shared with individuals not on the RWG or leaked to the media by a member of the RWG. The draft immediately appeared on an activist website in its entirety, was discussed at length in *Microwave News* and was referred to in a naive and distorted article in *RCR Magazine*. The theme of the articles was that an industry group developed a new draft that "weakened" the existing standard. Tell noted that the draft was prepared to stimulate discussion by the RWG at the September meeting (which was canceled because of the 9/11 event) but was not formally discussed until the 4th RWG meeting in Ft. Lauderdale one week before this meeting. He said that most of the time at the 4th RWG meeting was spent discussing ways to move forward.

Tell then summarized what he felt are key issues. He said that there was criticism about the lack of a rationale, that the draft was prepared and distributed before the literature and white paper process was completed, and the lack of an explanation regarding the relaxed limits. He said that a major difference between the 1991 standard and the draft is that a single tier is recommended in the draft that is based on a WBA SAR of 1 W/kg with an upper cutoff frequency of 3 GHz for the SAR region. Above 3 GHz, where surface absorption is important, the incident power density is averaged over a surface area of 20 cm^2 and the spatial peak SAR is limited to 100 mW/cm^2 over any 1 cm^2 area. Also the averaging mass for determining the peak spatial average SAR was changed from 1 g to 10 g of tissue. Changes in the averaging time were based on the results of the recommendations by Foster and Osepchuk – the remainder of the changes were based on the results of an extensive dosimetry questionnaire that was distributed about a year ago.

Tell then asked for guidance on how to proceed. Meltz suggested developing statements on the appropriateness of either 0.4, 1 or 2 W/kg based on the white papers and leaving a range of values in the draft until a specific value can be determined that is supported by the science. Adair pointed out that the science still supports 4 W/kg as an appropriate threshold for behavioral disruption in laboratory animals. She noted that 0.4 W/kg is about 1/3 of the BMR and about 4-5 times lower than the resting MR. She pointed out that the MR rate in humans could go as high as 16-18 W/kg. Regarding temperature, any temperature change associated with a WBA SAR of 0.4 W/kg would be minuscule. D'Andrea agreed that 4 W/kg is a valid threshold but SARs of 4-5 W/kg are required to obtain consistent results in animal experiments.

Elder raised the issue of the results of Adair's recent human study paper reported in *Bioelectromagnetics*, specifically the results obtained in a 31°C environment where two out of seven subjects judged the exposure "unacceptable." He noted that the study was carried out at 2450 MHz, the exposure duration was 45 min and the reported WBA SAR was 1 W/kg. He also noted that in the 450 MHz study, one subject exposed in a 31°C environment at 24 mW/cm^2 rated the conditions "uncomfortable." The peak SAR was less than 8 W/kg. Tell asked if the point is that some individuals exposed in excess of the current MPEs found the exposure

uncomfortable? Elder replied that it was since the exposure resulted in WBA SARs around 1 W/kg, which is what the RWG considering as the basic restriction.

Fichtenberg said that he is confused about this discussion. He asked how the committee can form a conclusion before all the white papers are completed, read and understood. Tell pointed out that we are only raising issues – the discussion is not intended to drive the next revision of the draft. McManus noted that the discussion originated with the discussion of 4 W/kg as a threshold. He noted that Elder raised questions about Adair's human studies, which provide biological support for the current threshold. He asked Elder if the expression of discomfort by one individual would cause him to change to a lower SAR. Elder replied that the MPEs have to apply to 24 h/day, 365 day per year exposures – this has to be considered when deriving an appropriate safety factor. Tell asked Elder if the "comfort factor" should be considered as a biological endpoint? Before Elder answered, Adair explained that the study subjects were asked "is the environment thermally acceptable?" She noted that the subject could terminate the exposure at any time – none did. Tell rephrased the question to Elder and asked if discomfort should be considered? Elder replied that the committee would have to decide that and then establish appropriate thresholds and safety factors.

In response to a question from Fichtenberg regarding the inclusion of Gandhi's millimeter-wave data, Tell responded that it should not be included. He explained that Gandhi's work applies well outside the SAR range and the energy is absorbed in a thin layer of tissue at the surface of the body – it is not thermoregulatory issue.

Meltz said that he is concerned about using discomfort as an end point. For example, a person sitting near a lamp or under the lamps in a lecture hall may experience discomfort but can move away – in many cases a person exposed to RF energy may not have control of the source or their exposure. Adair pointed out that her data should be useful for determining limits for partial-body exposure. Osepchuk agreed noting that partial-body exposure means more than just exposure of the extremities. Needy asked, rhetorically, if the standard was going to be based on science or subjective endpoints, e.g., discomfort? Pakhomov pointed out that exposure duration is also important, especially for chronic exposures. Lang noted that the issue seems to be associated with fear of certain technologies, e.g., wireless base-stations, which is also subjective. Needy asked if the revision is intended to provide protection to 100% of the population – Tell replied that there has been considerable discussion on this issue at the other meetings and the consensus is that it should protect most of the population but cannot protect all. He added that most safety standards are designed to protect the majority of the population and sensitive groups but do not protect 100% of the population. Fichtenberg insisted that Gandhi's millimeter-wave data be included in these deliberations.

Tell noted that "partial-body exposure" has not been defined adequately in the past. The draft refers to spatial averaging, e.g., over 20 cm^2 with maximum one-square centimeter power density average of 100 mW/cm^2 and, perhaps with an

absolute ceiling power density above some certain millimeter-wave frequency. Fichtenberg asked how children would be addressed with their smaller dimensions? Tell replied that children would be addressed and noted several dosimetry papers that address the issue, e.g., Gandhi's paper on cell phones.

Woods asked about the decision to use 3 GHz as the upper limit for the SAR region. Tell said that he thought it was reasonable based on penetration depth in tissue – the final decision is open to discussion. Referring to spatial averaging, Murphy pointed out that at the higher millimeter-wave frequencies, e.g., 30, 60, 100 GHz, 20 cm^2 might be too large an area because of the small spot sizes that can be produced at these frequencies. He pointed out that a ceiling value is also needed for short exposure durations, e.g., an energy/time limit. Ziskin agreed and pointed out that frequency dependence should also be considered.

Chou asked for a consensus on whether the upper frequency range of the SAR region should be 3 GHz or 6 GHz. Osepchuk suggested retaining the current value of 6 GHz unless there was a good reason for changing. He briefly noted that at the joint laser/RF meeting there was agreement on the MPE at 300 GHz (10 mW/cm^2) and pointed out that small spot sizes are only obtainable under unique near-field exposure conditions and probably not in the far field. Merritt asked if there is any documented evidence that anyone exposed at or below the current MPEs was harmed – the consensus was that there is no such evidence. D'Andrea pointed out that a peak MPE limit is needed for short exposure durations at millimeter-wave frequencies – Osepchuk suggested looking towards the laser community for guidance on this particular issue. Bruce Stuck, a member of ANSI ASC Z136 (and now chairman of the Z136 Technical Subcommittee on Biological Effects & Medical Surveillance) noted that the MPE in the infrared portion of the laser standard is 10 mW/cm^2 for small spot sizes and exposure durations greater than 10 s. He said that the MPE is based on worst case conditions at wavelengths where the energy is absorbed in a few μm of tissue. He noted that the threshold for skin damage and damage to the cornea is solidly based and has been substantiated. The corresponding MPE for larger spot sizes, i.e., 100 cm^2 or greater, is 10 mW/cm^2.

Meltz said that he is interested in figuring out a process that would move development of the normative sections of the revision forward. He suggested examining the draft, listing the recommended changes, providing a rationale for the each of the changes, distributing this information before the June meeting and voting on the changes in June. Tell pointed out that there is a wide range of opinions on most of the issues and he needs a clear signal on how to proceed. Chou recommended that the 1991 standard be used as a starting point and a rationale developed supporting each change that is considered necessary. Woods noted that the draft was prepared to stimulate discussion. He suggested that those who disagree with the draft should support any recommended changes in writing. Tell agreed – Adair also agreed and added that a rationale is also needed but not in the form of a large white paper.

Chou said that every white paper needs a conclusion supporting a change, either up or down, or no change. D'Andrea disagreed. He explained that the literature

evaluation has been the hold up. He said that the strawman represents a consensus viewpoint and suggested proposing changes considered necessary and providing a rationale. The purpose is to generate discussion and propose changes considered necessary for discussion. Meltz agreed and suggested hi-lighting the changes with their rationale. Woods asked if the intent is to continue to work on the draft and modify it, if necessary, as the white papers are completed – D'Andrea replied that the intent is to work on the strawman and use the white papers to develop the rationale. He said that the request to Tell to develop the strawman was to help jump-start the process while waiting for completion of the literature evaluation process. He complimented Tell for doing an outstanding job. Tell asked for specific guidance on moving forward. He said that working on the draft might not be the best way and suggested that opposing viewpoints on the suggested changes be prepared for discussion and consideration at the next meeting.

FOR ACTION

Members of the committee should e-mail to Chou, D'Andrea and Tell, the rationale for or against specific issues, e.g., one versus two tiers, supported by science and in time to be discussed at the next meeting.

Some of the key issues are:

1) One or two tiers including the WBA SAR limits.
2) 3 GHz or 6 GHz as the upper frequency for the SAR region.
3) 1 g versus 10 g averaging mass for the peak spatial-average SAR and the shape of the averaging volume.
4) Minimum measurement distance – should it be included in the document and, if yes, what should it be?
5) Time averaging – is the modified averaging time curve appropriate?
6) Should the current partial-body limits be retained?
7) Should recommendations regarding safety programs be included?
8) Safety factor – what should the components and the value be?
9) Definition of "thermal" and "non-thermal" effects or should a different approach be taken, e.g., "low-level" effects?
10) Limit for contact voltage to prevent arc-over.
11) Peak power limits – what should they be?
12) How should near-field, far-field and multiple source exposures be handled?
13) Plus the 14 issues raised by members of the federal RF the Interagency Work Group (see Attachment 8).

e) Annex Reports

Deferred

13. Interpretations Working Group

Hatfield reported that there has been no recent activity.

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14. Other Old Business

The following two action items from the June 2001 meeting were reviewed:

> **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.**

Meltz said that he is working on action item 2 – action item 1 cannot be dealt with in the near term. Heynick said that he would help with action item 2 but would not lead the effort. Meltz said that he would be considering the near-field/far-field issue from now forward and would consider the response of specific organs – he said that he would work off-line on this issue.

15. New Business

No new business.

16. Date and Place of Next meeting

The next meeting of SC-4 will be held in Quebec City, Canada, Friday June 28, 2002.

17. Adjourn

There being no further business, upon a motion to adjourn by L. Heynick that was seconded by A. Varanelli, the meeting was adjourned at 1645 h.

ATTACHMENTS

ICES Subcommittee 4

Sheraton Gunter Hotel
San Antonio, TX 78205

January 19, 2002

1. List of Attendees
2. Tentative Agenda
3. 4th Revision Working Group Meeting Summary
4. 4th Revision Working Group Meeting Summary – Revised
5. Time Schedule
6. Table from Lifespan and Cancer in Laboratory Mammals Whoite Paper
7. Tables from Ocular Effects White Paper
8. Issues Raised by Members of the Federal RF Interagency Work Group

Attendance List

ICES SC4 Meeting
San Antonio, TX
January 19, 2002

	t Name	t Name	Affiliation	Country	Status	E-mail
1.	Adair	Eleanor	Independent Consultant	US	M	eleanoradair@aol.com
2.	Baron	David	Holaday Industries, Inc.	US	M	baron006@tc.umn.edu
3.	Bassen	Howard	FDA/CDRH	US	O	hib@cdrh.fda.gov
4.	Blick	Dennis	AFRL/HEDR (Veridian)	US	M	dennis.blick@brooks.af.mil
5.	Bodemann	Ralf	Siemens AG	DE	M	ralf.bodemann@mchp.siemens.de
6.	Chou	C.K.	Motorola, Inc.	US	M	ck.chou@motorola.com
7.	D'Andrea	John	Naval Health Research Ctr.	US	M	john.dandrea@navy.brooks.af.mil
8.	Dovan	Thanh	SPI PowerNet Pty. Ltd.	AU	M	tdovan@spipowernet.com.au
9.	Elder	Joe	Motorola	US	M	joe.elder@motorola.com
10.	Fichtenberg	David	State of WA, Med Asst Ad	US	O	
11.	Gettman	Ken	Nat Electrical Manuf Assoc.	US	O	ken_gettman@nema.org
12.	Hammer	Wayne	SPAWAR Systems Ctr.	US	M	hammerw@spawar.navy.mil
13.	Hatfield	James	Hatfield & Dawson	US	M	hatfield@hatdaw.com
14.	Heynick	Louis	Independent Consultant	US	M	louhey@mindspring.com
15.	Kantner	Kimberly	AT&T	US	M	kkantner@att.com
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17.	Lang	Sakari	Nokia Research Ctr.	FI	M	sakari.lang@nokia.com
18.	Mason	Patrick	USAF/AFRL/HEDR	US	M	patrick.mason@brooks.af.mil
19.	McManus	Tom	Dept. Public Enterprise	IE	M	tommcmanus@dpe.ie
20.	Meltz	Martin	Ctr. for Env. Rad. Tox.	US	M	meltz@uthscsa.edu
21.	Merritt	James	USAF Research Lab	US	O	James.Merritt@brooks.af.mil
22.	Murphy	Michael	AFRL/HEDR	US	M	michael.murphy@brooks.af.mil
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25.	Pakhomov	Andrei	McKesson Bio Services	US	M	andrei.pakhomov@brooks.af.mil
26.	Petersen	Ronald	R C Petersen Associates	US	M	r.c.petersen@ieee.org
27.	Podhrasky	Robert	Garrett Metal Detectors	US	O	bob@garrett.com
28.	Proctor	Ken	US Army	US	O	kenneth.proctor@mail1.monmouth.army.mil
29.	Reilly	J. Patrick	Metatec Associates	US	M	jpatrickreilly@erols.com
30.	Roberts	Brad	US Army CHPPM	US	M	Brad.Roberts@apg.amedd.army.mil
31.	Stuck	Bruce	Army Med Res Det	US	O	bruce.stuck@brooks.af.mil
32.	Tell	Richard	Richard Tell Assoc. Inc.	US	M	rtell@radhaz.com
33.	Varanelli	Arthur	Raytheon Company	US	M	a.g.varanelli@ieee.org
34.	Vijayalaxmi		Univ. TX Health Science Ctr.	US	O	vijay@uthscsa.edu
35.	Watkins	Cleveland		US	O	
36.	Weller	Robert	Hammett&Edison	US	M	r.weller@ieee.org
37.	Woods	Richard	Sensormatic Electronics	US	M	richwoods@tycoint.com
38.	Ziskin, MD	Marvin	Temple Univ. Medical School	US	M	ziskin@temple.edu

M =Member
O = Observer

INTERNATIONAL COMMITTEE *on* ELECTROMAGNETIC SAFETY

ATTACHMENT 2

ICES Subcommittee 4

(IEEE SCC-28)

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

Saturday: January 19, 2002
8:00 AM – 5:00 P M
Sheraton Gunter Hotel
205 East Houston Street
San Antonio, TX 78205

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 June 8-9, 2001 Meeting**	*D'Andrea/Chou*
5.	**Secretary's Report**	*Petersen*
6.	**Chairman's Report**	*D'Andrea/Chou*
7.	**SCC28 EXCOM Report**	*Adair*
8.	**Risk Assessment Working Group Report**	*Tell*
12.	**Mechanism Working Group Report**	*Sheppard*
13.	**Harmonization with ICNIRP**	*Petersen*
14.	**Literature Evaluation Working Group Reports**	

15.

a) Literature Surveillance and Database Software *Heynick/Tell*
b) Engineering *Hurt*
c) In Vitro *Meltz*
d) In Vivo *Blick*
e) Epidemiology *Gorsuch*
f) Literature review results dissemination *Petersen*

16. Editorial Committee Reports

a) Fourth Revision Working Group meeting and **time schedule** *Chou*
b) Topic Reports

Topic leaders to report significant progress.

c) White paper reports

White paper authors to report significant progress.

d) Discussion of PRELIMINARY DRAFT *Tell*

Detailed discussion of each section of the draft is planned.

1. **Overview**
2. **References**
3. **Definitions**
4. **Recommendations**
5. **Explanation**

e) Annex reports

Annex A: Approach to standard revision [Linda Erdreich* and Mays Swicord]

Annex B: Selecting an adverse effect - summary of the literature evaluation results
[Asher Sheppard, Pat Reilly]

Annex C: Explanation of maximum permissible exposure limits [Asher Sheppard, Ric Tell]

Annex D: Technical similarities and differences of this standard and other protection guides [Bob Cleveland]

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

Annex F: Papers subjected to review [Lou Heynick]

Annex G: Papers identified as applicable to the development of the standard [Lou Heynick]

Annex H: Examples of application of the standard [John DeFrank]

13. Interpretations Working Group *Hatfield*

14. Other Old Business

15. New Business

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

1) Summer meeting, Quebec, Canada on June 22, 2002

17. Adjournment

IEEE/ICES SCC-28 Subcommittee 4

4th Revision Working Group Meeting Summary

January 10-11, 2002
Fort Lauderdale, Florida

Participants:
Adair, Blick, Chou (Chair), Cleveland, Curtis (1st day only), D'Andrea, Elder, Heynick, Hurt, Kantner, Kuster, Lang, Leonowich, Lotz, Morrissey, Owen, Petersen, Roberts, Sheppard, Swicord, Tell, Ziskin.

Based on our current understanding and pending the conclusion of the review and white paper process, the consensus of the Revision Working Group is as follows:

1. The RF safety standard should be based on science.
2. RF safety standard revision should be derived from peer-reviewed publications and documents that are reviewed by the SC4.
3. The adverse effect level remains at 4 W/kg subject to revision following completion of the literature evaluation and white papers.
4. The maximum exposure limits should be based on established adverse effects after inclusion of an appropriate safety factor(s).
5. Safety factor(s) should consider uncertainties in the biological database (e.g., unknown health consequences, measurements, environmental conditions, exposure duration, individual variability, and other factors.)
6. Non-thermal RF biological effects have not been established and none of the reported non-thermal effects are proven adverse to health (does not apply to electro-stimulation). Thermal effect is the only established adverse effect.
7. The microwave hearing effect is not adverse and should not be used for setting the peak power limit.
8. The shape and size of the averaging volume and the peak SAR limit will be determined after the WHO temperature workshop in March. The important end point is the temperature change.
9. RF standard should be harmonized with other international standards to the extent where scientifically defensible.
10. Rationales must be documented for all changes relative to the current standard.
11. Will add a section dealing with potentially sensitive subpopulations, such as children.
12. Keep the two-tier approach (whole body average SAR 0.4 and 0.08 W/kg) and leave the peak SAR value and averaging volume blank, which are to be decided after the WHO temperature workshop results become available.

ATTACHMENT 4

IEEE/ICES SCC-28 Subcommittee 4

4th Revision Working Group Meeting Summary

(Revised by SC4 on January 19, 2002)

January 10-11, 2002

Fort Lauderdale, Florida

Participants:

Adair, Blick, Chou (Chair), Cleveland, Curtis (1st day only), D'Andrea, Elder, Heynick, Hurt, Kantner, Kuster, Lang, Leonowich, Lotz, Morrissey, Owen, Petersen, Roberts, Sheppard, Swicord, Tell, Ziskin.

Based on our current understanding and pending the conclusion of the review and white paper process, the consensus of the Revision Working Group is as follows:

1. The RF safety standard should be based on science.
2. RF safety standard revision should be derived from peer-reviewed publications and documents that are reviewed by the SC4.
3. The adverse effect level remains at 4 W/kg subject to revision following completion of the literature evaluation and white papers.
4. The maximum exposure limits should be based on established adverse effects after inclusion of an appropriate safety factor(s).
5. Safety factor(s) should consider uncertainties in the biological database (e.g., ~~unknown health consequences~~, measurements, environmental conditions, exposure duration, individual variability, and other factors.)
6. Non-thermal RF biological effects have not been established and none of the reported non-thermal effects are proven adverse to health (does not apply to electro-stimulation). Thermal effect is the only established adverse effect.
7. The microwave hearing effect is not adverse and should not be used for setting the peak power limit.
8. The shape and size of the averaging volume and the peak SAR limit ~~will be determined after the WHO temperature workshop in March~~ are still to be determined. The important end point is the temperature change.
9. RF standard should be harmonized with other international standards to the extent where scientifically defensible.
10. Rationales must be documented for all changes relative to the current standard.
11. The editorial committee w~~W~~ill add in the informative section a paragraph dealing with potentially sensitive subpopulations, such as children.
12. Reconsider ~~Keep~~ the two-tier approach (whole body average SAR 0.4 and 0.08 W/kg) ~~and leave~~, the peak SAR value and the averaging volume. ~~blank, which are to be decided after the WHO temperature workshop results become available.~~

Time schedule:

1/19/2002 **SC4 meeting, San Antonio**

Discuss the consensus of 4th Revision WG

3/31/2002 **Editorial Committee**

Distribute 2nd draft to RWG

4/8-9/2002 **5th RWG meeting, DC**

Discuss 2nd Draft

4/30/2002 **Editorial Committee**

Distribute 3rd draft to RWG

5/15/2002 **RWG**

RWG comments back to editor

5/31/2002 **Editorial Committee**

Distribute 4th draft to SC4

6/28/2002 **SC4 meeting, Quebec**

Discuss 4th draft

8/15/2002 **Editorial Committee**

Distribute 5th draft to RWG

9/2002 **6th RWG meeting**

Discuss and revise 5th draft

10/2002 **Editorial Committee**

Distribute 6th draft to SC4

11/2002 **SC4 meeting**

Discuss 6th final draft

12/31/2002 **SC4**

SC4 balloting

ATTACHMENT 6

Table 1. Effect of RF Radiation on Lifespan and Cancer in Laboratory Mammals[1]

Species	Frequency (MHz)	Dose Rate[e] (W/kg)	Exposure	Lifespan	Cancer	Reference
Mouse	9270 PW[a]	40	4.5 min/d, 5 d/wk, 59 wk	Increase[g]	White cell cancer (leucosis)[g]	Prausnitz and Susskind (1962) (See Kirk, 1984)
Mouse	800 CW[b]	12.9	2 h/d, 5 d/wk, 35 wk	NS[h]	ND[i]	Spalding et al. (1971)
Mouse	2450 CW	35	20 min/d, 4 d (prenatal)	NS	Delayed tumor development; no change in total tumors	Preskorn et al. (1978)
Mouse	2450 CW	2-3	2 h/d, 6 d/wk, up to 10.5 mo	Decrease	Increase in spontaneous mammary tumors, BP-induced skin cancer, and lung cancer colonies	Szmigielski et al. (1982)
		6-8	2 h/d, 6 d/wk, up to 10.5 mo	Decrease		
Mouse	2450 CW	1.2	2.5 h/d, 6 d/wk, until death (~26 wk)	NS NS	NS	Santini et al. (1988)
	2450 PW	1.2	2.5 h/d, 6 d/wk, until death (~26 wk)		NS	
Rat	2450 PW	0.15-0.4	21.5 h/d, 7 d/wk, 25 mo	NS	Increase in primary malignancies	Chou et al. (1992)
Mouse	2450 CW	2	1 h/d, 5 d/wk, 31 mo	NS	ND	Liddle et al. (1994)
Mouse	2450 CW	6.8	1 h/d, 5 d/wk, 27 mo	Decrease	ND	
Mouse	435 PW	0.32	22 h/d, 7 d/wk, 21 mo	NS	NS	Toler et al. (1997)
Mouse	2450 CW	0.3	20 h/d, 7 d/wk, 18 mo	NS	NS	Frei et al. (1998a)
Mouse	2450 CW	1.0	20 h/d, 7 d/wk, 78 wk	NS	NS	Frei et al. (1998b)
Rat	836 M[c] (TDMA)	0.3-.7 0.7-1.4 (br)[f] (calc) 1.8-2.3 (br) (meas)	2 h/d, 4 d/wk, 24 mo	NS	NS	Adey et al. (1999)
Rat	836 M (FM)	0.3-.7 0.7-1.4 (br) (calc) 1.8-2.3 (br) (meas)	2 h/d, 4 d/wk, 731 d	NS	NS	Adey et al. (2000)
Mouse	UWB[d]	0.0098	2 min/wk, 12 wk	NS	NS	Jauchem et al. (2001)
Rat	860 CW	1 W/kg (br)	6 h/d, 5 d/wk, 22 mo	NS	NS	Zook and Simmens (2001)
	860 PW	1 W/kg (br)	6 h/d, 5 d/wk, 22 mo	NS	NS	
Mouse	902.4 PW	0.35	1.5 h/d, 5 d/wk, 78 wk	NS	NS	Heikkinen et al. (2001)
	902.5 M	1.5	1.5 h/d, 5 d/wk, 78 wk	NS	NS	

[a] PW = pulsed wave
[b] CW = continuous wave
[c] M = modulated signal
[d] UWB = ultra-wide band (rise time 176 ps, fall time 3.5 ns, pulse width 1.9 ns, peak E-field 40 kV/m, repetition rate 1 kHz)
[e] wb = whole body SAR unless shown as brain (br) SAR
[f] br = brain dose rate
[g] A critical review determined that the report was of poor quality; therefore, the effects on lifespan and cancer have not been accepted (see Kirk, 1984).
[h] NS = not significant
[i] ND = not determined

[1] From white paper: *Lifespan and Cancer in Laboratory Mammals Exposed to Radiofrequency Radiation*, J. Elder)

ATTACHMENT 7

Table 1. Cataracts and Related Studies (Near-field Exposure)[a]

Effects	Species	Frequency (MHz)	Intensity (mW/cm^2)	Exposure (days x min)	SAR (W/kg)	Reference
Cataract	Dog	2,500	5000	1 x 1	Not determined	Baille (1970)
Cataract and transient effects (acute inflammatory reactions of cornea, iris, and/or ciliary body)	Rabbit	5,500 (CW and PW)	470-785*	1 x 2-100	300-500†	Birenbaum *et al.* (1969a)
Cataract and iritis	Rabbit	800 (CW) 4,200 (PW) 4,600 (PW) 5,200 (PW) 5,400 (CW and PW) 5,500 (CW and PW) 6,300 (PW)	785* 785* 785* 500-785* 500-785* 500-785* 785*	1 x 25 1 x 17 1x 15 1 x 5-12 1 x 3-4 1 x 2-3 1 x 5	500† 500† 500† 350-500† 300-500† 300-500† 500†	Birenbaum *et al.* (1969b)
Cataract and transient effects (swelling and chemosis of bulbar and palpebral conjunctivae, papillary constriction, hyperemia of iris and limbal vessels, and vitreous floaters and filaments)	Rabbit	2,450 (CW)	180* 120-180	1 x 240 20 x 60	Not determined	Carpenter (1979)
No cataract	Rabbit	2,450 (CW)	75	20 x 60	Not determined	Carpenter (1979)
Cataract and transient effects (pupillary constriction and anterior chamber turbidity)	Rabbit	2,450 (CW)	150	1 x 100	138††	Guy *et al.* (1975)
Cataract	Rabbit	2,450 (1000 Hz mod)	285	1 x 30	15.3(head)	Foster et al. (1986)
Cataract and transient effects (pupillary constriction, hyperemia of bulbar and palpebral conjunctivae)	Rabbit	2,450 (CW) 10,000 (CW)	295 375	1 x 30 1 x 30	Not determined	Hagan and Carpenter (1976)
Cataract and transient effects (constricted pupil, dilated conjunctival and iris vessels, turbid anterior chamber)	Rabbit	2,450 (CW)	180	1 x 140	100††	Kramar *et al.* (1978)
Second-to-third degree nasal burns; no ocular effects	Rhesus monkey	2,450 (CW)	300	1 x 22	115††	Kramar *et al.* (1978)

Table 1. Cataracts and Related Studies (Near-field Exposure)[a] (Continued)

Effects	Species	Frequency (MHz)	Intensity (mW/cm^2)	Exposure (days x min)	SAR (W/kg)	Reference
No ocular effects	Monkey	9310 (PW)	150 (av)	30-40 x 294 -665††	20 W/kg (see below: McAfee et al., 1983)	McAfee *et al.* (1979)
No cataracts; no effects on cornea, aqueous and vitreous humors or retina; no loss of visual capability	Monkey	9310 (PW) 9310 (PW) 2450	150 (av) 300 (av)	408–946 min over 34 mo. 275-594 min over 34 mo. 549–750 min over 4 mo.	20 40 20	McAfee et al. (1983)
No cataract but inflammation of cornea (keratitis)	Rabbit	35,000 107,000	40 40	1 x 60 1 x 60	>175# >238#	Rosenthal *et al.* (1976)

[a] Adapted from Elder (1984). "Special Senses" in Biological Effects of Radiofrequency Radiation, EPA-600/8-83-026F, Table 5-14, p. 5-65.

* Estimate of average power density calculated by dividing the microwave power by the irradiated area (d = 1.27 cm) of the eye.

† Estimate based on the assumption that all incident power was absorbed in the eye (2 g).

† † Maximum SAR in the eye.

Estimated SAR values for the cornea.

Table 2. Ocular Effects (Far-Field Exposure)[a]

Effects	Species	Frequency (MHz)	Intensity (mW/cm^2)	Exposure (days x min)	SAR (W/kg)	Reference
No ocular effects, including no lenticular changes	Rabbit	3000 (CW)	100, 200	1 x 15, 30	14, 28*	Appleton *et al.* (1975a)
Acute ocular changes, e.g., hyperemia of lids and conjunctiva, meiosis, anterior chamber flare, engorgement of iris vessels, and periorbital cutaneous burns; no lenticular changes			300, 400, 500	1 x 15	42, 56* 70*	
Death			300 500	1 x 30 1 x 15	42* 70*	
No cataracts; no effect on blood measures and pathology	Rabbit	2450 (CW and PW)	1.5	1 x 120 (x 3 mo)	1.6 (head)	Chou et al. (1982)
No cataracts; no effect on body mass, blood measures and pathology	Rabbit	2450 (CW)	0.5, 5	5 x 420 (x 13 wk)	0.55, 5.5 (head)	Chou et al. (1983)
No cataracts	Rabbit	385 (CW) 385 (CW) 468 (CW)	60 30 60†	10 x 15 10 x 90 10 x 20	48* 24* 8.1	Cogan *et al. (*1958)
No cataracts	Rabbit	2450 (CW)	10	5 x 480 (x 8-17 weeks)	1.5*	Ferri and Hagan (1976)
No ocular effects	Rabbit	2450 (CW)	10	180 x 1380	17#	Guy *et al. (*1980)

[a] Adapted from Elder (1984), Table 5-15, p. 5-65
* Estimated average whole-body SAR values (Durney *et al.* 1978, Figure 31).
†Waveguide average whole-body exposure.
††Total exposure time in minutes for the entire 30- to 40-day exposure period.
Maximal SAR in head.

Table 3. Corneal, Retinal and Other Ocular Effects (Near-field Exposure)

Effects	Species	Frequency (MHz)	Intensity (mW/cm^2)	Exposure Duration	SAR (W/kg)	Reference
No corneal endothelial abnormalities, cataracts, or effects on retina or vitreous humor [corneal effects due to CW exposure in Kues et al. (1985) not confirmed]	Monkey -anesthesia	2,450 (CW)	15.9-43	240 min	4.1-11 (cornea)	Kamimura et al. (1994)
No effect	Monkey +anesthesia	2,450 (PW) 10 us, 100 pps	5 (cornea)	240 min once a wk for 2 wk	1.3 (cornea)	Kues *et al.* (1985)
Transient corneal endothelial abnormalities			10 (cornea)	240 min once a wk for 2-11 wk	2.6 (cornea)	
Transient corneal endothelial abnormalities			15 (cornea)	240 min	3.9 (cornea)	
Transient corneal endothelial abnormalities and increased vascular permeability of iris (ophthalmic drug pretreatment)	Monkey +anesthesia	2,450 (PW) 10 us, 100 pps	1	240 min daily for 3 d	0.26	Kues *et al.* (1992)
No effects on cornea, iris or lens	Rabbit and monkey +anesthesia	60,000 (CW)	10 (cornea)	8 hr or five daily 4 hr exposures	Not determined	Kues et al. (1999)
No corneal abnormalities detected by same procedure used in Kues et al. (1985, 1992) but corneal effects detected at high magnification (TEM); no overall change in iris vascular permeability; retinal degeneration reported	Monkey -anesthesia	1,250 (PW) 0.5 or 10 us, 1 or 16 pps, 1 MW peak power		240 min daily for 3 d x 3 wk	3.5-5.0 (retina)	Kues and Monahan (1993)

Table 3. Corneal, Retinal and Other Ocular Effects (Near-field Exposure) – (Continued)

Effects	Species	Frequency (MHz)	Intensity (mW/cm^2)	Exposure Duration	SAR (W/kg)	Reference
No retinal effects [retinal degeneration in Kues and Monahan (1993) not confirmed] Enhanced cone photoreceptor response to light flash (authors did not consider this change an adverse effect)	Monkey -anesthesia	1,250 (PW), 1.04 MW peak power, 5.59 us pulse width at 0, 0.59, 1.18 and 2.79 pps		240 min daily for 3d x 3 wk	4.3, 8.4 and 20.2 (retina) 8.4 and 20.2 (retina)	Lu et al. (2000)
Degenerative retinal changes observed by electron microscopy; no lens opacities and no effect on blood brain barrier or blood-retina barrier permeability.	Rabbit	3,100 (PW) , 1.4 us pulse length, 300 pps	55	1-1.5 h once or 1 h/d, 3d/wk up to 53 exposure hours over 3 months	30 W/kg at retina (est.); "…40 ^{o}C near the retina 3 min after irradiation."	Paulsson et al. (1979)

Table 4. Ocular Effects in Human Beings

Effects	Comments	Frequency (MHz)	Intensity (mW/cm^2)	Reference
No difference in presence or absence of opacities, vacuoles and posterior subcapsular iridescence	Clinical survey of 91 US Army Signal Corps personnel (135 controls)	Not specified	Not specified	Appleton and McCrossan (1972)
No difference in presence or absence of opacities, vacuoles and posterior subcapsular iridescence	Clinical survey of 1542 US Army personnel (801 controls)	Not specified	Not specified	Appleton et al. (1975b)
Lens opacities with no decrease in vision and retinal lesions (2 cases with decrease in vision) [retinal effects not confirmed by Hathaway et al. (1977)]	68 radar/microwave workers (30 controls) in electronics industry	Not specified	Not specified	Aurell and Tengroth (1973)
No significant risk of cataracts	Case-control study of 2946 US military veterans (2164 controls)	Not specified	Job classification used as indicator of exposure	Cleary et al. (1965)
More subclinical lens changes than controls, but no cataracts and no decrease in visual acuity	736 microwave workers (559 controls)	Not specified	Not specified	Cleary and Pasternack (1966)
No lenticular or retinal defects [retinal effects reported by Aurell and Tengroth (1973) not confirmed]	705 microwave workers (US Army)	Not specified	Majority not exposed > 0.1 mW/cm^2	Hathaway et al. (1977)
No statistically significant increase in posterior subcapsular cataracts (PSCs) in individuals but significant increase in PSCs in eyes.	53 radiolinemen; 39 controls	558 kHz-527 MHz	0.08-3956 mW/cm^2	Hollows and Douglas (1984)
Lens opacities but no impairment in visual acuity	102 microwave workers employed for >4 years (100 controls); subset of above 400 workers	600-10,700	Not specified	Majewska (1968)
No difference in lens anomalies. The subsets of controls and "exposed" groups having a familial history of eye problems showed a higher percent of lens changes in exposed personnel but no statistical test applied.	377 US military personnel involved in operation or maintenance of radar equipment (320 controls)	Not specified	Not specified	Odland (1973)

Table 4. Ocular Effects in Human Beings (Continued)

Effects	Comments	Frequency (MHz)	Intensity (mW/cm^2)	Reference
No statistically significant changes in lens opacities, lens vacuoles and posterior subcapsular iridescence.	447 military microwave workers; 340 controls	Not specified	Not specified	Shacklett et al. (1975)
No differences in lens opacities.	507 radar workers (334 controls)	Not specified	0.2-6 mW/cm^2 (workers); <0.2 mW/cm^2 (controls)	Siekierzynski et al. (1974)
Uveal melanoma (Odds Ratio = 4.2)	6 cases	Mobile phone emissions	"Probable/ certain mobile phone exposure"	Stang et al. (2001)

ATTACHMENT 8

RF Guideline Issues

Identified by members of the federal RF Interagency Work Group, June 1999

Issue: Biological basis for local SAR limit

The C95.1 partial body (local) exposure limits are based on an assumed ratio of peak to whole body SAR; that is, they are dosimetrically, rather than biologically based. Instead of applying a dosimetric factor to the whole body SAR to obtain the local limits, an effort should be made to base local SAR limits on the differential sensitivity of tissues to electric fields and temperature increases. For example, it seems intuitive that the local limits for the brain and bone marrow should be lower than those for muscle, fat and fascia; this is not the case with the current limits which implicitly assume that all tissues are equally sensitive (except for eye and testicle). If no other data are available, differential tissue sensitivity to ionizing radiation should be considered.

If it is deemed necessary to incorporate dosimetric factors into the resulting tissue-specific SAR limits these should be based on up-to-date dosimetric methods such as finite-difference time-domain calculations utilizing MRI data and tissue-specific dielectric constants. For certain exposure conditions FDTD techniques and MRI data may allow better simulation of peak SAR values. Consideration should be given to the practical tissue volume for averaging SAR and whether this volume is relevant to potential effects on sensitive tissues and organs.

Issue: Selection of an adverse effect level

Should the thermal basis for exposure limits be reconsidered, or can the basis for an unacceptable/adverse effect still be defined in the same manner used for the 1991 IEEE guidelines? Since the adverse effect level for the 1991 guidelines was based on acute exposures, does the same approach apply for effects caused by chronic exposure to RF radiation, including exposures having a range of carrier frequencies, modulation characteristics, peak intensities, exposure duration, etc., that does not elevate tissue temperature on a macroscopic scale?

Selection criteria that could be considered in determining unacceptable/adverse effects include:

a) adverse effects on bodily functions/systems
b) minimal physiological consequences
c) measurable physiological effects, but no known consequences

If the adverse effect level is based on thermal effects in laboratory animals, the literature on human studies (relating dose rate to temperature elevation and temperature elevation to a physiological effect) should be used to determine if the human data could reduce uncertainties in determination of a safety factor.

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Issue: Acute and chronic exposures

There is a need to discuss and differentiate the criteria for guidelines for acute and chronic exposure conditions. The past approach of basing the exposure limits on acute effects data with an extrapolation to unlimited chronic exposure durations is problematic. There is an extensive data base on acute effects with animal data, human data (e.g. MRI information), and modeling to address thermal insult and associated adverse effects for acute exposure (e.g., less than one day). For lower level ("non-thermal"), chronic exposures, the effects of concern may be very different from those for acute exposure (e.g., epigenetic effects, tumor development, neurologic symptoms). It is possible that the IEEE RF radiation guidelines development process may conclude that the data for these chronic effects exist but are inconsistent, and therefore not useable for guideline development. If the chronic exposure data are not helpful in determining a recommended exposure level, then a separate rationale for extrapolating the results of acute exposure data may be needed. In either case (chronic effects data that are useful or not useful), a clear rationale needs to be developed to support the exposure guideline for chronic as well as acute exposure.

Issue: One tier vs two tier guidelines:

A one tier guideline must incorporate all exposure conditions and subject possibilities (e.g., acute or chronic exposure, healthy workers, chronically ill members of the general public, etc.). A two tier guideline, as now exists, has the potential to provide higher limits for a specific, defined population (e.g., healthy workers), and exposure conditions subject to controls, while providing a second limit that addresses greater uncertainties in the data available (about chronic exposure effects, about variations in the health of the subject population, etc.). A greater safety factor would have to be incorporated to deal with greater uncertainty in the scientific data available. Thus, a two-tier guideline offers more flexibility in dealing with scientific uncertainty, while a one-tier guideline would force a more conservative limit to cover all circumstances including the scientific uncertainties that exist.

Issue: Controlled vs. uncontrolled (applicability of two IEEE exposure tiers)

The current "controlled" and "uncontrolled" definitions are problematic, at least in the civilian sector, particularly since there are no procedures defined in the document to implement the "controlled" condition. The new guidelines should offer direction for the range of controls to be implemented and the training required for those who knowingly will be exposed (e.g. workers), along the lines of the existing ANSI laser safety standards. This essential element needs to be included for whatever limits are defined, be they one-tier or two-tier.
For example, the OSHA position is that the "uncontrolled" level is strictly an "action" level which indicates that there is a sufficiently high exposure (compared to the vast majority of

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locations) to merit an assessment to determine what controls and training are necessary to ensure persons are not exposed above the "controlled" limit. Many similar "action" levels are part of OSHA and public health standards. Should this interpretation be incorporated into the IEEE standard as a means to determine the need to implement a safety plan? [The laser standard has a multi-tiered (Class I, II, III, IV) standard which similarly requires additional controls for more powerful lasers to limit the likelihood of an excess exposure, even though the health effect threshold is the same.]

On the other hand, if it is determined that certain populations (due to their health status or age) are more susceptible to RF exposures, then a multi-tiered standard, applicable only to those specific populations, may be considered.

The ANSI/IEEE standard establishes two exposure tiers for controlled and uncontrolled environments. The following statement is made in the rationale (Section 6, page 23): "The important distinction is not the population type, but the nature of the exposure environment." If that is the case, consideration should be given to providing a better explanation as to why persons in uncontrolled environments need to be protected to a greater extent than persons in controlled environments. An uncontrolled environment can become a controlled environment by simply restricting access (e.g., erecting fences) and by making individuals aware of their potential for exposure. After such actions are taken, this means that the persons who previously could only be exposed at the more restrictive uncontrolled levels could now be exposed inside the restricted area (e.g., inside the fence) at controlled levels.

What biologically-based factor changed for these people? Since the ostensible public health reason for providing greater protection for one group of persons has historically been based on biological considerations or comparable factors, it is not clear why the sentence quoted above is valid.

Issue: Uncertainty factors

The uncertainties in the data used to develop the guideline should be addressed. An accepted practice in establishing human exposure levels for agents that produce undesirable effects is the application of factors representing each area of uncertainty inherent in the available data that was used to identify the unacceptable effect level. Standard areas of uncertainty used in deriving acceptable human dose for agents that may produce adverse (but non-cancer) effects include

(1) extrapolation of acute effects data to chronic exposure conditions,
(2) uncertainty in extrapolating animal data to humans in prolonged exposure situations, (3) variation in
(4) incomplete data bases,
(5) uncertainty in the selection of the effects basis, inability of any single study to adequately add

If guidelines are intended to address nonthermal chronic exposures to intensity modulated RF radiation, then how could uncertainty factors be used; how would this use differ from the

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historical use of uncertainty factors in establishing RF radiation guidelines to limit exposure to acute or sub-chronic RF radiation to prevent heat-related effects?

There is a need to provide a clear rationale for the use of uncertainty factors.

Issue: Intensity or frequency modulated (pulsed or frequency modulated) RF radiation

Studies continue to be published describing biological responses to nonthermal ELF-modulated and pulse-modulated RF radiation exposures that are not produced by CW (unmodulated) RF radiation. These studies have resulted in concern that exposure guidelines based on thermal effects, and using information and concepts (time-averaged dosimetry, uncertainty factors) that mask any differences between intensity-modulated RF radiation exposure and CW exposure, do not directly address public exposures, and therefore may not adequately protect the public. The parameter used to describe dose/dose rate and used as the basis for exposure limits is time-averaged SAR; time-averaging erases the unique characteristics of an intensity-modulated RF radiation that may be responsible for producing an effect.

Are the results of research reporting biological effects caused by intensity-modulated, but not CW exposure to RF radiation sufficient to influence the development of RF exposure guidelines? If so, then how could this information be used in developing those guidelines? How could intensity modulation be incorporated into the concept of dose to retain unique characteristics that may be responsible for a relationship between exposure and the resulting effects?

Issue: Time averaging

Time averaging of exposures is essential in dealing with variable or intermittent exposure, e.g., that arising from being in a fixed location of a rotating antenna, or from moving through a fixed RF field. The 0.1 h approach historically used should be reassessed, but may serve this purpose adequately. Time averaging for other features of RF exposure is not necessarily desirable, however, and should be reevaluated specifically as it deals with modulation of the signal, contact and induced current limits, and prolonged, or chronic exposure. These specific conditions are discussed in a little more detail elsewhere.

If prolonged and chronic exposures are considered to be important, then there should be a reconsideration of the time-averaging practices that are incorporated into existing exposure guidelines and used primarily to control exposure and energy deposition rates in acute/subchronic exposure situations.

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Issue: Lack of peak (or ceiling) limits for induced and contact current

A recent change in the IEEE guidelines allows for 6 minute, rather than 1 second, time-weighted-averaging for induced current limits. This change increases the concern about the lack of a peak limit for induced and contact currents. Will the limits for localized exposure address this issue, i.e., for tissue along the current path?

Issue: Criteria for preventing hazards caused by transient discharges

The existing IEEE recommendation states that there were insufficient data to establish measurable criteria to prevent RF hazards caused by transient discharges. If specific quantitative criteria are still not available, can qualitative requirements be included in the standard to control this hazard (e.g., metal objects will be sufficiently insulated and/or grounded, and/or persons will utilize sufficient insulating protection, such as gloves, to prevent undesirable transient discharge.)?

ISSUE: Limits for exposure at microwave frequencies

Concerns have been expressed over the relaxation of limits for continuous exposures at microwave frequencies above 1500 MHz. The rationale provided in the current guideline (Section 6.8) references the fact that penetration depths at frequencies above 30 GHz are similar to those at visible and near infrared wavelengths and that the literature for skin burn thresholds for optical radiation "is expected to be applicable." The rationale then implies that the MPE limits at these high frequencies are consistent with the MPE limits specified in ANSI Z136.1-1986 for 300 GHz exposures. This is apparently the rationale for "ramping up" to the MPE limits for *continuous* exposure of 10 mW/cm^2 at frequencies above 3 GHz (controlled) or 15 GHz (uncontrolled). The rationale should be given as to why this ramp function has been established at relatively low microwave frequencies (i.e., 1500 MHz and above), rather than being implemented at higher frequencies that are truly quasi-optical. For example, one option could be two ramp functions, one beginning at 300 MHz, based on whole- or partial-body dosimetry considerations, and another at higher frequencies (say 30-100 GHz) to enable consistency with the laser standard. Such a revision should help reduce concern that the standard is not restrictive enough for continuous exposures at lower microwave frequencies where new wireless applications for consumers could make this an issue in the future.

Issue: Replication/Validation

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

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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 replication/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).

Issue: Important Health Effects Literature Areas:

Documentation should be provided that the literature review process included a comprehensive review of the following three areas:

1) long-term, low-level exposure studies (because of their importance to environmental and chronic occupational RFR exposure);
2) neurological/behavioral effects (because of their importance in defining the adverse effect level in existing RFR guidelines); and
3) micronucleus assay studies (because of their relevance to carcinogenesis).

Issue: Compatibility of RFR guidelines

Compatibility of national and international RFR guidelines remains a concern. It is important for the IEEE Committee to address this issue by identifying and discussing similarities and differences in a revised IEEE guideline and other RFR guidelines.
Compatibility/noncompatibility issues could be discussed in the revised IEEE guideline or as a companion document distributed at the time the revised IEEE guideline is released to the public.

ATTACHMENT 8

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