DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

National Institute for Occupational
Safety and Health
Robert A. Taft Laboratories
4676 Columbia Parkway
Cincinnati OH 45226-1998
June 17, 1999

Mr. Richard Tell
Chair, IEEE SCC28 (SC4)
Risk Assessment Work Group
Richard Tell Associates, Inc.
8309 Garnet Canyon Lane
Las Vegas, NV 89129-4897

Dear Mr. Tell:

The members of the Radiofrequency Interagency Work Group (RFIAWG) have identified certain issues that we believe need to be addressed to provide a strong and credible rationale to support RF exposure guidelines. I am writing on behalf of the RFIAWG members to share these ideas with you and other members of the IEEE SCC28, Subcommittee 4 Risk Assessment Work Group. Our input is in response to previous requests for greater participation on our part in the SCC28 deliberations on RF guidelines. The issues, and related comments and questions relevant to the revision of the IEEE RF guidelines, are given in the enclosure. No particular priority is ascribed to the order in which the issues are listed.

The views expressed in this correspondence are those of the members of the Radiofrequency Interagency Work Group and do not represent the official policy or position of the respective agencies.

The members of the RFIAWG appreciate your consideration of our comments and welcome further dialog on these issues. Feel free to contact me or any member of the RFIAWG directly. A list of the members of the RFIAWG is enclosed, with contact information for your use.

Sincerely yours,

W. Gregory Lotz, Ph.D.
Chief, Physical Agents Effects Branch
Division of Biomedical and
Behavioral Science

Enclosures (2)
cc: N. Hankin
J. Elder
R. Cleveland
R. Curtis
R. Owen
L. Cress
J. Heale

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.

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 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 the susceptibility (response/sensitivity) among individuals,

(4) incomplete data bases,
(5) uncertainty in the selection of the effects basis, inability of any single study to adequately address all possible adverse outcomes.

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 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.

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 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.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

JUL 16 2003

OFFICE OF
AIR AND RADIATION

C. K. Chou, Ph.D.
Co-Chairman, International Committee on Electromagnetic
Safety (ICES), Subcommittee-4
Motorola Incorporated, Florida Research Laboratory
8000 West Sunrise Boulevard
Plantation, FL 33322

Dear Dr. Chou:

This letter is in response to your proposal of a meeting with the federal Radiofrequency Interagency Work Group (RFIAWG) that would provide an opportunity for the IEEE ICES SC4 to give the Work Group an update of the revision of the C95.1-1999 standard.

We look forward to your presentation regarding the items listed in your proposed agenda, i.e., approaches of standard setting, literature review, rationale, basic restrictions and reference levels, and responses to the 14 issues raised by the RFIAWG in the June 17,1999, letter to Richard Tell.

The RFIAWG is particularly interested in how these 14 issues are to be treated in the revision process. In addition, the RFIAWG is submitting the following additional issues for the ICES consideration and response.

Issue: Exclusion of pinna

If the pinna is to be considered an extremity and subjected to exposure limit of 20 W/Kg over 10 g of tissue, then a clear rationale for treating the pinna as an extremity should be presented. This rationale should include biological properties of the pinna that qualifies it for this exclusion. If thermal effects would be the basis for the ICES standard, then the thermophysiology of the pinna and the skin, bone and other head tissues adjacent to the pinna should be discussed for all body sizes exposed.

Issue: Rationale for relaxation of current limits

Federal agencies, as well as the general public and the public health community, are very concerned about a relaxation of exposure guidelines that may result in increased exposure in the future. A rationale should be presented for relaxation of standards. The rationale should include a clear explanation of the impact of the exposures that may

result, i.e., the description of the exposures and the effects on critical tissues and organs. An explanation should be given as to why the current standard should be relaxed. The issue of safety factors should be also be addressed as part of the rationale for relaxation of current limits.

Issue: Sensitivity of different tissues

A clear explanation on how the revision has taken into account sensitivity of different tissues to temperature. Effects of acute and chronic exposure to elevated temperature should be adequately covered. We consider it appropriate to include as a part of the revised standard a description of the risk analysis that was done.

We ask that the RFIAWG be provided with a copy of the ICES response to all of the issues raised by the RFIAWG in advance of a meeting so that the Work Group members have sufficient time to study them and prepare for the meeting. We also request that you provide any other materials that you feel would be of value to the Work Group in preparing for a meeting.

Please be aware that comments and opinions that may be expressed by the RFIAWG participants are their personal comments and opinions and have not been reviewed and/or approved by their management or their agencies.

Sincerely,

Norbert N. Hankin
Center for Science and Risk Assessment
Radiation Protection Division

Enclosure

cc: H. Bassen
C. Blackman
R. Cleveland
R. Curtis
H. Cyr
A. Desta
J. Healer
W.G. Lotz
E. Mantiply
R. McGaughy

Radiofrequency Interagency Work Group Members

Alphabetical Listing

Cleveland, Robert
Senior Scientist
Federal Communications Commission
Office of Eng & Technology, Room, 230
2000 M St. NW
Washington, DC 20554
(202) 418-2422
(202) 481-1918 (fax)
rclevela@fcc/gov

Cress, Larry
US FDA, CDRH
Radiation Biology Branch, DLS, OST
9200 Corporate Blvd. (HFZ-114)
Rockville, MD 20850
(301) 443-7173
(301) 594-6775 (fax)
lwc@cdrh.fda.gov

Curtis, Robert A.
OSHA
Dir-U.S. Dept. of Labor/OSHA
OSHA Health Response Team
1781 S. 300 W.
Salt Lake City, UT 84115-1802
(801) 487-0521, ext. 243
(801) 487-1190 (fax)
rac@osha-slc.gov

Elder, Joseph A.
US Environmental Protection Agency
U.S. EPA, NHEERL (MD-87)
2525 Highway 54
Research Triangle Park, NC 27711
(919) 541-2542
(919) 541-4201 (fax)
elder.joe@epamail.epa.gov

Hankin, Norbert N.
U. S. Environmental Protection Agency
Mailcode 6604J
U.S. EPA
Washington, DC 20460
(202) 564-9235
(202) 565-2038 (fax)
hankin.norbert@epamail.epa.gov

Healer, H. Janet
NTIA
Department of Commerce (H-4099)
14th & Constitution Ave., NW
Washington, DC 20230
(202) 482-1850
(202) 482-4396 (fax)
jhealer@ntia.doc.gov

Lotz, W. Gregory
Chief, Physical Agents Effects Branch
National Institute for Occupational Safety and Health
4676 Columbia Parkway C-27
Cincinnati, OH 45226-1998
(513)533-8153
(513) 533-8139 (fax)
wlotz@cdc.gov

Owen, Russell D.
U.S. FDA/CDRH (HFZ-114)
Chief, Radiation Biology Branch (HFZ-114)
9200 Corporate Blvd.
Rockville, MD 20850
(301) 443-7153
(301) 761-1842 (fax)
rdo@cdrh.fda.gov

A 2013 presentation by the FCC shared the RFIAWG Charter.

Research Needs and Activities for Compliance Assessment

Robert D. Weller

Federal Communications Commission
Office of Engineering & Technology
Washington, DC USA

Approved Minutes – 17 January 2013 TC95 SC3/SC4 Meeting

ATTACHMENT 10

RFR Regulation in the U.S.A.

- FCC establishes and enforces RF exposure limits from regulated facilities and equipment, but FCC is not a health agency
- U.S. Health and Safety agencies are responsible for monitoring research and advising FCC on appropriate safety limits. FCC has regular meetings with experts from:
  - EPA
  - FDA
  - NIH
  - NIOSH
  - OSHA

Radiofrequency Interagency Work Group

Environmental Protection Agency
Federal Communications Commission
Food and Drug Administration
National Telecommunications and Information Administration
National Institutes of Health
National Institute of Occupational Safety and Health
Occupational Safety and Health Administration

Charter

The Radiofrequency Interagency Work Group (RFIAWG) is composed of Federal agencies which have regulatory or public health responsibility to evaluate or control the risk to public health from the use of specific devices or exposure to radiofrequency energy, or have responsibility for regulation and management of the use of the radiofrequency spectrum.

The purpose of the Radiofrequency Interagency Work Group is to provide a forum to discuss public health and regulatory issues pertaining to radiofrequency radiation, and to provide a basis for technical and policy coordination among member agencies in their approach to human exposure to radiofrequency energy. The RFIAWG may address the development of non-ionizing electromagnetic radiation exposure standards, guidance or guidelines to better understand the implications of exposure on human health and the environment, and prudent use of specific devices or technologies. The RFIAWG provides a forum for discussion of specific RF radiation-related activities and policies of the member Agencies that could affect other federal agencies represented in the Group. The Work Group also provides a forum to discuss developing issues, research, and to address the need for long-range federal strategy. It is intended that such coordination and discussion will lead to a more coordinated federal approach to potential health issues associated with existing and proposed technologies which use and produce human exposure to RF energy.

The RFIAWG was originally established by formal invitation to executives of the