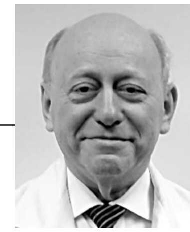
COMAR Technical Information Statement the IEEE exposure limits for radiofrequency and microwave energy



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Introduction

Excessive exposure to radiofrequency (RF) or microwave energy produced by radio transmitters, some industrial equipment, and other sources can be hazardous. For this reason, the IEEE has developed limits for human exposure to RF energy, and these limits have been widely influential around the world.

The IEEE standard represents a consensus of scientific opinion about safe levels of exposure to RF energy, and its scientific rationale is consistent with conclusions of numerous expert groups and health agencies throughout the world. Nevertheless, laypeople often have questions about the adequacy of the standard or the process by which it was developed. This Technical Information Statement discusses the development and rationale for exposure limits for RF energy.

The present focus is on the process that led to the IEEE C95.1 standard [1] covering the frequency range 3 kHz–300 GHz, which includes the radiofrequency part of the spectrum. Other major exposure limits, in particular the widely-referenced guidelines of the International Commission on Nonionizing Radiation Protection (ICNIRP) [2] have a similar rationale but were developed using different processes.

History of IEEE Exposure Limits for RF Energy

The origin of the IEEE C95.1 standard traces back to 1960 when the American Standards Association (now ANSI, a clearing house for standards of all sorts) approved the Radiation Hazards Standards Project C95 and established a committee charged with developing RF exposure standards [3]. The first C95 standard, USASI C95.1-1966, was published in 1966, and major revisions were published in 1974 and 1982. In 1989, the IEEE assumed sponsorship of the committee, which became IEEE Standards Coordinating Committee 28 (SCC-28). In 2001 SCC-28 adopted the name IEEE International Committee on Electromagnetic Safety (ICES).

Under both IEEE and ANSI bylaws, standards (of all sorts) must be periodically updated and revised. The latest standard, IEEE C95.1-1991 was approved by the IEEE Standards Board in 1991 and by ANSI in 1992. This standard was reaffirmed in 1997 and a supplement published in 1999. It is presently undergoing another round of revision, with publication of the revised standard anticipated in 2004.

Thus, the present IEEE exposure guidelines have a lineage that extends back for nearly half a century. While the C95.1 standards are voluntary, they have had a major influence on government policy in the United States and in the development of exposure limits in many places around the world.

Scientific Basis of IEEE/ANSI (ICES) Standard

When considering possible hazards of RF energy, it is important to distinguish between levels of fields outside the body (the exposure), and field levels or absorbed energy within body tissues (the dose). The exposure is measured in terms of the electric or magnetic field strength, or power density incident on the body. The dose depends on the exposure, as well as on body geometry, size, its orientation with respect to the external field, and other factors.

Between approximately 100 kHz and 10 GHz, the specific absorption rate (SAR) is the dosimetric quantity that correlates best with reported biological effects of RF energy. The whole-body-averaged SAR is the total power absorbed by the animal or human (in watts) divided by the body mass (kilograms), and is expressed in units of W/kg. The whole-body SAR is computed or measured experimentally, frequently using "phantom" models whose electrical characteristics are similar to those of tissue.

For localized exposures to parts of the body, for example the head of the user of a mobile phone, a more useful measure is often the partial body exposure, which is the power absorbed per unit mass in a localized region of tissue, also expressed in W/kg.

At frequencies below about 100 kHz, a more useful measure of dose is often the electric field strength in tissue, in units of volts per meter.

The IEEE standard is based on a limit to the SAR (called a basic restriction) set on the basis of biological data. In addition, it defines limits to the exposure, as measured by field strength outside the body, which will ensure that the absorbed power within the body meets the basic restriction, which were set on the basis of engineering studies. The ICNIRP guidelines are similar, both in their use of a basic restriction and exposure limits, and in the numerical values of the limits.

As with exposure limits to many potentially hazardous substances, radiofrequency safety standards in most countries have two tiers, which vary in definition but correspond approximately to limits for occupational groups and the general public. For a number of reasons, exposure limits for many agents are higher for occupational groups as compared to the general public.

In the IEEE standard, two tiers are defined as applying to exposures in controlled and uncontrolled environments. In a controlled environment, the exposure is limited to individuals who are aware of the possibility of exposure. Uncontrolled environments are accessible to individuals who may not have this awareness, including the general public, which may limit their ability to respond appropriately if they enter areas with excessive exposure. For that reason, the standard provides lower exposure limits in uncontrolled areas.

Identification of Hazard

The IEEE C95.1-1991 standard was based on a comprehensive review of the scientific literature, covering all reliable studies that reported biological effects of RF/microwave energy. This task, and the development of a draft standard, was accomplished by a 125 member subcommittee (Subcommittee 4) of IEEE Standards Coordinating Committee 28 (Table 1).

The scientific literature related to biological effects of RF energy is highly diverse, both in terms of scientific quality and in terms of relevance to possible health and safety risks to humans. Consequently, the review process examined only studies that met selection criteria that included adequate dosimetry and experimental design, and independent confirmation of reported effects. Studies that were not published in the peer reviewed scientific literature, and those that were inadequately described to permit critical analysis, were excluded from consideration.

Based on its review, the subcommittee concluded that disruption of food-motivated learned behavior in laboratory animals is the most sensitive biological response that is both well confirmed and predictive of hazard. This effect, known as behavioral disruption, has been observed in laboratory animals ranging from rodents to monkeys exposed to RF fields at frequencies ranging from 225 MHz to 5.8 GHz. Depending on the animal species and RF frequency, the exposure needed to produce behavioral disruption varied widely, from about 100 to 1400 W/m^2. However, the whole-body SAR in the animals varied over a smaller range, from 3.2 to 8 W/kg. The threshold for behavioral disruption has been associated with an increase in body temperature of the animals of about 18 °C.

Setting Basic Restriction and Exposure Limits

From its literature review, the subcommittee chose a value of 4 W/kg for the whole-body-averaged SAR as the threshold for behavioral disruption in animals. It reduced this SAR by a factor of 10 to establish the basic restriction for exposure in controlled environments, and then added another factor of 5 for exposure in uncontrolled environments. The resulting basic restrictions on whole body SAR are 0.4 W/kg for controlled environments, and 0.08 W/kg for uncontrolled environments. The basic restrictions are, as a result, a factor of 10 to 50 below whole-body exposure levels shown to produce behavioral disruption in animals in exposures ranging from several minutes to several hours in duration.

Table 1(a). Affiliations of the 125 members of Subcommittee 4 of IEEE Standards Coordinating Committee 28 at the time the 1991 standard was approved. This Subcommittee drafted the standard.

Affiliation		Number	Percentage
Research	University:	37	29.6
	Nonprofit	8	6.4
	Military	15	12.0
	Government (FDA, EPA, etc.)	30	24.0
Industry		12	9.6
Industry—consulting		4	3.2
Government—administration		5	4.0
General public and independent consultants		14	11.2
Total		**125**	**100.0**

Table 1(b). The principal disciplines of the 125 members of Subcommittee 4 of IEEE Standards Coordinating Committee 28 at the time the 1991 C95.1 standard was approved.

Principal Discipline	Number	Percentage
Physical sciences (physics, biophysics, engineering, etc.)	41	32.8
Life sciences (biology, genetics, etc.)	54	43.2
Medicine (physicians)	12	9.6
Radiology, pharmacology, toxicology	4	3.2
Others (law, medical history, safety, etc.)	14	11.2
Total	**125**	**100.0**

Based on engineering analysis, the committee then established limits to the external field (exposure) that would ensure that the basic restrictions are met. Because the absorption properties of the body depend on frequency, the resulting exposure limits do also. Other limits were developed for partial body exposure and for fields of unusual characteristics, such as very short pulses of very high intensity.

Also based on engineering considerations, the subcommittee established limits to partial body exposure. This was based on observations that the maximum SAR in any part of the body is approximately 20 times higher than the whole-body average SAR under many exposure conditions. Consequently, the subcommittee (Subcommittee 4 of IEEE Standards Coordinating Committee 28) established a limit of 8 W/kg for partial body exposure for controlled environments, and 1.6 W/kg for uncontrolled environments. These exposures are to be averaged over small volumes (corresponding to 1 gram) of tissue.

Approval of Standard

The draft 1991 IEEE standard underwent a long and rigorous process before being finally approved by IEEE. The first stage in this process was balloting at the level of Subcommittee 4. Consistent with IEEE procedure, the voting was done in several stages. After each preliminary round of balloting, all negative votes and comments were circulated to the subcommittee, and members who had originally submitted ballots were given the opportunity to comment or reaffirm or change their votes; final approval required 75% affirmative votes of those submitting ballots. After being approved by Subcommittee 4, the draft standard was moved to the main committee (SCC-28) for approval using the same balloting process, and then to the IEEE Standards Board for final approval. The final approved IEEE standard was then forwarded to the American National Standard Institute (ANSI) which required a period of public comment and response by the original IEEE standards committee. In 1992, ANSI adopted the standard as an American National Standard.

Presently the standard is undergoing yet another revision, which is expected to be completed in 2004. Working groups of Subcommittee 4 are evaluating approximately 1300 scientific papers related to biological effects of RF fields. These were selected from the peer-reviewed scientific literature, with inputs from federal agencies and other organizations. Another working group is evaluating the literature to determine a threshold SAR for which potentially deleterious effects are likely to occur in human beings. As part of this review, a number of "white papers" have been prepared that review the extant literature relevant to specific topic areas. Many of these papers will be published in a special issue of the journal *Bioelectromagnetics* [4]. As with earlier versions of the standard, an extensive approval process is required, which is designed to provide transparency and documentation of the process at every level [5, 6].

Concerns Raised About the IEEE Standard

Some laypeople have expressed concern about the adequacy of the standard or of the process by which it was developed. Some of these concerns are addressed below.

Concern 1. The IEEE standards setting process for RF energy is captive of industry and represents only industry viewpoints.

The IEEE exposure limits are developed through an open process, which helps to ensure a level of transparency and documentation that is unique in RF exposure limits. The procedures used by the IEEE Standards Association Standards Board, which govern ICES, are explained in [5], and the particular procedures used by ICES are described in [6].

To illustrate the diversity of participants in the IEEE standards development process, the 1991 standard was drafted by a 125-member subcommittee of the main committee, whose members were broadly distributed as to their place of employment and specialty (Table 1).

This committee represented a very broad range of expertise, including physicians, basic scientists, and engineers. Only a minority of its members were from industry; the largest group of members was from academia. The ICES committee that is developing the latest revision of the standard has a similar broad representation as shown in Table 2(a) and (b).

Concern 2. The standard ignores effects of long term exposure and "nonthermal" effects.

The IEEE and other RF/microwave exposure limits standards are based principally on laboratory studies of animals using short exposure durations (hours at most). The limiting effect for whole body exposures (behavioral disruption) is clearly a thermal phenomenon.

Some investigators have reported effects at much lower exposure levels, which are sometimes called "nonthermal" effects. Each version of the IEEE standard has acknowledged the existence of such reports, while at the same time indicating that they were insufficient to be considered a health hazard or to be used as a basis to develop exposure guidelines. For example, the 1991 standard states that "research on the effects of chronic exposure and speculations on the biological significance of nonthermal interactions have not yet resulted in any meaningful basis for alteration of the standard. It remains to be seen what future research may produce for consideration at the time of the next revision of this standard". Other organizations have independently reached this same conclusion.

In summary, the IEEE and other exposure limits are designed to protect against identified hazards of RF energy. During each revision of the standard, ICES and earlier committees failed to find credible evidence of cumulative effects due to chronic exposure, including cancer, or other hazardous effects from low-level exposure.

This judgment, while based on a large body of research that extends back to the 1950s and before, is always open to reevaluation in future revisions of the standard. Other refinements in the standard are being considered in the present revision cycle of the IEEE standard. For example, discussion continues over improving the internal consistency of the standard and elaborating on the use of safety factors in deriving exposure limits.

Concern 3. Other countries have lower limits than the IEEE/ANSI standards, and offer higher protection to their citizens.

The exposure limits for RF energy vary widely in different countries. However, the guidelines of the great majority of countries are similar to those of IEEE or the closely similar guidelines of ICNIRP. A few countries have chosen much lower limits, in part due to differences in philosophy in setting limits. IEEE and most other Western exposure limits are designed on the basis of identified thresholds for hazards of RF fields and thus are science-based. The philosophy behind other exposure limits is very different [7].

For example, Switzerland, Italy, and a few other countries have adopted "precautionary" exposure limits for RF energy. These are not based on identified hazards, but reflect the desire to set exposure limits as low as economically and technically practical, to guard against the possibility of an as-yet-unidentified hazard of RF exposure at low levels.

A quite different situation exists with RF exposure limits of Russia, other states from the former Soviet Union (FSU), and several Eastern European countries, which have long been much lower than those of the United States and Western Europe. This situation has existed since the 1960s or before, and has long been a source of public controversy in the West. The scientific basis for the Russian limits is not clearly stated in their guidelines, and the original research by scientists in the FSU has been difficult to evaluate in detail by Western scientists. While these limits appear to reflect a conviction on the part of FSU scientists that low exposures to RF energy produces health effects, Western health agencies have been uniformly unable to identify any health hazard at exposure levels below IEEE or ICNIRP exposure guidelines.

For both philosophical and practical reasons, it is desirable to "harmonize" exposure limits around the world. This is the goal of a project begun in 1998 by the EMF Project of the World Health Organization, which was motivated in part by the desire to bring similar levels of health protection to different populations around the world [8]. Commercial considerations, related to the increasing globalization of trade, will also encourage countries to adopt uniform exposure limits for RF energy in the future.

COMAR believes that science-based guidelines, such as those of IEEE or the generally similar guidelines of ICNIRP, offer a high level of protection against all identified hazards of RF energy and should serve as models throughout the world. The standards are living documents and will be revised as more scientific data become available.

Table 2(a). Affiliations of the 128 members of the current Subcommittee 4 of ICES.

Category	Number	Percentage
Academic	33	25.8
Consultant	28	21.9
Government	42	32.8
Industry	21	16.4
General Public	2	1.6
Other	2	1.6
Total	**128**	**100.0**

Table 2(b). Principle Disciplines of the 128 members of the current Subcommittee 4 of ICES.

Principle Discipline	Number	Percentage
Physical sciences (physics, biophysics, engineering, etc)	69	53.9
Life sciences (biology, medicine, genetics, etc)	48	37.5
Others (law, medical history, safety, etc)	11	8.6
Total	**128**	**100.0**

Acknowledgments

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(continued on page 121)

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COMAR Reports *(continued from page 117)*

membership and by the IEEE EMBS Executive Committee.

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