Safety Standards

for Exposure to RF Electromagnetic Fields

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Looking back at the past 40 years of development and forward to the new millennium, this article reviews the subject of safety standards for exposure to microwave/RF energy. The present standards are highly advanced with the use of modern dosimetry and a thorough computerized review of the literature. The bioeffects and hazards are predominantly thermal in nature and applicable standards, whether for exposure or product performance, incorporate large safety factors. These standards are the result of broad consensus among an appropriate balance of scientists, engineers, and stakeholders that results under the due process of the IEEE Standards system.

The challenge for the future centers on the international expansion of the key committees IEEE Standards Coordinating Committees 28 and 34, which are already over roughly 20% in non-U.S. participation. We look forward to a key role of the IEEE through these committees in establishing world-wide consensus and the ultimate goal of international harmonization of standards for electromagnetic energy. In so doing, reliance on science-based standards will withstand current attacks from other philosophical approaches to safety based on caution and uncertainty.

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Characteristics of Biological Tissues and RF Absorption

Contemporary safety standards for exposure to radiofrequency (RF) electromagnetic energy cover frequencies up to 300 GHz and down to at least 3 kHz. Although the term "microwaves" usually means frequencies well above 100 or 300 MHz, related bioeffects/hazards, thermal in nature, exist down to roughly 100 kHz. Below 100 kHz, the dominant effects are electrostimulation in nature. Attention will be focused on thermal effects; the reader is referred to an authoritative treatment on the subject of electrostimulation by Reilly [1].

The IEEE is playing a leading role in preserving science-based standards as the accepted credible basis for assuring the safe use of electromagnetic energy

Bioeffects caused by exposure of a biological body to microwave/RF are related to the internal E and B fields associated with the exposure. The distribution of the internal fields is related to a number of parameters, including the dielectric properties of the tissues in the biological body, the geometrical properties of the body, the orientation of the incident field vectors, whether the exposure is in the near or far field, to mention a few. Although modern numerical simulations are used effectively to determine internal field distribution for complex heterogeneous models, e.g., near-field exposure to hand-held wireless transceivers, simple but important properties of the absorption can be illustrated by simple models.

The dielectric properties of various tissues have been tabulated in popular references such as the *Radiation Dosimetry Handbook*, edited by Durney [2] and in Gabriel, et al. [3]-[5] (which is also available on the Internet, http://www.brooks.af.mil/AFRL/HED/hedr/reports/dielectric/home.html) and on interactive Internet sites such as the one hosted by the FCC [6] (http://www.fcc.gov/fcc-bin/dielec.sh). Table 1 shows a tabulation of the approximate values for muscle-like tissue obtained from the above sources.

The complex permittivity is given by:

$$\varepsilon = \varepsilon_r \varepsilon_o + j\frac{\sigma}{\omega} \tag{1}$$

where $\varepsilon_o = 8.86 \times 10^{-12}$ f/m. The penetration depth δ, i.e., the distance from the boundary of a medium to the point at which the field strengths or induced current densities have been reduced to $1/e$ of their initial boundary value in the medium, is given by (2) for a plane-wave incident on a planar surface.

$$\delta = \frac{1}{\omega}\left[\left(\frac{\mu_0 \varepsilon_r \varepsilon_0}{2}\right)\left(\sqrt{1+\left(\frac{\sigma}{\omega \varepsilon_r \varepsilon_0}\right)^2}-1\right)\right]^{-1/2}. \tag{2}$$

As can be seen in the table and (2), the penetration depth at low RF frequencies is considerably more than 10 cm but rapidly decreases to a millimeter or less at millimeter-wave frequencies. The penetration depth and reflection at the external surface determine how much energy reaches deep into the body. Although the penetration depth found from (2) is large at lower frequencies, the amount of energy that penetrates a con-

Table 1. Approximate dielectric parameters for muscle tissue at various frequencies*.

Frequency (MHz)	Relative Dielectric Constant (ε_r)	Conductivity (σ) (S/m)	Penetration Depth (δ) (cm)
0.1	1850	0.56	213
1.0	411	0.59	70
10	131	0.68	13.2
100	79	0.81	7.7
1000	60	1.33	3.4
10,000	42	13.3	0.27
100,000	8	60	0.03

* Muscle-like tissue, field parallel to tissue fibers [5].

ducting body is small because of the shunting of the electric field. For example, for a small spherical object, Schwan [7] has shown that at 60 Hz the internal E-field is nearly six orders of magnitude less than the external E-field, even though the theoretical penetration depth is quite large. Osepchuk [8] estimates that only around the "resonance" frequency of man, i.e., around 100 MHz, is the internal E-field deep in the body within one order of magnitude of the external field. In the millimeter-wave frequency range, the E-field deep in the body is many orders of magnitude below the external field because of small penetration depth.

The principles of modern dosimetry have recently been reviewed by Chou, et al. [9]. In the frequency range of approximately 100 kHz to 6-10 GHz, the specific absorption rate (SAR) is the important dosimetric quantity. SAR is defined as the mass averaged rate of energy absorption in tissue (NCRP [10]), i.e.,

$$SAR = \frac{d}{dt}\left(\frac{dW}{dm}\right) = \frac{d}{dt}\left(\frac{dW}{\rho\, dV}\right) \tag{3}$$

and is related to the internal E-Field by

$$SAR = \frac{\sigma |E|^2}{\rho} \text{ W/kg} \tag{4}$$

where σ is the conductivity of the tissue in S/m, ρ is the mass density in kg/m^3, and E is the rms electric field strength in V/m. Thus, SAR is a measure of the electric field, and indirectly the magnetic field and current density at the point under study, and also a measure of the local heating rate dT/dt, viz.:

$$\frac{dT}{dt} = \frac{SAR}{c} \ {}^{\circ}\text{C/s} \tag{5}$$

where c is the specific heat capacity of the tissue in J/kg °C. This assumes "ideal" nonthermodynamic circumstances, i.e., no heat loss by thermal diffusion, heat radiation, or thermoregulation (blood flow, sweating, etc.). Thus, a SAR of 1 W/kg is associated with a heating rate less than 0.0003 °C /s in muscle tissue ($c \cong 3.5$ kJ/kg°C), a very small heating rate since even without blood or other cooling it would take more than 1 hour to increase the temperature 1 degree Celsius.

SAR is a key concept in planning and analysis of experiments, both in vivo and in vitro, and serves as the basis of contemporary RF/microwave safety standards for human exposure. Both whole-body average SAR and the local peak spatial-average SAR are important in these endeavors. There is extensive literature on the calculation of whole-body average SAR for various models of animals, including man, especially those based on ellipsoids, which are summarized in Durney, et al. [2]. Figure 1 shows the calculated whole-body-averaged SAR versus frequency SAR for average man based on such a model, when exposed to three different polarizations of a plane wave. The incident power density is 1 mW/cm^2. E-polarization is where the E-field is parallel to the main axis, H-polarization is where the H-field is parallel to the main axis, and k-polarization is where the direction of propagation is parallel to the main axis of the body. A low-Q resonance is observed at about 70-80 MHz for standard man (and at about half that frequency when standing on a conducting ground plane). The peak SAR is highest for E-polarization and is equal to about 0.2 W/kg per mW/cm^2 incident power density. At high frequencies, the SAR decreases to an asymptotic "quasi-optical" value 5 to 6 times lower than the SAR peak. At very low frequencies, the SAR varies as f^2, as expected. At resonance, small animals are more efficient absorbers than man, e.g., for a mouse at its resonance frequency of about 2 GHz, the peak SAR is somewhat over 1.0 W/kg per mW/cm^2.

The SAR distributions are quite complicated even when resulting from plane-wave exposure. Depending upon the size and orientation of the animal and the frequency, it is possible that one or more SAR peaks ("hot spots") could occur. Kritikos and Schwan [11] point out, however, that such internal SAR peaks are very unlikely for man but are more probable for small animals.

Biological Effects

The world literature on microwave bioeffects is immense, with an estimated total of over 20,000 papers. These can be classified as

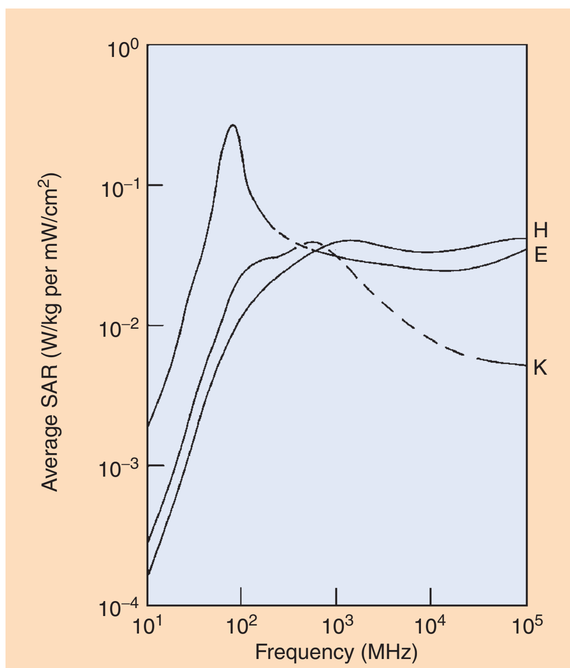

Figure 1. *Calculated whole-body average SAR versus frequency for models of the average man for three standard polarizations. The incident power density is 1 mW/cm^2. (Source: Durney, et al. [2])*

- Experimental data on humans
- Epidemiological
- Experiments on animals-in vivo
- In vitro experiments with biological tissue or cells, animal or human
- Dosimetry, the art and science of relating internal measures of exposure to external fields for a given animal.

To better understand experiments in microwave exposure as well as their relation to safety standards, it is useful to refer to the "exposure diagram" of Figure 2. In this diagram, with log-log coordinates of power (or power density or SAR-specific absorption rate) on the ordinate and time on the abscissa, we can draw the threshold for various effects and hazards. For example, to heat a finite sample to a given temperature, the threshold is a constant SAR for long periods of time, while, for short periods of time during which no heat is lost from the sample, the threshold curve is a line of constant specific absorption (SA = SAR × time) which is at 45° from the horizontal in Figure 2. The intersection of the two lines, constant SAR and constant SA, determines the applicable thermal time constant or associated "averaging time" in exposure standards. Similar curves would result from the threshold for burns using the classic data of Henriques and Moritz [12] for threshold temperature for burns, which is around 60 °C for 5 seconds, but approaching 45 °C for long exposure times, where 45 °C is also the threshold temperature for pain sensation in humans.

In view of the vast literature, how can one encompass or review this literature? We believe it is important to remember that many of the key papers were written long ago, but, as Prof. Herman Schwan, IEEE Edison Medal recipient, has stated, "Good science is never outdated" [13]. The extensive literature on microwave bioeffects has been surveyed often. Some of the classic papers are reproduced, along with extensive bibliographies and commentaries in a Reprint Volume [14] produced by the IEEE Committee on Man and Radiation (COMAR). Other good reviews before 1990 include a special issue [15] of the *Proceedings of the IEEE* and an extensive review [16] by the EPA. In addition, over the years Polson and Heynick [17] have produced critical reviews of the literature, under the sponsorship of the U.S. Air Force. Excellent texts have been written or edited by Michaelson and Lin [18], Gandhi [19], and Polk and Postow [20].

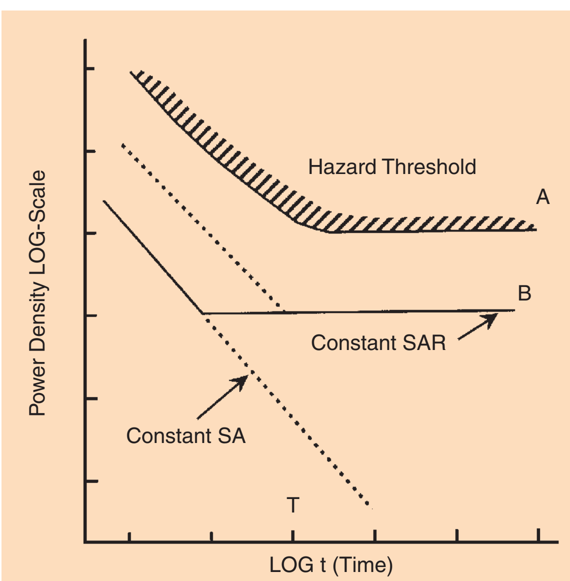

Figure 2. *Thresholds for various effects and hazards expressed as a function of time.*

Many of the early studies on thresholds for lethal exposures reflected the curve shown in Figure 2 as well as the frequency dependence of absorption showing a resonant frequency. Thus, Michaelson [21] found for a dog a lethal threshold of 165 mW/cm^2 and 2-4 hours at 2.8 GHz, while Addington [22] found a threshold of only 20 minutes at 220 mW/cm^2 and 200 MHz. In the Soviet literature [23], the lethal threshold for the rat was 40 mW/cm^2 and 90 minutes at 3 GHz, but at 70 MHz the lethal threshold was 1,000 mW/cm^2 for 100 minutes. This physical understanding based in heating was further strengthened when experiments [24] with fruit flies (Drosophilae) showed no effect when exposed at 2.45 GHz to over 6,500 mW/cm^2 and 45 minutes duration. This result is eminently reasonable to the engineer well acquainted with the absorption cross-section theory that shows absorption decreasing rapidly as the square of the animal dimension. (It also explains the mystifying–to the layman–observation that isolated small ants are not perturbed in an operating microwave oven.) In 1971, Samaras et al. [25] demonstrated the expected, but still dramatic, dependence on environmental temperature. At room temperature, the lethal threshold for a rat at 2.45 GHz for 17-minute duration was 100 mW/cm^2, but, at freezing temperatures below 0 °C, that same power density was life preserving for the rat.

In 1979, Tell and Harlen [26] analyzed data in the literature demonstrating thermal effects in animals and showing a coherent picture, which, when extrapolated to man, predicted (at least for frequencies above 1 GHz) that 100 mW/cm^2 was a conservative estimate for the threshold exposure producing a 1 °C core temperature rise for exposure durations more than 1 hour. Their analysis suggested also that the thermal time constant for the human undergoing whole-body heating was an hour or more. In the last decade, however, Adair [27], in experiments with humans, has shown that no core temperature rise results for exposures of 45 minutes at either 450 MHz or 2.45 GHz at power densities ten times the MPEs (maximum permissible exposure) or 4W/kg = 10 × 0.4 W/kg. Adair is proceeding with further experiments with humans in the resonance frequency range at or below 100 MHz.

In animal experiments, many endpoints of health have been studied, but we select only that of "cata-

Table 2. Comparison of power density and SAR thresholds for behavioral disruption in trained laboratory animals.

Species and Conditions	225 MHz (CW)	1.3 GHz (Pulsed)	2.45 GHz (CW)	5.8 GHz (Pulsed)
Norwegian rat				
Power density	—	0 mW/cm^2	128 mW/cm^2	20 mW/cm^2
SAR	—	2.5 W/kg	5.0 W/kg	4.9 W/kg
Squirrel monkey				
Power density	—	—	45 mW/cm^2	40 mW/cm^2
SAR	—	—	4.5 W/kg	7.2 W/kg
Rhesus monkey				
Power Density	8 mW/cm^2	57 mW/cm^2	67 mW/cm^2	140 mW/cm^2
SAR	3.2 W/kg	4.5 W/kg	4.7 W/kg	8.4 W/kg

racts" because of the myths attached to this subject in the 1970s and even today. The hard science on this subject shows a threshold [28] for cataracts (usually defined as opacities of the lens of the eye that interfere with normal vision) in rabbits of roughly 180 mW/cm^2 for a half-hour or more at 2.45 GHz, with the animal restrained or under anesthesia and only when the energy is applied locally to the eyes. At X-band, attempts to produce cataracts resulted first in skin burns around the eyes. Attempts to produce cataracts at UHF resulted in the death of the animal before a cataract could be produced. Long-term exposure of the rabbit by Guy et al. [29] at 2.45 GHz and 10 mW/cm^2 showed no ocular damage. Microwave-induced cataracts have not been demonstrated in primates, but in the last 2 decades, there have been some reports [30] of corneal damage from high peak power pulsed fields at moderate average power densities around 10 mW/cm^2. Attempts to replicate these findings have failed [31].

It is appropriate to give special attention to experiments by de Lorge [32] on the disruption of food-motivated learned behavior of animals. Thresholds for this effect, which is believed to be the most sensitive and reproducible known effect, have been the basis for most modern safety standards, beginning with the C95 series of standards produced by the IEEE. Disruption occurs reliably at whole-body averaged SARs between 2 and 9 W/kg across frequency and animal species from mice to baboons (see Table 2) [10], [33]. It should be pointed out that these experiments are at frequencies reasonably close (i.e., within a factor of 10) to the resonance frequencies of animals. The use of the threshold SAR at resonance in standards, therefore, is conservative at frequencies well removed from resonance.

Most confirmed bioeffects are associated with significant temperature rise in experimental animals, but there is one exception, that of the microwave auditory effect [34]. It has been shown that exposure of the human head to microwave pulses results in audible clicks above a threshold of roughly 40 μJ/cm^2 incident energy density at 2.45 GHz. This effect is not believed to be hazardous, but it has been used in some safety guidelines to set limits for exposures to pulsed fields.

Despite the substantial literature supporting modern safety standards, critics often suggest there is a dearth of evidence on the possible existence of long-term low-level chronic exposure effects, especially cancer. There have been many expensive animal studies [35]-[38] of this type, and, in the main, no convincing evidence of any deleterious effect has been found. There has been one recent study [39] of a large number of transgenic mice that implied a connection of low-level microwave exposure with cancer. Unfortunately, the experiment was done in a metal enclosure, and it is known that exposures in metal cavities, lightly-loaded, most probably are chaotic and unpredictable. Replication studies are now underway in which more reliable exposure chambers are being used (an anechoic chamber).

Recent well-publicized reviews [40]-[42] of the subject of microwave bioeffects have tended to ignore the past bulk of literature on confirmed effects, and, instead, they focus on more recent controversial claims of low-level or "athermal" effects, particularly for ELF amplitude-modulated RF/microwave exposures, where it is claimed that the modulation frequency is important. These claims of "athermal" effects, in general, are characterized by lack of replication and by the presence of artifacts. There are valid scientific considerations that make such claims implausible. The extensive paper by Valberg et al. [43] has shown that claims of low-level mechanisms are implausible at low frequencies. It is worthwhile to recall that similar claims of "specific" rather than "thermal" effects were prevalent during the first half of the 20th century. The challenge presented then by Mortimer et al. [44] is applicable today, viz. the burden of proof remains on those who claim other than heating as a mechanism for observed microwave bioeffects.

One should not forget that man has experienced substantial robust exposure to microwave/RF energies in the last century without any significant sign of serious hazard. Millions of people were exposed to diathermy treatments of typically 15 to 30 minutes of exposure to power up to 125 W. In the last few decades, diathermy became less popular, perhaps because of electrophobia, but new medical procedures [45] have continued such magnitude of exposures to people through magnetic resonance imaging (MRI) and hyperthermia [46], which is used in the treatment of cancer. Epidemiological studies are few, and most have been done in recent years. They are plagued, however, with the intractable problem of exposure assessment. The bottom line conclusion, by the scientific and governmental communities, is that man's exposure to broadcasting and other sources of microwaves in the last century has not resulted in any noticeable health problem.

History of RF Safety Standards

For purposes of this paper, RF/microwave safety standards refer to regulations, recommendations, and guidelines that specify either emission limits for sources, e.g., the microwave oven leakage standard, or exposure limits for people for the purpose of protecting human health. Although a number of recommendations for limiting exposure to RF/energy have been used by various organizations throughout the world

Table 3. Affiliations of the 125 members of Subcommittee 4 of IEEE SCC 28 at the time the 1991 IEEE C95.1 standard was approved.

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

Table 4. Principal disciplines of the 125 members of Subcommittee 4 of IEEE SCC 28 at the time the 1991 C 95.1 standard was approved.

Principle Discipline	Number	Percentage
Physical sciences (physics, biophysics, 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

since about 1953 [47], the first standards project was approved in 1960 by the American Standards Association when they approved the establishment of a committee charged with developing standards through an open consensus process. Originally the committee was called the United States of America Standards Institute (USASI) C95 Committee and published its first standard in 1966. It later became the American National Standards Institute (ANSI) C95 Committee and published revisions of the standard in 1974 and 1982 [48]. In 1989, this committee, originally under cosponsorship of the U.S. Department of the Navy and the IRE (now IEEE) became IEEE Standards Coordinating Committee 28 (SCC-28). The latest standard, IEEE C95.1-1991 [33] was approved for use as an American national standard by ANSI in 1992. Each revision was more scientifically sound, albeit more complex, than its predecessor, and, unlike most standards and recommendations, the 1991 standard includes detailed rules for implementation.

Although some may view the IEEE committee as a U.S. or North American committee or an industry committee comprised solely of engineers, nothing could be farther from the truth. SCC-28 is truly an international committee, with representation from more than 12 countries, including China, Bulgaria, and New Zealand. The majority of the members of the subcommittees that actually develop the standards are from academia and public health agencies. The makeup and disciplines of the subcommittee that developed the 1991 standard is shown in the Tables 3 and 4.

Another organization with established scientific committees to review the literature and make recommendations regarding exposure to RF/microwave energy is the National Council on Radiation Protection and Measurements (NCRP). The NCRP is a non-profit corporation chartered by the U.S. Congress to collect, analyze, develop, and disseminate in the public interest information and recommendations about (1) protection against radiation and (2) radiation measurements, quantities, and units, particularly those concerned with radiation protection. Although the NCRP is concerned mostly with ionizing radiation, in 1986, Scientific Committee 53 (SC-53 - now SC-89-5), which consisted of 6 members, 5 advisory members and 5 consultants - 8 of whom were also members of the ANSI C95 committee, recommended limits for exposure to RF/microwave energy based on the 1982 ANSI C95 limits [49].

The International Radiation Protection Association's (IRPA) International Commission on Non-Ionizing Radiation Protection (ICNIRP) also publishes guidelines for exposure to RF/microwaves. The most recent ICNIRP guidelines were approved in November 1997 and published in 1998 [50]. At the time the guidelines were developed, the Commission included the participation of 17 scientists and 11 external experts from 12 different countries, including Sweden, Australia, Great Britain, Germany, Poland, and the U.S. Of the three organizations mentioned, only IEEE SCC-28 operates through an open consensus process.

Contemporary Exposure Standards (ICNIRP/IEEE)

Rationale

RF/microwave safety standards are based on the results of critical evaluations and interpretations of the relevant scientific research; ideally, all laboratory and epidemiology research that relates any biological response, from short-term and long-term exposure, would be included. From this evaluation, a threshold SAR is established for the most sensitive confirmed response that could be considered harmful to humans regardless of the nature of the interaction mechanism. To account for uncertainties in the data and to increase confidence that the standard is below the levels at which adverse effects could occur, the resulting threshold is lowered by a somewhat arbitrary safety factor, usually 10 to 50 times below the observed threshold. (An adverse biological response is considered any biochemical change, functional impairment or pathological lesion that could impair performance and reduce the ability of an organism to respond to additional challenge. Adverse biological responses should be distinguished from biological responses in general, which could be adaptive or compensatory, harmful or beneficial.) The threshold SAR is sometimes called a "basic restriction." The derived external field limits and induced current limits, called the maximum permissible exposure levels (MPE), sometimes called "investigation levels" or "reference levels," ensure that the resulting SAR and induced current densities are below the corresponding thresholds under all circumstances of exposure. In the absence of any convincing evidence for long-term effects at low levels, modern RF/microwave safety standards and guidelines are based on short-term effects. Although cancer is a major consideration in assessing risk from long-term, low-level exposures, the weight of the evidence does not support the idea that RF energy can cause cancer in animals or humans or change cells the way that known carcinogens do.

Scientific literature shows that, at sufficiently high levels, adverse effects can occur from RF exposure. Laboratory studies have shown a continuum of effects from increases in temperature at sufficiently high exposure levels, and the concurrent accompanying physiological changes, to the disruption of learned behavioral tasks, at moderate exposure levels. At lower exposures, there is no convincing evidence that effects deemed adverse occur, but sensitive studies can detect adaptive responses, such as increased sweating or decreased metabolic rate. These responses have been observed in numerous studies in several species and exposure levels, and other research and other knowledge about physiology confirm the relevance of these observations for humans. Reported effects at even lower exposure levels, sometimes called "nonthermal" effects, have not been confirmed.

Studies in monkeys and in laboratory rats, using several different frequencies, help to identify dose-response patterns and thresholds. The most sensitive and reliable confirmed biological response that could be considered potentially harmful to humans has been found to be the disruption of food-motivated learned behavior. Because this effect is modest and represents an adaptive response, it serves to identify a threshold for potentially harmful effects. The threshold for behavioral disruption, in terms of whole-body-averaged SAR, has been found to be between approximately 2 and 9 W/kg across animal species and frequency (see Table 2) and is accompanied by an increase in body temperature, usually of about 1 °C. Contemporary RF/microwave exposure standards and guidelines are based on this response and a threshold SAR of 4 W/kg across the range of frequencies where SAR is the valid dosimetric parameter, i.e., from approximately 100 kHz to 6 GHz. A safety factor of 10 is incorporated for exposure in the workplace or controlled environments and an additional factor of 5 for exposure in uncontrolled environments. Thus the basis for contemporary RF/microwave safety standards is limiting the whole-body-average SAR to 0.4 and 0.08 W/kg. Subtle differences in the derived limits developed by different organizations are associated with the underlying engineering assumptions used to derive the MPEs, not with the specific biological response or its threshold.

Above 6 GHz, substantial liaison with the laser standards community in recent years has assured a scientifically defensible transition from the principal microwave range below 6 GHz to a standard based on surface absorption assessment that matches the laser standard at 300 GHz. Below 100 kHz, IEEE SCC-28 is working on improved transitions to the rules based on electrostimulation, which will match a new standard being developed for frequencies below 3 kHz.

Process

Wthin the ICNIRP and NCRP committees, the process is closed, informal, and nontransparent, whereas the IEEE process is open and transparent. Moreover, throughout their history the C95 committees (and now IEEE SCC-28) have been by far the most innovative and had the greatest influence on RF/microwave safety standards world-wide [51]. For these reasons, the IEEE process will be described briefly.

The process begins at the subcommittee level (which is open to everyone) with the identification by the Literature Surveillance Working Group of reliable studies reporting biological responses, from reversible effects and responses of adaptation to irreversible and biologically harmful effects. (The Literature Surveillance Working Group has identified approximately 1,400 relevant citations from a number of databases as well as from inputs from federal agencies and other organizations that are regularly polled.) Selected papers undergo a comprehensive engineering review by two randomly selected reviewers from the Engineering Evaluation Working Group and by two randomly selected reviewers of the appropriate biological evaluation working group, e.g., in vivo, in vitro, epidemiology, and, when necessary, a statistical evaluation is carried out. The reviewers are subject-matter experts, many of whom are not members of the subcommittee. Theoretical papers, e.g., papers that speculate on various mechanisms of interaction, are reviewed separately, and judgments made as to their relevance for standard setting. In order to expedite the process of handling large amounts of data (several thousand evaluation forms), the process has been computerized.

Summaries of the evaluations are provided to the Risk Assessment Working Group, who evaluate the implied risk for human beings and define a threshold SAR for which potentially deleterious effects are likely to occur in humans. During the review process, several concerns that have been raised regarding the 1991 standard are now being addressed, including:

- An appropriate averaging time at the higher microwave and millimeter wave frequencies
- Reexamination of the basis and need for two tiers
- Reexamination of the basis for the magnitude of the spatial peak SAR limits and the corresponding averaging volume
- Development of a scientific basis for the averaging time at frequencies below 100 kHz and for induced current and contact current
- Development of a scientific basis to protect against spark discharges.

Draft standards developed by the subcommittees are subjected to a rigid but open balloting process before they can be moved to the main committee for approval. Approval by both the subcommittee and the main committee requires a letter ballot with at least 75% of all ballots returned and 75% affirmative votes. Attempts must be made to reconcile every negative ballot and all unreconciled negative ballots must be circulated to offer voting members an opportunity to comment, affirm or change their vote. If, after the unreconciled disapprovals have been circulated, 75% of the initial number of returned ballots remain affirmative, the draft is sent to the IEEE Balloting Center for balloting by the main committee. The main committee is comprised of the stakeholders that have to apply the standard. Once approved by the main committee, the draft is submitted to the IEEE Standards Board. The Standards Board has oversight to ensure that due process has been followed, e.g., all negative ballots and appeals have been addressed, and coordination has taken place. Once approved by the Standards Board, the document becomes an IEEE standard and is forwarded to the ANSI for approval as an American national standard.

Current Issues

In the painstaking work, now of global dimension, of the standards community to develop continually improved and refined standards, many issues remain to be resolved. Some of the most troubling are discussed here.

Quality of the Literature

It is a fact that much, if not most, of the world's literature on microwave bioeffects is invalid or not useful for standards setting. Foster and associates have written critical papers [52], [53] pointing out the prevalence of many papers in the literature that could not be replicated or confirmed. They posed the question of when such research efforts that never finds robust confirmed effects should be terminated. An example of such literature is that of the former Soviet Union, and to some extent Germany, which reported frequency-sensitive effects of millimeter-wave radiation at low levels around 1 mW/cm^2. These reports led to extensive application of millimeter-waves for medical purposes in Russia and the Ukraine. Neither the research nor the medical practice have been found valid in the West, however (see discussion in [19]). More recently, there was a report of bioeffects at extraordinary low levels of power density ~ 10^{-19} W/cm^2 at a millimeter-wave frequency [54]. We, however, have shown that this extraordinary claim is most probably invalid because of the lack of control of significant energy at the harmonic frequencies [55]. This is only one example of the presence of microwave artifacts that mar many of the papers in the literature. Other artifacts include the great nonuniformity of microwave heating of objects, which is often neglected. Thus it is reported sometimes that the object temperature is some value when in actuality the object has a wide spatial variation in temperature, as well demonstrated in careful studies by Guy et al. [56]. These artifacts and other occur in both in vitro and in vivo studies.

The general public is often disposed to accept all scientific and technical literature at face value. They do not know that much of the literature is not valid. If rational public discourse is to occur, there must be a widespread action to make known the broad consensus of the professional communities on this subject. One avenue underway is the computerized literature review conducted in the work of IEEE SCC-28 to revise the C95.1 standard. Other groups in the world shun this task, and publish noncritical reviews of the literature. As the global aspect of IEEE standards work grows through the international expansion of SCC-28 and SCC-34, there will be a significant advance towards world-wide consensus on the literature. This expansion will require the support of all stakeholders, including professional societies.

Safety Factor

The concept of "safety factor," no doubt, in large measure is derived from common sense applications of prudence in ordinary life. Thus, whether in protecting against collapse of a structure or experiencing an undesirable effects from microwave heating, all stakeholders intuitively appreciate the meaning of a safety factor of 10 vs. 100 vs. 1,000, etc. In fact, the setting of safety factors in large measure is a practical judgment that should involve all stakeholders because of the subjectivity in the choice of a specific number that represents the ratio of threshold exposure to permitted exposure, for example. In setting of safety standards, it

Exposure standards state rules that people should follow to avoid harm. _Product performance_ standards specify bounds on a performance parameter. _Environmental_ standards specify the field levels allowed in the environment

is only reasonable to apply the same safety factor across the spectrum, if only not to favor industries exploiting one part of the spectrum over competitors using a very different part of the spectrum. Thus we should use common units in expressing safety factors, like dB.

There are some in the world-wide community who state that establishment of safety factors is only science. Often they couple this view with the proposal to replace the term "safety factor" by the term "uncertainty factor," as if uncertainty in scientific data were the only reason for the safety factor. This would imply that the MPE level in a standard is set just below the threshold for harm for some exquisitely abnormal and sensitive person in the world, and with no real safety factor or margin of safety for that person. We believe this thinking is tautological and not based on reality or the purposes of a safety standard which should be to give confidence of safety to people and not to alarm. Again as the global influence of IEEE grows through expansion of SCC-28 and SCC-34, we believe the world-wide consensus will be to retain the sound concept of safety factor.

Precautionary Principle

In the last 10 years, there has been a movement, mostly within environmentalist circles, for the widespread application of the precautionary principle (PP), originally conceived when facing the possibility of catastrophic results from a new technology, as in considering the ozone hole or global warming. But now in Europe, it is being examined for potential application to any technology, even electromagnetic energy [57]. Of course, in a sense, this idea is merely the end point in the thinking of Paul Brodeur [58], history Professor Steneck [59], and Nair and Morgan [60], who promoted the concept of “prudent avoidance” at the height of the power-line scare, which is now generally acknowledged [61] as baseless. The PP and the preceding ideas are all attacks on reliance on science-based standard for safety. They all advocate imposing the most restrictive controls on technology just short of extinguishing the technology, just in case there is a hazard, whether or not there is any credible scientific evidence or not. This kind of thinking adds to electrophobia and those who exploit electrophobia by selling a variety of gadgets ranging from microwave oven leakage detectors to protective devices for wireless phones. It inevitably encourages unwise behavior like that of the IEEE staff person who exchanged an electric stove for a gas stove in the early 1990s to reduce hazards of EMF, while ignoring real hazards of gas. In another case, a TV personality publicly encourages people to “run out of the kitchen” when turning on the microwave oven.

Again, the best response to the spread of the PP is to strengthen the position of science-based standards as the IEEE expands its global position in this field through committees such as SCC-28 and SCC-34 as well as COMAR.

Product Safety Standards

In addition to safety standards that recommend exposure criteria for humans, product safety standards play a major role in translating exposure criteria into easy-to-measure quantities for electronic products, e.g., power density for leakage from microwave ovens. For some products, however, the situation is complex, e.g., the SAR in the head of cellular telephone users, and here the goal is to develop meaningful protocols that lead to repeatable results.

Product performance standards for the microwave technologies arose after the passage of the Radiation Control for Health and Safety Act of 1968 [62]. This led to the emission standard for microwave ovens and to some control of industrial and other microwave sources. In the United States, both the FCC as well as the FDA and other agencies support voluntary standards developed through an open consensus process, such as that of the IEEE. Although the FDA has the authority to develop performance standards for all microwave equipment including wireless phones, it has instead supported the creation of a new committee to develop such standards, IEEE SCC 34.

IEEE SCC-34 is a relatively new committee having been established in 1995 for the purpose of developing product performance standards relative to the safe use of electromagnetic energy for specific products. The committee uses the exposure criteria and basic restrictions developed by SCC-28, and in some cases by other committees, to develop standardized assessment procedures, emission limits, etc., to allow manufacturers to readily ensure that their products comply with these criteria. The goal is to develop unambiguous protocols that yield repeatable results. The first standard the committee developed describes an experimental protocol for the measurement of the peak spatial-average SAR associated with the use of hand-held radio transceivers intended to be operated while held next to the ear.

The peak spatial-average SAR associated with the use of hand-held cellular telephones has become an important issue lately and the validity of assessment protocols used by different organizations has been questioned, not by the engineering community but by the media. Since 1993, when a guest on a TV talk show alleged that his wife’s brain tumor was exacerbated by the use of a cell phone, the media has focussed on this issue and inordinate attention continues to be given to preliminary results of every study reported that even suggests an association between untoward medical effects and the use of these devices. Although cell phone manufacturers recently agreed to provide the consumer with SAR information about their products, the reliability of the assessment procedure has been challenged by the media. Recent attention has focussed on differences between SAR measurement results reported by different laboratories for the same phone. By a major leap of logic, small differences that are not unexpected in light of the different protocols being used to test cell phones, are translated to a theme of uncertainty about cell phone safety. This seems to occur more in this field than in many others, i.e., a focus on uncertainty related to small differences in analytical or measurement results while completely ignoring the issue of how far below established safety criteria (exposure) the results may be.

A part of the $25-27 million research program to examine cell phone safety issues was the establishment of a dosimetry working group to develop uniform protocols for assessing exposure from wireless handsets. When funding was withdrawn for this particular project, the working group, which by then included representatives from most handset manufacturers, a number of test houses, and academia, evolved into Subcommittee 2 of SCC-34.

Two separate recommended practices are being developed by SCC-34:

- One is based on experimental techniques
- The other on numerical techniques.

The experimental technique utilizes robot-controlled miniature electric field probes to scan and measure the E-field in a homogeneous tissue-simulating liquid-filled anthropomorphic model of the human head. The numerical technique applies the FDTD method to solving Maxwell’s equations in a heterogeneous representation of the human head developed from CT and MRI scans of humans. Models with resolutions of $2 \times 2 \times 2$ mm [63], $1.1 \times 1.1 \times 1.4$ mm using subgridding in some regions [64] and $0.9 \times 0.9 \times 1.5$ mm [65] have been reported. The advantage of the experimental technique is that the actual phone is used for the measurement; the disadvantage is that the homogeneous head model is not a faithful representation of the heterogeneous human head. To ensure that the results are conservative, head size, the dielectric properties of the "head tissue" simulant, and the thickness of the spacer representing the pinna are standardized to represent a worst case situation, i.e., the results will be an overestimate of the SAR induced in the brain. The advantage of the numerical technique is that the head model is an accurate representation of a human head; a disadvantage is that the handset has to be modeled, usually as a simple metal box with an appropriate antenna. CAD files of actual phones complete with some internal structures have been used and differences between these and the results from the simple model are being investigated. Another advantage is that the numerical technique can be applied at the design stage to optimize antenna performance and ensure that the peak SAR is below the specified limit.

Most manufacturers, test houses, and the FCC are using the experimental technique to certify/verify that wireless handsets meet the appropriate peak spatial-average SAR requirements; one reason is that measurement systems are available commercially. (The peak spatial-average SAR of wireless handsets marketed in the United States must be less than 1.6 W/kg averaged over any 1 g of tissue in the shape of a cube. In Europe and some other countries the limit is 2 W/kg averaged over any 10 g of contiguous tissue.) Thus, the initial effort of IEEE SCC-34 has been directed towards first completing the experimental protocol, which will be issued as a recommended practice. Much of the information needed to complete this document was not available in the literature, e.g., the uncertainty associated with each component of the system and the overall assessment uncertainty, but was developed in the laboratories of the committee members as the practice evolved. This included series of interlaboratory comparisons of canonical models such as standard half-wave dipoles above a flat phantom or sphere and a cooperative effort by three manufacturers to develop a generic phone for further interlaboratory comparisons. Included in the draft (now undergoing balloting) are detailed descriptions of the measurement concepts, techniques and instrumentation, calibration techniques, recipes for "head-tissue" simulant, and the procedures for calibrating E-field probes used for SAR measurements. Procedures for assessing system uncertainties associated with calibration, probe positioning, and tissue properties and detailed standardized procedures are also provided.

Because of common committee membership, the SCC-34 recommended practice is in harmony with protocols being developed by committees of other standards developing organizations, e.g., the European Committee for Electrotechnical Standardization (CENELEC), the International Electrotechnical Commision (IEC) TC106, including the CAD file for constructing the head model. Rational harmonized national and international standards for assessing exposure should go a long way towards mitigating some of the media-driven anxiety about wireless devices exemplified by a recent series of TV "specials" calling attention to the uncertainty of cell phone safety, in this case, the uncertainty of the peak SAR. Future IEEE SCC-24 projects will be the extension of the handset protocols to other wireless devices, e.g., wireless modems and body-mounted radio transceivers.

Environmental Standards

The IEEE standards community has a long and fruitful history. Today the IEEE is a leading world-wide organization that sponsors development of standards with due process (transparency, openness, balance of interests, documentation, strict balloting, etc.) and the ability to achieve truly broad consensus through a large community of volunteers from around the world and with all stakeholders represented. Besides its own work, this IEEE community maintains close liaison with all relevant groups in the world, including ICNIRP and WHO. A common long-term goal is international harmonization of standards. There are many obstacles in this direction, and one of them is terms and concepts. Only the IEEE has well-developed concepts of minimum ambiguity. Thus in the IEEE system we have standards (shall), recommended practices (should), and guides (may). Elsewhere there are "guidelines" but without specificity on the degree of compliance sought.

If rational public discourse is to occur, there must be widespread action to make known the broad consensus of the professional communities on this subject

Likewise, the IEEE distinguishes the type of standards in nature of application. Thus *exposure* standards (in the inclusive sense) apply to people and state rules that people should follow to avoid harm. There is some degree of voluntary nature implied here. On the other hand, *product performance* standards apply to products and specify some bound on a performance parameter—e.g. leakage in the case of a microwave oven. Product standards should be compatible with and generally are derived from exposure standards but they are distinctly different.

Other existing standards that relate to this subject include guides on safe distances from RF radiators for use of EEDs (electroexplosive devices) and susceptibility standards on medical devices to ensure their performance in the presence of fields in the environment or workplace. One type of standards conspicuous by its absence is an *environmental* standard, which would specify the field levels allowed in the environment. This includes all localities accessible to the general public and implies no knowledge or control of the EM energy by the general public. As such there is no reason for time averaging, etc., as in exposure standards. Furthermore the levels may be set after consideration of many factors, including low-level RFI phenomena, possible side effects like corona or arcing around objects (like a big crane) and even societal factors. Thus lower limits are envisaged for environmental limits than in safe exposure standards, without impugning the validity of the exposure standards. Presently, environmental limits effectively are set by applying an exposure limit, e.g., the lower tier of the present C95.1 standard, while somewhat loosely applying the averaging time concept, if at all.

In the future, there may evolve the desire for environmental standards. By definition, it will involve a broader group of stakeholders. It may help diffuse the desire for application of the PP by environmentalists. Lastly, it may be a tool in the eventual harmonization with the former Communist countries like Russia and China. In those countries, the environmental limit is set very low by extrapolating an exposure limit to long duration of 24 hours in the arbitrary fashion of inverse dependence on exposure time. Thus, their exposure limits for short durations, e.g., minutes, are comparable to those in the West. Since most real exposures are short term, there is the basis for possible agreement on exposure limits, even if limited in time while agreeing that an environmental limit set apart from artificial time relation can be set acceptably low, i.e., more stringent than exposure limits but not seriously infringing on the practice of today's technology.

Again the international expansion of SCC-28 and SCC-34 will play important roles in the ability of the IEEE to promote international harmonization.

Conclusions

The IEEE process is a fully-documented, open consensus process. The subcommittee that develops the exposure standards has a 40-year history of standards development. The required scientific talents of the subcommittee and the policy, legal, and compliance engineering specialties of the main committee membership, provide the largest consensus process for any standard that addresses RF/microwave safety. The 1991 standard is by far the leading authoritative work in the United States, with the broadest scientific consensus. Unlike many other standards and recommendations, detailed rules for implementation are included as part of the standard. Although the IEEE C95.1-1991 is considerably more complex than other guidelines and recommendations, the complexity is more than offset by the advantage of having scientifically defensible limits that realistically address potential RF/microwave hazards by ensuring, with an adequate margin of safety, that known thresholds for adverse effects are not exceeded.

The challenge in the new millennium is to expand the IEEE standards process to serve a more global purpose. In so doing, considerable international expansion of the IEEE committees and increased liaison with other groups in the world is required and will require support by all concerned sectors of society. If successful, the IEEE can play an important role in preserving science-based standards as the accepted credible basis for assuring the safe use of electromagnetic energy.

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