IEEE SCC-28 Subcommitte 4
Revision Working Group Meeting
Safety Levels with Respect to Human Exposure to Radio Frequency
Electromagnetic Fields, 3 kHz to 300 GHz

Motorola Florida Research Laboratories
8000 West Sunrise Blvd.
Plantation, Florida
March 30-31, 2000
8:15 to 5:30 PM

Agenda

30-Mar
8:15 1. Call to Order Chou/D’Andrea
8:15 2. Introduction of those Present Chou/D’Andrea
8:18 3. Approval of Agenda Chou/D’Andrea
8:20 4. Chairmen report Chou/D’Andrea
8:25 5. Risk Assessment Working Group Report Tell
8:30 6. Mechanism Working Group Report Sheppard
8:35 7. Literature Evaluation Working Group Reports
8:40 a) Literature Surveillance Heynick
8:42 b) Engineering Hurt
8:44 c) In Vitro Meltz
8:46 d) In Vivo Blick
8:48 e) Epidemiology Erdreich
8:50 8. Topic Reports
8:50 a) Spark discharge and induced current (Reilly)
   * Criteria for Preventing Hazards Caused by Transient Discharges
   * Lack of Peak (or Ceiling) Limits for Induced and Contact Current
   * Mechanism and measurement techniques for 3 -100 kHz
9:10 Bob Ashley's issues related to induced currents
9:15 b) Thermoregulation (Adair)
   * Thermal effects
   * Surface vs. depth heating
9:35 c) Non-thermal effects (Heynick)
9:55 d) Selection of an Adverse Effect Level (Sheppard)
   * Amplitude modulation
10:15 Break
10:30 e) Whole body SAR limit (Chou/D’Andrea)
10:50 f) Biological Basis for Local SAR Limit (Meltz)
11:10 g) Spatial averaging, averaging volume (Tell)
   * Important Health Effects Literature Areas
11:30 h) Single vs. two tier (Erdreich)
   * One-Tier vs. Two-Tier Guidelines
   * Controlled vs. Uncontrolled (Applicability of 2 IEEE Exposure Tiers)
   * Uncertainty Factors
12:00 Lunch
13:00  (Single vs. two tier continued)
13:30  i) Peak power limits  (D'Andrea)
     *  Pulsed (Intensity) or Frequency-Modulated RF Radiation
13:50  j) Low power device exclusion, measurement distance  (Petersen)
     *  Compatibility of RFR Guidelines
14:10  k) Averaging time 6 GHz to 300 GHz  (Foster)
     *  Time Averaging
     *  Limits for Exposure at Microwave Frequencies
14:30  l) Replication/Validation (Curtis)
14:50  Break
15:10  9. Discuss working format
17:30  Adjourn
18:30  Dinner

31-Mar
8:15   10. Working group meeting
       (Details to be determined on March 30)
10:00  Break
10:20  (working group meeting continued)
12:00  Lunch
13:00  (working group meeting continued)
17:00  11. New Business
17:15  12. Date and Place of Next Meeting
       Chou/D'Andrea
       *  SC4 meeting in Munich June 9, 2000
       *  2nd Working Group meeting, ?, September 2000
17:30  13. Adjourn
1. The meeting was called to order at 8:15 am. It was noted that the agenda for the day would be modified slightly to accommodate the later arrival of Marty Meltz, shifting his report until later in the agenda (notes will follow the order of the actual session). It was noted that Ron Petersen would not be attending but that he sent a summary statement covering the low power device exclusion and the averaging volume. All in attendance at the start of the meeting then contributed to a round the table introduction.

2. Attendees: Eleanor Adair, Robert Ashley, Dennis Blick, Jerrold Bushberg, CK Chou, Jules Cohen (first day only), John D’Andrea, Linda Erdreich, James Hatfield, Lou Heynick, William Hurt, Johnathan Kiel, B. Jon Klauenberg, Martin Meltz, J. Patrick Reilly, Deborah Sena (first day only), Asher Sheppard, Mays Swicord, Ric Tell.

3. The agenda was approved.


5. **Risk Assessment Working Group Report**

Ric Tell reviewed the current position of the RAWG. Without having access to the reviews of the literature surveillance, the RAWG has concluded that, in the absence of identified adverse effects attributable to other mechanisms, only thermal effects would be considered for setting numerical standards. Physicians in the group emphasized that the standard should be safe (protective) for everyone (95% of the population). A one-tier standard was proposed, with possible exclusions for those in shape (not compromised). For the physically fit, core body temperature can be elevated by 1°C. Some stated the opinion that the standard should be based on exposure levels that produce no body temperature elevation.

A question was raised whether or not the standard needed to address the issue of RF EMI and pacemakers/defibrillators. Tell responded that the RAWG was not addressing that issue. Chou responded that EMI requirements of those systems should take care of this. Tell said that it was not true for small populations [what’s meant here? “a relatively few users of implanted medical devices”?] particularly because the spatially averaged field may include localized regions with higher field strength. Swicord ended the discussion by reiterating that this is not a direct impact of the RF, that it is an EMC issue for the device manufacturers.
6. **Mechanism Working Group**

Asher Sheppard reported that related work on mechanistic influences on the selection of adverse effects level would be presented later in the meeting.

7. **Literature Surveillance Working Group**

Lou Heynick reported that currently there are 1378 citations entered in the database. They are categorized as pertaining to the Engineering, Epidemiology, In Vitro, and In Vivo WGs, plus a file “Peripheral” (in which some citations are relevant to one or more WGs but not necessarily to be formally reviewed).

[As a member of the Editorial Committee] He also provided suggested text that describes the procedures of the four working groups, for use in the Rationale section.

William Hurt reviewed the engineering progress. The goal is to have 386 papers reviewed by at least 2 reviewers. Helen Sheriff digitized 436 reviews, 41 reviews still need to be digitized. The number of papers still out with reviewers is 87. Heynick brought up the point that papers with experimental data and exposure methodology need also be reviewed by the Engineering WG. Blick commented that the usability issues still remain. Tell stated that he wants the whole RAWG to have access to the reviews.

Dennis Blick reported on the in vivo status. There are 800 papers to be reviewed (2 reviewers for each of 400 papers). To date 545 have been evaluated, 202 are completed. He stated that some reviewers are holding papers. Chou offered to send a letter to urge completion. There was also some discussion over using existing published reviews, but that is not possible because they would not be in the format required for the database.

Linda Erdreich reported on the epidemiology review status. There are 110 papers to be reviewed, 96 are completed and a couple are digitized. She called for help on a computer system glitch and also proposed that there should be a new chair. At this time there are only 2 active reviewers, participation is limited due to lack of interest. Deborah Sena mentioned that the people doing the WIRC (www.wirc.org) review of studies are epidemiologists and may be interested in participating.

It was discussed that streamlining the review process could start by eliminating those studies where exposure assessment methodology was not well documented. Some concern was express that the experts reviewing had no experience with RF and there was a need that they be ‘comfortable’ with the technical terms and parameters of RF exposure. It was suggested that some joint work could be done with the engineering group. Someone remarked that all papers with deficient exposure assessment provide some information and should not be discarded.

Linda also commented on how epidemiology is used. It can demonstrate health effects that may corroborate laboratory research or may fail to demonstrate health effects that
may be suggested from laboratory findings and on *a priori* grounds, which are often speculative. She stated that generally it is not used for quantitative use in standards setting.

8. **Topic Reports**

*Spark discharge and induced currents*

Patrick Reilly gave a presentation which included view graphs of graphs, tables and other information that were distributed in the meeting.

As the peak pulsed fields were discussed, John D’Andrea commented regarding electro-stimulation avoidance that it is adverse but not health-threatening, with no cumulative evidence for the latter.

Reilly went on the talk about the duty factor- large peaks can exceed threshold. We can go to 3 MHz in the laboratory, theoretical models go beyond that. The recommendations are as follows:

- **Controlled Environment:** Probability of painful reaction would be 1% (most sensitive). It was noted that the ratio of pain to perception threshold is very small, 1:4.
- **Uncontrolled Environment:** Added safety factor of 3. Uncertainties of methods, for general public- not scientific based.

There are 2 consistent studies, the ratio of pain to perception was greater. A question was raised about not real world measures- that none exist, a response was the MRI machines represented a real world scenario.

The point was made about having a different philosophy than other standards until now- removed the safety factor for uncontrolled. A question of what data was available/used, was raised. ICNIRP/Europe has no basis.

An example was raised- magnetic induction heaters. Linda Erdreich asked what was the risk assessment support for using the 3X safety factor?

**Induced currents**

Reilly said that a proposal has been sent to the working group. The difference from C95.1 is a lower level touch contact for the general public in addition to the grasping contact limit for the controlled environment.

**Spark Discharge**

Reilly reported that there has not been a lot more research done. Currently there are only guidelines. There is no MPE in C95.1 for spark discharge.
Bob Ashley’s issues related to induced currents

Bob submitted his comments as a document to the group. See the attachment. At the meeting the following brief comments were made. We need the nuts and bolts. The electric field inside the body is what we need. It takes care of non-linear fields. The burden is on the enforcement agencies to come up with how to measure, especially current density in the ankles.

Thermoregulation

Eleanor Adair presented on the topics of thermal effects and surface versus depth heating. Handout was distributed. She opened by stating that the standards to date are all based upon animal data. We now have human data to focus on to fill the holes. We need to build bridges between human and animal studies. Certain techniques from the classical thermophysiological literature will be very valuable. These include:

- Computerized models (such as the work Ken Foster has done, based on Hardy/Stolwijk formulation)
- Heat/balance equation
- Heat stroke hazard as a defined upper limit

The committee needs to decide what the thermal hazard is. Asher Sheppard questioned whether it [thermal hazard used as the basis of the standard? Adair’s research?] is the worst case in the real environment. Adair went on to review her recent human study work. The partial-body exposures were 50 & 70 mW/cm² at 2450 MHz (range 13% from center point to rest of exposed area) centered on the subject’s back. This summer she is tooling up to study physiological effects of exposure to 100 MHz in a new chamber.

Non-thermal effects

Lou Heynick discussed non-thermal effects. He put forth a strawman that was sent around prior to the meeting.

It was recommended that the RAWG should address the ‘reported effects’. There was some discussion on the use of term associated with these effects, such as calling them ‘weak’. Mays Swicord objected to using that term. It was felt that the introduction to the new standard needed to address mechanism contributions. Also there was a need to address what is an established adverse health effect.

Selection of an Adverse Effect Level

Asher Sheppard offered definitions of the terms “adverse effect” and “potentially adverse effect” and stated presented a categorization of adverse and potentially adverse effects for mechanisms described in terms of direct and induced currents in the body, increased body temperature, behavioral responses, physiological responses observed in animal studies, and physiological effects observed in cell and tissue preparations. That there was work on a definition of “adverse”- where it was well established. He also addressed modulation-related effects, the temporal nature of effects, and several possible bases for setting numerical standards. He also described the relationship between adverse effects and
dosimetric quantities measured in the laboratory and in the environment. Finally, he mentioned the influence of scientific uncertainty and knowledge gaps in setting an adverse effects level. There was discussion of getting rid of the 2nd tier which was cited as “potentially trouble – draws a bull’s eye” [around ??]. He brought up the point that with "weight of evidence," something doesn’t exist if there is no data.

**Whole Body SAR**
Chou and D’Andrea then led the discussion on whole body SAR. The question was if the new standard would maintain the current limit. It was accepted that the current limit was viewed as “conservative” and could be raised. If it was raised, however, how would the change be explained. Ric Tell offered that with the new human data we could say we had a better explanation and more confidence in the limit. Is this as critical as actual exposure (to humans) or other factors? Adair said she could provide the equivalent responses at 4 W/kg for humans.

**Spatial averaging, averaging volume**
To accomplish spatial averaging, the fields must be analyzed. Foster says we should throw away the concept of averaging volume. Ashley said we should use current density or the internal E-field. Adair said we should use temperature increases in core and skin as criteria. Cohen and Tell brought up non-uniform exposure vs partial-body exposure for discussion. The IEEE 1.6 W/kg over 1 gram average was contrasted with the ICNIRP 2 W/kg over 10 gram average. The need to emphasize practicality in the new standard was emphasized.

**Single vs. two tier**
Linda Erdreich commented that the current limits did look across 35 species. She did raise: what about standard errors in the data, long term exposure data, and not sure of adaptation potential. The data show no long-term effects on tissue toxicity or cancer. She also discussed safety vs uncertainty factors.

Jerry Bushberg commented that is discussing having only one tier, or relaxing requirement for certain situations (now know as ‘controlled’ environments) the environmental situation can be higher but because of protective gear and training, the actual exposure is no higher than the standard. The following conditions would apply: take whatever measures necessary to protect the worker. It was brought up that some tasks are difficult to impossible to execute with the gear/training recommended (real world). One comment presented was what are we going for, providing comfort or protecting against an adverse effect? It was suggested that the goal was one standard. Ellie Adair commented that providing the exceptions/details for the ‘relaxed’ exceptions might be unwieldy.

There was a consensus reached that a single set of exposure limits would be developed. This set of exposure limits would protect against adverse biological effects. We recognize the fact that some exceptions can be made so that certain tasks can be
accomplished if appropriate protection is provided. John D'Andrea commented about the question of balloting and the larger acceptance of what will be proposed- as the venue to confirm the tier issue.

**Literature Evaluation- In Vitro**

Due to his later arrival, Marty Meltz was next to present the status review for the in vitro Literature Evaluation. The articles being reviewed include mutagenesis and carcinogenesis. Ninety articles have been reviewed, 51 reviewed by 2 people with only 1 discordance and 38 have been reviewed by 1 person. Eighty-nine have ratings below 2. Therefore it is clear that the literature is not of good quality in this area. A chairman check-off/comment is still needed but all are on disk. Many papers are still not reviewed.

Mays Swicord asked about increase of the temperature in small tissue mass. With a few peak pulses, how long to impact cells (hyperthermia at a certain temperature for a time period)? The reply was that for continuous wave (CW) maybe, for pulsed wave (PW) may need some time exposure limit for 1°C. The example of the eye was mentioned. Temperature over time is what is critical for particular organ (need to cover all so no surprise) for not using peak SAR. Again, “Show me the Data”.

The question of WTR results was brought up and Marty commented that looking at the abstract, it did not look like the work could be replicated. It was reiterated that one positive result is never accepted as establishing genotoxicity. He said while we need temporal and spatial averaging, we may not need a high peak. He was willing to go up to 30 W/kg peak.

Both Ric Tell and John D’Andrea responded that there is 1 study (not replicated) that showed eye impact with repeated exposure below the threshold (cumulative?).

Marty concluded that it should stay where it is (pulsed limit) because there is no new data showing effects above or below. Yes, there are a lot of ultra wideband pulse experiments going on, but he does not see careful controls comparing it to continuous wave.

John D’Andrea said that we could go up for peak restrictions. He emphasized that we need to deal with ultra wideband (which is now in DoD work). We need restrictions for both narrowband and wideband.

Marty questioned what about testes hotspots? Asher Sheppard interjected that Annex H should address this, keep actual standard simple. Details should be in the annex.

The question was raised, what about low level effects? The response is that those that exist- there is not a lot of data and it is mostly unpublished. It was mentioned that there is no one looking at CDMA pulse- there is no data. A comment was presented that the concern should be with public access, don’t worry about it for the standard, it can be part of the exceptions (ultra wideband). The big issue with spread spectrum/wideband is with the dosimetry.
Mays Swicord then commented that there is information (a graph) on the WHO web page summarizing the research that is under way. Glancing through the list he counted 128 studies funded at $100 M that are going on or planned.

**Low power device exclusion, measurement distance**
Petersen was not in attendance and Chou read his submitted email covering the status. Petersen says to keep the low power device exclusion and extend it to higher frequencies to cover cell phones. He can get appropriate data from SCC34 with regard to compliance testing. Is the 1.6 W/kg currently in use going to change? Petersen also counsels that the new standard retain the 5 cm measurement distance from direct radiators as well as the 20-cm distance from re-radiating objects.

**Averaging time 6GHz to 300GHz**
John Osepchuk sent in a report for Ken Foster. He recommended a 2 slope model with a break at 30 GHz.

**Replication/Validation**
Bob Curtis did not attend.

9. **Discuss Working Format**
Mays Swicord started the discussion by suggesting a working proposal would be to ‘paste & cut’ based upon contributions and the existing standard outline/document. The first part of the document would be normative and the second part would be informative which gives details and background.

Meltz commented that if you don’t get an effect at higher exposures, you can’t assume no effect at low exposures because it may inhibit the low-level effect.

The counter was offered that where you have higher exposure you do have some lower exposure so it is covered.

Erdreich commented about the public acceptance of any temperature rise by RF. Deborah Sena emphasized that the concern will be differentiated by whether or not the exposure is voluntary or involuntary.

Tell mentioned other criteria to be considered besides core temperature. Discussion of Ellie’s work, actual SAR, establishment of work practices to ameliorate rise over 8 hour exposure. Tell said he couldn’t get an answer from the developers of the 8 hour averaging, what about public?
There was discussion as to what constitutes reasonable conditions. That there is no public acceptance of perception of a bio effect as differentiated from an adverse effect. The question of developing worst case scenarios was also resurfaced.

Erdreich commented that there would be value in basing it on noticing physiological changes and do away with safety factors.

There was a questioned raised about finding anything (paper) on local SAR review (technically derived bio effect).

1 W/kg was discussed as the limit. Ric Tell brought up non-uniform modeling.

Pat Reilly mentioned that the current direction of the new standard could prompt a headline such as “IEEE gives up all pretense of considering effects besides thermal”. There was concern raised that this path would result in opposition to the standard. There was then more discussion of the current standard and how it is perceived as not considering other effects.

Erdreich stated that we must remember to document replicated studies effects. There was more discussion on the existing standard- 2 tier, additional safety factors for public, etc.

Tell commented that reporter will ask, “who wrote the standard?”

The topic of the FDA rationale for submitting weak papers asking for a NTP (National Toxicology Program). The comments included, “they will do their own thing.” Erdreich commented that we are doing it ‘their way’ with risk assessment, etc.- it will be acceptable.

Meltz commented that the challenge will be grandmas, babies, spatial averaging, part of body susceptibility. Tell questioned temperature variations throughout the body. Adair replied it is very small except for the surface. It was mentioned that the worst case absorption would be infants. Guy’s work on scale models of adults in different position was cited. Also Van Leuwen calculations on changing brain temperature with cell phone.

It was brought up that Ellie’s work has only been done at 2 frequencies, 1 study as a data point. [That study is now complete.]

Marty suggested a compromise of dropping the 5x safety for the public but retaining the 10x. As an alternative more to 1.

Tell expressed concern that the proposal to base the standard on temperature would impact measurements and research- all studies now use SAR.

Jon Klauenberg summarized the groups consensus.

⇒ There will be a single tier standard
⇒ Protect against physiological change [Note: This is impossible, as physiological change is ongoing all the time.]
⇒ The threshold is thermal/basis will be thermoregulatory response

Friday’s work session would be broken up by section. The chairs for each would be: A- Erdreich, B- Sheppard, C- Tell, D-H not to be addressed now.

10. **Working Group meetings on March 31, 2000**

Summary of March 30-31, 2000 Meeting of SCC28/SC4 Revision Working Group

a. Reviewed status of literature review per agenda (3/30)
b. Items 8.a through 8.1 of agenda (3/30)
c. Consensus decision at this time was only thermal (>100 kHz), and electrostimulation hazards are established. Other potential bases for standard setting are under scrutiny. (3/30)
d. Consensus that a single set of exposure limits will be derived. (3/30)
e. The group was subdivided according to the outline for the Informative Section. (3/31)
   - Annex A (Approach to Standard Revision) will incorporate risk assessment principles for weighing the evidence, assessing variability, and identifying adverse effects and dose-response relationships.
   - For preparation of Annex B (Summary of Literature Evaluation), the list of 1378 papers in the database was subdivided by topic to enable scientific evaluation in coordination with the technical merit reviews. Requested peer review of document that proposed low-frequency limits. Proposed to identify established bioeffects for assessment by the RAWG.
   - Annex C (Explanation of Maximum Permissible Exposure Limits) refined the objective of presenting unified limits applicable for particular frequencies based on electrostimulation effects below 100 kHz (with possible extensions for pulsed fields up to 3 MHz), whole-body and partial-body thermal and/or other effects (100 kHz to 6 GHz), and surface heating above 6 GHz. Inconsistencies among several exposure metrics in the present standard will be resolved. Protection against RF burns from spark discharges was discussed for possible inclusion in the standard.
f. The meeting work product is to be further developed for submission to CK Chou by May 15 for review by the Revision WG. It will be submitted to the RAWG by July 10 for review and completion.

11. **New Business**

12. **Date and place of next meeting**

Chou will contact SC4 members who work for the federal government, about where and when to meet in September in order to get government inputs to the standard.

13. **Adjourn** 4:30 pm