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93-62

Thomas P. Stanley, Chief Engineer
Office of Engineering and Technology
Federal Communications Commission
Mail Stop 1300
1919 M Street, N.W.
Washington, D.C. 20554

Dear Dr. Stanley:

In accordance with its responsibilities under Section 309 of the Clean Air Act (CAA), the Environmental Protection Agency (EPA) is pleased to submit comments to the Federal Communications Commission (FCC) on the Notice of Proposed Rulemaking (NPRM), Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, ET Docket No. 93-62. The CAA responsibilities have been delegated from the Office of Federal Activities to the Office of Radiation and Indoor Air for this specific review. This proposal, if adopted, would use the 1992 American National Standards Institute/Institute of Electrical and Electronics Engineers (ANSI/IEEE) standard to update and amend the FCC guidelines for evaluating the environmental effects of radiofrequency (RF) radiation emitted by FCC-regulated facilities on public health and safety.

The 1992 ANSI standard represents a significant revision of the earlier 1982 ANSI standard. Improvements with regard to protection are reflected in (1) the development of a 2-level exposure standard specifying maximum permissible exposure (MPE) limits for "controlled" and "uncontrolled" environments to replace the single-tier 1982 standard, and (2) the extension of the low frequency range from 300 kHz to 3 kHz to limit the possibility of low-frequency RF shock and burn. Other significant changes in the 1992 standard, however, are not improvements, in our view. Changes that allow for a two-fold increase in the MPE at high frequencies over the MPE permitted by the 1982 ANSI standard, and the application of the same MPE for both controlled and uncontrolled environments for frequencies from 15 GHz to 300 GHz are not improvements. Therefore, EPA recommends against adopting the 1992 ANSI/IEEE standard because it has serious flaws that call into question whether its proposed use is sufficiently protective of public health and safety.

To have a more protective public exposure standard, EPA recommends that the FCC instead adopt the exposure criteria

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recommended earlier by the National Council on Radiation Protection and Measurements (NCRP) in their report entitled "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields (NCRP 1986)." The bases for this recommendation are noted below:

a. NCRP's RF radiation exposure limits consider both workers and the public.

b. Their exposure criteria are more protective at higher frequencies.

c. There are no substantive differences in the literature base supporting both standards, except for the literature on RF shocks and burns.

d. NCRP is chartered by the U.S. Congress to develop radiation protection recommendations and is recognized as one of the leading authorities in this area.

In addition, EPA recommends that the FCC consider including limits for induced and contact RF currents for the frequency range of 300 kHz to 100 MHz to protect against shock and burn along with the FCC proposal for low-power device exclusions as modified in the attachment to this letter. The Agency believes these recommendations provide a more protective alternative to the 1992 ANSI/IEEE standard. The basis for EPA's recommendations are provided in the detailed comments in the enclosure to this letter.

Furthermore, the Agency recommends that the FCC consider requesting the NCRP to revise its 1986 report and provide an updated, comprehensive report on the biological effects of RF radiation and recommendations for exposure criteria. EPA endorses such a request as reasonable and appropriate.

In summary, EPA recommends the following:

1. The FCC should not adopt the 1992 ANSI/IEEE standard. There are serious flaws in the standard that call into question whether the proposed use of the 1992 ANSI/IEEE is sufficiently protective. The following four points address several key Agency concerns.

a. The 1992 ANSI/IEEE allows a two-fold increase in the MPE at high frequencies above that permitted by the current FCC guideline.

b. The two-level revised standard is not directly applicable to any population group but is applicable to exposure environments called "controlled" and "uncontrolled" environments

that are not well defined and are discretionary. The Agency disagrees with this approach.

c. The 1992 ANSI/IEEE conclusion that there is no scientific data indicating that certain subgroups of the population are more at risk than others is not supported by NCRP and EPA reports.

d. The thesis that the 1992 ANSI/IEEE recommendations are protective of all mechanisms of interaction is unwarranted because the adverse effects level in the 1992 ANSI/IEEE standard is based on a thermal effect.

2. The FCC should consider the exposure criteria recommended by the NCRP in NCRP Report No. 86, "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields," with the addition of:

a. the 1992 ANSI/IEEE limits for induced and contact RF currents, for the frequency range of 300 kHz to 100 MHz, to protect against shock and burn, and

b. the FCC proposal for low power device exclusions (FCC 93-142, pp. 7-8) as the standard for the public, where the definition of "public" includes all persons using these devices unless the user is operating a device as a concomitant of employment.

3. The FCC should consider requesting the NCRP to revise its 1986 report to provide an updated, comprehensive review of the biological effects on RF radiation and recommendations for exposure criteria.

More specific comments are enclosed for your consideration. We appreciate the opportunity to comment on the the FCC proposal. If you have any questions concerning EPA's comments, please feel free to contact Norbert Hankin in the Radiation Studies Branch at (202) 233-9235.

Sincerely,

Margo T. Oge

Margo T. Oge
Director, Office of Radiation
and Indoor Air

Enclosure

Environmental Protection Agency (EPA) Comments to the Federal Communications Commission (FCC) on FCC 93-142, April 1993, Notice of Proposed Rulemaking; Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation.

Introduction

The FCC currently uses the 1982 ANSI (American National Standards Institute, Inc.) radiofrequency (RF) radiation guidelines for evaluating the environmental effects, particularly on public health and safety, of RF radiation emitted by FCC regulated facilities. In November 1992, ANSI adopted a revised standard now known as ANSI/IEEE C95.1-1992 (IEEE Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz, IEEE C95.1-1991). The FCC now proposes to amend and update the guidelines and methods that it uses to evaluate the environmental effects of RF radiation by adopting the new ANSI/IEEE standard. The 1992 recommendations contain a number of significant changes when compared to the 1982 single-level guideline based on a 10-fold safety factor. The revised guideline is a two-level standard, i.e., it contains two sets of exposure limits, one for the controlled environment and one for the uncontrolled environment, incorporating safety factors of 10 and 50, respectively. Another change is the extension of the frequency range from 300 kHz - 100 GHz to 3 kHz - 300 GHz. In addition, 1992 ANSI/IEEE allows a two-fold increase in the MPE at high frequencies above that permitted by the 1982 ANSI standard.

EPA welcomes the opportunity to comment on the FCC proposal and to address the complexity and what we believe are the limitations of ANSI/IEEE C95.1-1992. EPA review of 1992 ANSI/IEEE leads us to believe that it is a standard with flaws that cast doubt about whether it is sufficiently protective of public health and safety, and its claim that "the recommended exposure levels should be safe for all."

EPA comments on the FCC proposed standard address: derivation of standards; the claim of protection for all persons from all interaction mechanisms; controlled and uncontrolled environments; database limitations; modulation; low-power devices; and, other contemporary exposure standards.

Discussion

Approach to Derivation of Standards

The rationale provided in ANSI/IEEE to explain fundamental characteristics of the 1992 ANSI/IEEE guidelines, in many cases, lacks explanation, consistency, and well-founded justifications. In addition, there is concern that the complexity of the 1992 ANSI/IEEE standard may make it difficult to comply with or effectively enforce.

No explanation is given for the decision to employ safety factors of 10 and 50; there is no discussion that supports the introduction of the standard for the "uncontrolled" environment. In fact, the stated conclusion that "the recommended exposure levels should be safe for all" (at the controlled environment working basis of 0.4 W/kg) and the support given for this conclusion in the standard's rationale constitute an argument for a single-tier, not a two-tier standard. The addition of the second level of protection for exposure in an

uncontrolled environment with the application of an additional safety factor is done without any justification.

When available, human data is preferable to laboratory animal data in standards development. Therefore we consider the 1992 ANSI/IEEE guidelines to be deficient in this area because reports published after 1986 that presented human data were not considered. We would expect that future efforts to develop or update RF radiation standards would include analysis of available human thermophysiological information and models.

Claim of Protection for All Persons from All Interaction Mechanisms

The new ANSI/IEEE standard states that the "intent was to protect human beings from harm by any mechanism, including those arising from excessive elevations of body temperature" (IEEE p.27), i.e., the 1992 ANSI/IEEE standard is purported to be protective of all persons and all interaction mechanisms. We believe that this position has not been supported, as shown by the following discussion.

In the 1992 ANSI/IEEE standard, as well as in the 1986 NCRP guidelines, the biological basis for maximum permissible exposure level varies with frequency. In the frequency range from 100 kHz to 6 GHz, maximum permissible exposure levels are based on whole-body averaged SAR (specific absorption rate expressed in watts per kilogram of body mass, W/kg). More specifically, the working threshold for unfavorable biological effects in human beings in the frequency range from 100 kHz to 6 GHz is defined as 4 W/kg. Safety factors of 10 and 50 were used to derive the maximum permissible exposures for controlled and uncontrolled environments, respectively.

This adverse effect level for human beings, 4 W/kg, is the threshold for a specific biological effect, i.e., behavioral disruption (work stoppage) in nonhuman primates that is associated with an increase in body temperature. Work stoppage, the failure of a food-deprived animal to perform a learned task to gain a food reward, is interpreted to result from thermal stress, caused by the absorption of RF energy, that is sufficiently severe to deter hungry animals from working for food.

Since the ANSI/IEEE hazard level is an SAR associated with an effect resulting from a known mechanism of interaction (RF heating) that is associated with an increase in body temperature (as is the NCRP hazard level), the ANSI/IEEE C95.1-1992 standard is based on a thermal effect of RF radiation and, by extension, is protective of effects arising from a thermal mechanism, but not from all possible mechanisms. Therefore, the generalization that 1992 ANSI/IEEE guidelines protect human beings from harm by any mechanism is not justified.

In contrast to the 1992 ANSI/IEEE standard, 1986 NCRP states that a response to RF radiation may have a "thermal basis, an athermal basis, or a combined basis," and that a "determination of which of these three classes of causation is operative in a given context rests upon appropriate experimentation and inference, not presumption." NCRP

also claims that there is "no intent to define exposure criteria solely in terms of SAR," and that "consideration is also given to other factors where appropriate." These factors include, among others, possible modulation- and carrier-frequency specific biological responses.

Exposure Environments - Controlled and Uncontrolled

EPA believes that the proper approach in defining exposure environments to which guidelines are applied should be in terms of the populations to be protected, i.e., the traditionally defined populations being workers and the public. However, the ANSI/IEEE standard takes a different approach.

The 1992 ANSI/IEEE standard recommends exposure limits for a controlled environment and an uncontrolled environment. Controlled environments are defined as locations where exposure may be incurred by persons who are aware of the potential for exposure or as the result of transient passage. Uncontrolled environments are locations where exposures may be incurred by persons who are unaware of the potential for exposure. In the uncontrolled environment, an additional safety factor is applied for exposure in the resonant frequency range and for low-frequency exposure to electric fields. As defined in the standard, controlled environments are discretionary, i.e., identification of controlled environments is at the discretion of the operator of a source (see IEEE, p. 9, footnote 1).

The 1992 ANSI/IEEE standard states clearly that the distinction between the two exposure environments is based on the nature of the exposure environment and not on the population type (see IEEE 1991, p. 23). ANSI/IEEE does not allow for any variation in sensitivity to RF radiation. It states that there is no reliable evidence that certain subgroups of the population [such as infants, aged, ill and disabled, persons dependent on medication, persons in adverse environmental conditions (excessive heat and/or humidity), voluntary vs. involuntary exposure] are more at risk than others (IEEE 1991, p. 23). This conclusion is not in agreement with conclusions in the EPA report "Biological Effects of Radiofrequency Radiation" (EPA 600/8-83-026F, 1984) or in the NCRP Report No. 86, "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields" that the general population has groups of individuals particularly susceptible to heat.

Other contemporary guidelines agree with NCRP and EPA; the Food and Drug Administration (FDA) 1988, National Radiological Protection Board (NRPB) 1991, International Radiation Protection Association (IRPA) 1991, and the International Electrotechnical Commission (IEC) 1993, guidelines define groups of people who are less heat tolerant than others. These include the elderly, infants, pregnant women, and people who are obese, have hypertension, or take drugs such as diuretics, tranquilizers, sedatives, or vasodilators that decrease heat tolerance.

The basis for the ANSI/IEEE guideline in the frequency range of 0.1 MHz to 6.0 GHz, the frequency range in which most of FCC licensed transmitters operate, is an effect due to RF heating. Since, as mentioned above, the general population contains individuals

particularly susceptible to heat, we recommend against the use of controlled and uncontrolled environments and recommend consideration of 1986 NCRP as a means of avoiding this problem.

We strongly disagree with the use of the concepts of control and awareness in the discretionary manner presented in 1992 ANSI/IEEE. In the standard there are no firm rules given to differentiate between controlled and uncontrolled environments, and therefore the concept will be difficult to apply because people seldom agree on discretionary areas of exposure. The standard could be applied arbitrarily and inconsistently since ANSI/IEEE does not impose conditions to describe or create the state of awareness. An individual's degree of awareness could vary from complete understanding of RF sources to only a vague awareness that RF radiation exists in his controlled environment.

If awareness in a controlled environment can vary from complete knowledge to almost no knowledge, then the degree of control over safety is uncertain. Unspecified awareness in itself does not constitute a controlled situation. A controlled environment could be established with measures imposed to ensure strict adherence to the standard to prevent the possibility for exposure of any individual in the controlled environment to exposures greater than recommended by the standard. However, 1992 ANSI/IEEE does not recommend the actions that should be taken to establish a controlled environment, and if it would, it could not provide the authority for control. In our view, "awareness" is not equivalent to protection.

The FCC proposal (paragraph 13) presents a reasonable way to apply the guidelines to the public that is more consistent with traditional definitions of workers and the public. This is also the method used in the 1986 NCRP exposure criteria. NCRP recognizes that there is variability in human response, that there are categories of individuals with susceptibilities that place them at greater risk for potential harm, and that workers, who may be relatively well informed of potential hazards of RF radiation exposure, may have the opportunity to make personal decisions in regard to their exposure. Therefore it is appropriate for the FCC to adopt this approach to apply the more conservative guidelines where there is any question of possible exposure of the general public (which might also include nontechnical employees) to RF radiation, and to apply the more restrictive exposure limits to any transmitters and facilities that are located in residential areas or locations where the RF source may be accessible to the public. We suggest that the phrase "accessible to the public" replace the word "unrestricted" in the FCC proposal because the former phrase more accurately describes the locations.

Limitations of data

Availability of chronic exposure information

It is clear that the adverse effect threshold of 4 W/kg is based on acute exposures (measured in minutes or a few hours) that elevate temperature in laboratory animals including nonhuman primates, and not on long-term, low-level (non-thermal) exposure. Only a few chronic exposure studies of laboratory animals and epidemiological studies of human populations have been reported. The majority of these relatively

few studies indicate no significant health effects are associated with chronic, low-level exposure to RF radiation. This conclusion is tempered by the results of a small number of reports suggesting potentially adverse health effects (cancer) may exist (e.g., Szmigielski - Bioelectromagnetics 1982; Chou - Bioelectromagnetics 1992; Milham - NEJM 1982, Lancet 1985, Am. J Epid. 1988). A determination of the significance of such potential adverse effects awaits independent confirmation of the experimental results.

The limitations of the data used to define the adverse effect level in the 1992 ANSI/IEEE recommendations do not support the claim that the recommended MPEs in 1992 ANSI/IEEE are protective of all mechanisms and all people.

Publication Cut-off Date

The 1992 ANSI/IEEE standard is based on literature published before 1986, except for a few papers on RF shock and burn. The cut-off date for the literature review supporting the NCRP recommendations is 1982. Even though the 1992 ANSI/IEEE guidelines had more recent data for consideration than did 1986 NCRP, the recommendations are basically similar for the resonant frequency range in that both use work stoppage at 4 W/kg as the adverse effect basis for standard setting and also safety factors of 10 and 50 to establish two levels of MPE. Therefore it cannot be argued that the 1992 ANSI/IEEE standard is preferable because it is based on more recent information except for the recommendations on shock and burn. Although the Agency believes the ANSI/IEEE standard to be generally deficient, EPA concurs with the FCC proposal to adopt the 1992 ANSI/IEEE standard with respect to exposure limitations for shock and burn.

Extremely Low Frequency (ELF)-Modulated RF Radiation

As noted in the FCC proposal (paragraph 25), the NCRP guidelines include a special provision with respect to exposure of workers to RF carrier frequencies modulated at ELF frequencies. This recommendation is apparently based on experimental results showing neurophysiological effects of modulated fields. The modulation provision for workers in the NCRP guidelines is unique; no other RF exposure guideline contains such a provision. For certain modulation conditions, the exposure criteria for occupational exposures is the generally 10-fold more stringent general population exposure criteria.

While studies continue to be published describing biological responses to nonthermal ELF-modulated RF radiation, the effects information is not yet sufficient to be used as a basis for exposure criteria to protect the public against adverse human health effects.

Pulse-modulated vs. continuous-wave (CW) RF radiation

Many other studies provide evidence that nonthermal modulated-RF exposures produce effects that are not produced by CW (unmodulated) RF radiation. Meaningful studies of biological and health effects of nonthermal, pulse-modulated RF radiation exist including studies that show injury to the eye (Kues et al., Johns Hopkins Applied Physics Laboratory (JHAPL). The significance of these results, even at the early stages of this continuing research, was responsible for the

development and adoption of an RF radiation exposure standard by JHAPL (in 1984) for their personnel. The JHAPL MPE for frequencies from 30 MHz to 100 GHz is 0.1 mW/cm^2. This standard provided the basis for the 0.1 mW/cm^2 action level used to protect personnel from harm from RF radiation-generating equipment at the Hughes Aircraft Company. The JHAPL MPE is a factor of 100 times more stringent than the 1992 ANSI/IEEE MPE for controlled environments for the frequency range of 3.0 GHz and above.

Pulse-modulated RF radiation can produce a response that is called "microwave hearing". This effect seems well established and probably results from very rapid thermoelastic expansion of the brain, creating a sound wave in the head. Conditions under which the auditory effect can be invoked in people with normal hearing should be avoided according to the National Radiological Protection Board (NRPB) draft recommendations for workers and the public. In contrast to this recommendation, the 1992 ANSI/IEEE standard states that the human auditory effect is clearly not deleterious; it recommends a limit for pulsed radiation that is well above the threshold for the auditory effect.

Low-power Devices

We recommend that the two population groups, workers and the public, be used in the following suggested modifications to the FCC proposal regarding exposure to hand-held devices and amateur radio facilities (see FCC 1993, p.6, footnote 16). Non-users exposed to hand-held devices and amateur radio facilities should be considered as the public. Users of hand-held devices and amateur radio facilities should be considered as the public unless the user is operating a device as a concomitant of employment. This recommendation is based on the difficulty of differentiating between individuals who are cognizant or noncognizant of the potential for RF exposure and is consistent with the NCRP recognition of the two population groups, workers and the public. If NCRP is used, the problem of differentiating between cognizant workers and cognizant public would be avoided, and it would not be necessary to distinguish between users and non-users.

Other Contemporary Radiofrequency Radiation Guidelines

In addition to the differences identified and discussed between the 1992 ANSI/IEEE standard and the 1986 NCRP recommendations, there are significant differences between 1992 ANSI/IEEE and other contemporary RF radiation exposure guidelines, including those of the Food and Drug Administration (FDA), National Radiological Protection Board (NRPB), International Radiation Protection Association (IRPA), the International Electrotechnical Commission (IEC), and the Johns Hopkins Applied Physics Laboratory (JHAPL). The comments in this section address some of the differences.

The 1992 ANSI/IEEE guidelines are based on literature published before 1986 except for several papers on shock and burn. Other contemporary recommendations use more recent information and appear to be strongly influenced by clinical and modeling data describing thermoregulatory responses of patients and volunteers exposed in magnetic resonance imaging devices. As noted, the 1992 ANSI/IEEE adverse-effects level is based only on laboratory animal data.

The 1992 ANSI/IEEE standard claims that the recommendations protect against harm by any mechanism, that is, both thermal and nonthermal. It contends that chronic exposure data and information on nonthermal interactions are not meaningful for standards development. While there is general, although not unanimous, agreement that the data base on low-level, long-term exposure is insufficient to provide a basis for standards development, some contemporary guidelines state explicitly that their adverse-effect level is based on an increase in body temperature (NRPB 1993). Furthermore, they do not claim that the exposure limits protect against both thermal and nonthermal effects. EPA does not agree with the claim that the 1992 ANSI/IEEE guidelines protect against effects of any mechanism; we believe that the only claim that can be made is that the 1992 ANSI/IEEE standard applies only to thermal effects and electric shock.

Although several mechanisms of interaction of RF radiation with living systems have been proposed, the established and noncontroversial mechanism for acute exposures is heating. This is reflected in several guidelines for protection of patients from the physiological consequences of an increase in temperature due to exposure to RF radiation during magnetic resonance imaging procedures. These guidelines include: the 1988 FDA guidance, 1991 NRPB guidelines, the 1991 IRPA guidelines, and the 1993 draft IEC standard.

The 1993 NRPB draft recommendations for workers and the public state that restrictions on acute exposure to RF radiation of frequencies greater than 100 kHz are intended to avoid adverse effects resulting from whole-body and partial-body heating, and adverse effects resulting from pulsed RF radiation.

The 1992 ANSI/IEEE standard recommends limits for controlled and uncontrolled environments, using as its basis the position that the it is the nature of the exposure environment, not population type, that is important. This position is based partially on the conclusion that no reliable scientific data exists indicating that certain subgroups of the population are more at risk than others. However, other contemporary guidelines state the opposite conclusion. The FDA (1988), NRPB (1991), IRPA (1991), and the IEC (1993) guidelines define groups of people who are less heat tolerant than others. This information should be considered in development of an exposure standard.

Summary of EPA Recommendations

1. The FCC should not adopt the 1992 ANSI/IEEE standard. There are serious flaws in the standard that call into question whether the proposed use of 1992 ANSI/IEEE is sufficiently protective. The following four points address some of our concerns.

a) 1992 ANSI/IEEE allows a two-fold increase in the MPE at high frequencies above that permitted by the current FCC guideline.

b) The two-level revised standard is not directly applicable to any population group but is applicable to exposure environments called controlled and uncontrolled environments that are not well defined and are discretionary. We disagree with this approach.

c) The 1992 ANSI/IEEE conclusion that there is no scientific data indicating that certain subgroups of the population are more at risk than others is not supported by NCRP and EPA reports.

d) The thesis that the 1992 ANSI/IEEE recommendations are protective of all mechanisms of interaction is unwarranted because the adverse effects level in the 1992 ANSI/IEEE standard is based on a thermal effect.

2. The FCC should consider the exposure criteria recommended by the National Council on Radiation Protection and Measurements (NCRP) in NCRP Report No. 86, "Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields," with the addition of

(a) the 1992 ANSI/IEEE limits for induced and contact RF currents, for the frequency range of 300 kHz to 100 MHz, to protect against shock and burn, and

(b) the FCC proposal for low power device exclusions (FCC 93-142, pp. 7-8) as the standard for the public, where "public" includes all persons using these devices unless the user is operating a device as a concomitant of employment.

EPA recommends consideration of 1986 NCRP for the following reasons.

a) 1986 NCRP recommends RF radiation exposure limits specifically for both workers and the public.

b) 1986 NCRP is more protective than 1992 ANSI/IEEE at higher frequencies.

c) There are no substantive differences in the literature base supporting 1986 NCRP and 1992 ANSI/IEEE except for the literature on RF shocks and burns.

In addition, NCRP is chartered by the U.S. Congress to develop radiation protection recommendations.

3. The FCC should consider requesting that the NCRP revise its 1986 report to provide an updated, critical, and comprehensive review of the biological effects on RF radiation and recommendations for exposure criteria.

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