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FEDERAL COMMUNICATIONS COMMISSION
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Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, DC 20554

*In the matter of
Guidelines for Evaluating
the Environmental Effects of
Radiofrequency Radiation*

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ET Docket No. 93-62

**SUPPLEMENT TO REPLY COMMENTS OF
THE ELECTROMAGNETIC ENERGY POLICY ALLIANCE
(NOW THE ELECTROMAGNETIC ENERGY ASSOCIATION - EEA)**

Dinah D. McElfresh
Executive Director
Electromagnetic Energy
Association
1255 Twenty-Third St., NW
Suite 850
Washington, DC 20037
202/452-1070

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Executive Summary

The Electromagnetic Energy Association strongly urges the Federal Communications Commission to adopt, in its entirety, ANSI/IEEE C95.1-1992 as was proposed in the 1993 Notice of Proposed Rulemaking. Adoption of C95 is supported by an overwhelming majority of respondents to the Notice.

The guidelines of ANSI/IEEE C95.1-1992 represent the most current and broadest consensus of the scientific community on RF safety issues. C95 is now being used by a number of government agencies such as OSHA, DOD and DOE. OMB Circular A-119 directs federal agencies to support and adopt voluntary standards and to coordinate their views on important issues involving these standards. The Commission's adoption of C95, the only voluntary RF safety standard in the U.S. and one that has been adopted by other Federal agencies, is consistent with this directive.

Moreover, the continued lack of Federal safety criteria for the RF spectrum remains a problem for many organizations and industries, as well as for the public who rely more than ever on the safe use of the electromagnetic spectrum. Adoption of a standard that is not in use by other Federal agencies diminishes the credibility of all RF safety guidelines and feeds into the public's misconception that there is no scientific consensus on this issue.

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The Electromagnetic Energy Association ("EEA")¹, formerly the Electromagnetic Energy Policy Alliance ("EEPA") submits herewith a supplement to its reply comments filed in response to the public record established to date regarding the above captioned Notice of Proposed Rule Making ("Notice")².

EEA in its comments on the Notice supported the adoption of ANSI/IEEE C95.1-1992 ("C95") in its entirety, as did the overwhelming majority of respondents to the Notice. EEA understands that contrary to this consensus, FCC is now considering adopting a hybrid of C95 and the 1986 recommendations of NCRP Scientific Committee SC-53³. EEA believes that this decision is being influenced mainly by criticism in EPA's Comments on the above Notice and by recent discussions with members of EPA. EEA believes that EPA's concerns, as expressed in their Comments, have been adequately addressed in the Reply comments of IEEE Standards Coordinating Committee SCC-28⁴. EEA also believes the issue has become an issue of policy and, for the following reasons,

¹ EEA, formerly the Electromagnetic Energy Policy Alliance (EEPA), was formed in 1984 to represent a broad range of manufacturers and users of products producing electromagnetic energy. EEA promotes the concept of a rational public policy, based on scientific consensus, for electromagnetic energy with respect to regulation, research and education.

² Notice of Proposed Rule Making in Docket 93-62.

³ *Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields*, NCRP Report No. 86, National Council on Radiation Protection and Measurements, Bethesda, MD.

⁴ *Reply Comments of the IEEE SC-28: Prepared by the Working Group on Interpretations and Endorsed by a Consensus of Subcommittee 4*. Submitted April 21, 1994.

asks the Commission to abandon the concept of the scientifically non-defensible hybrid approach and instead adopt ANSI/IEEE C95.1-1992 in its entirety:

- 1) ANSI/IEEE C95.1-1992 resulted from the broadest consensus for the development of RF safety standards.**
- 2) ANSI/IEEE C95.1-1992 was developed following an open consensus process which required soliciting and responding to public comment.**
- 3) ANSI/IEEE C95.1-1992 provides guidance and explanations for implementing the safety criteria.**
- 4) IEEE is supported by extensive on-going standards activities within the largest professional society in the world.**
- 5) ANSI/IEEE C95.1-1992 is now being used by a number of federal agencies and companies developing cellular and personal communications services and already has been included in the FCC's regulations regarding personal communications services.**
- 6) Adoption of ANSI/IEEE C95.1-1992 is consistent with OMB A-119 which directs federal agencies to support and adopt voluntary standards and to coordinate standards activities with other federal agencies.**
- 7) There exists substantial detailed records (in print) of the deliberations and studies by the scientific community over the eight years ANSI/IEEE C95.1-1992 was developed.**
- 8) Adoption of regulations different from those of FDA, OSHA, DOD and others will cause confusion and a lack of confidence in all safety criteria.**

- 9) ANSI/IEEE C95.1-1992 is basically consistent with the most modern standards throughout the world, including the laser safety standards above 300 GHz. Adoption by the FCC of an older guideline (NCRP-1986) would place the FCC in an isolated position among the world's regulatory agencies.

- 10) The FCC should heed the advice of the premier health agency which deals with RF radiation, namely the FDA. The FDA recommended that the FCC adopt ANSI/IEEE C95.1-1992 except for the low-power device exclusion.

Each of these reasons are addressed in detail below:

- 1) **ANSI/IEEE C95.1-1992 resulted from the broadest consensus for the development of RF safety standards.**

The ANSI/IEEE C95.1-1992 standard was developed by a group of more than 125 eminently qualified scientists. The approximate distribution of the affiliations of the members of the subcommittee that developed the 1992 standard (Subcommittee 4) was as follows:

Research:

- Academia: 30%
- Nonprofit Research Organizations: 6%
- Military Research Laboratories: 12%
- Non-Military Research Laboratories (FDA, EPA, NIOSH, etc.): 24%

Industry: 10%

Consultants for Industry: 3%

Government (Administration): 4%

General Public and Independent Consultants: 11%

The approximate distribution of the principal discipline of these individuals is as follows:

Physical Sciences: 33%

(physics, biophysics, engineering, bioengineering, etc.)

Life Sciences: 43%

(biology, physiology, cell biology, genetics, etc.)

Medicine: 10%

(physicians)

Radiology, Toxicology, Pharmacology: 3%

Others: 11%

(law, medical history, safety, etc.)

In addition, a number of recognized specialists with expertise in behavior, biorhythms, cardiovascular, the central nervous system, development and teratology, endocrinology, visual systems, genetics, hematology-immunology, metabolism-thermoregulation, oncology, modulation, and physiology participated in the literature evaluation process but were not members of the subcommittee.

At the time the standard was approved by the IEEE Standards Board and ANSI Board of Standards Review, 1991 and 1992, respectively, the Vice-Chairman of SCC-28 was Dr. A.W. Guy who was also Chairman of the NCRP Committee that developed the recommendations in the earlier 1986 NCRP report.

In contrast, the NCRP Scientific Committee SC53 which developed the 1986 report was comprised of only six voting members (including the Chairman), five advisory members and five consultants, many of whom were also members of Subcommittee 4 of IEEE SCC-28.

2) ANSI/IEEE C95.1-1992 was developed following an open consensus process which required soliciting and responding to public comment.

The ANSI/IEEE C95.1-1992 standard was developed through an open consensus process. To attain consensus, the draft standard had to be

approved by the developing subcommittee (SC-4) through a balloting process. This process requires that at least 75% of the ballots are returned and 75% of the returned ballots are approved. Negative ballots are circulated to the subcommittee for consideration and concerted efforts are directed toward resolution. Once approved, the draft standard was submitted through an identical process at the parent committee level (SCC-28), which in addition required approval by coordinating societies, i.e., societies within and outside of IEEE with similar interests and mandates. Once approved by the parent committee, the standard was reviewed by the IEEE Standards Board. The Standards Board has responsibility for ensuring that due process is followed. After approval as an IEEE standard, it was submitted to the American National Standards Institute's ("ANSI") Board of Standard Review ("BSR"). The standard was then advertised by ANSI with a 60 day period for public comment. All comments that were received were addressed. Once the external review process was completed and the BSR was convinced that due process had been followed, the standard was approved for use as an American National Standard. Even after approval by ANSI, interested parties could appeal the decision before the BSR.

NCRP follows no such open process. Consensus at the Scientific Committee level is defined by the Chair. A few selected experts and the 75 member Council⁵ review, provide comments and approve the final draft. There are no provisions in the process for external review or input - nor is there any formal written record.

3) ANSI/IEEE C95.1-1992 provides guidance and explanations for implementing the safety criteria.

While the exposure criteria in the NCRP report and the ANSI/IEEE C95.1-1992 standard may appear similar, at least for a portion of the RF spectrum, only the ANSI/IEEE standard provides guidance for implementing these criteria. Moreover, within IEEE SCC-28 are standing working groups that respond to requests for interpretations and clarifications of the content of the C95 standard.

⁵ Most of the Council members have expertise in ionizing radiation; very few of the Council members have expertise in non-ionizing radiation.

NCRP has no such procedures for addressing requests for clarifications and interpretations relating to the recommendations in NCRP Report No. 86.

- 4) ANSI/IEEE C95.1-1992 is supported by extensive on-going standards activities within the largest professional society in the world, the IEEE (with close to 400,000 members worldwide).**

The IEEE has a large Standards Board which meets four times per year and a large Standards Department staffed by engineers and administrators. SCC-28, with about 70 members, operates under strict IEEE rules of due process with completely open meetings and detailed documentation. There are working groups (subcommittees) with a total of more than 150 volunteers from all disciplines - engineers, life scientists, medical doctors, etc. There are about 350 people on the SCC-28 mailing list. Balance on the Committee and Subcommittees is assured with representation from a diverse list of interests including consumers, labor, research, government, industry and professional societies.

Meetings are held frequently and supplemented by correspondence, FAX, e-mail, etc. Procedures and people are in place to provide interpretations and clarifications, as well as to develop supplements to the standard and revisions every five to eight years. As Dr. John Rankine of the IEEE Standards Board stated before the US Senate in 1992, the C95 standard is a "living standard."

By comparison, the NCRP has no on-going standards committee in this field, and has no procedures for addressing requests for clarifications or interpretations relating to the recommendations in NCRP Report No. 86.

- 5) ANSI/IEEE C95.1-1992 is already being used by a number of agencies and companies developing cellular and personal communications services.**

ANSI/IEEE C95.1-1992 is being used by OSHA, DOD, DOE and other federal agencies, by local jurisdictions such as San Diego County and Santa Barbara County in California, King County in Washington, Southampton Township in

New York and by the telecommunications industry. The FDA uses the C95 standards to assess potential hazards in the case of non-compliance with their microwave-oven leakage standard. Moreover, the FDA in collaboration with NIOSH and OSHA has used C95 in guidelines for safe exposure near RF heat sealers and heaters.

Furthermore, the FCC has already recognized and incorporated C95 into its regulations concerning Personal Communications Services ("PCS"). In 47CFR24.52 regarding "RF Hazards," licensees and manufacturers must ensure that their facilities and equipment comply with the limits of ANSI/IEEE C95.1-1992. The C95 low-power device exclusion has also been incorporated by the FCC into its regulations concerning PCS.

6) Adoption of ANSI/IEEE C95.1-1992 is consistent with OMB A-119 which directs federal agencies to support and adopt voluntary standards.

OMB Circular A-119 strongly encourages federal agency participation in voluntary standards bodies and standards-developing groups when it is in the public interest and compatible with the agency's mission (see attachment). Because development of ANSI/IEEE C95.1-1992 involved extensive federal agency participation (FCC, DOE, EPA and OSHA) and is a voluntary standard, while development of the NCRP guidelines involved only a very small group of privately appointed committee members, compliance with OMB A-119 is consistent with the adoption of C95 by the FCC.

Furthermore, under A-119 the OMB strongly encourages two or more federal agencies to make a good faith effort to coordinate their views on important issues involving voluntary standards. Currently agencies including OSHA, DOD, DOE and NASA have already adopted the C95 guideline and the FCC adoption of C95 is consistent with the A-119 directives.

- 7) Substantial detailed records (in print) are available of the deliberations and studies by the scientific community over the eight years that ANSI/IEEE C95.1-1992 was developed.**

The substantial detailed records that exist of the scientific studies and deliberations that went into the development of ANSI/IEEE C95.1-1992 are available to anyone wishing to review them. These records date back to 1982 and are maintained for all subcommittees, ad hoc committees and the parent SCC-28 Committee.

- 8) Adoption of regulations different from those of FDA, OSHA, DOD and others will cause confusion and a lack of confidence in all safety criteria.**

The C95 standard is currently being used by the FDA, OSHA, DOD and other federal, state and local government agencies to assess the safety of RF emitting devices and radio services. Should the FCC adopt a guideline other than the standard being used by other government agencies, confusion will exist for FCC licensees who must show compliance with regulations of all applicable federal agencies, not just those of the Commission.

Moreover, potential conflicts between federal agencies over this issue has the potential to diminish public confidence in any RF safety criteria and will destroy the credibility of federal agencies to protect from potential environmental hazards. At the same time, there will be no increased level of safety to the general public.

- 9) ANSI/IEEE C95.1-1992 is basically consistent with the most modern standards throughout the world, including the laser safety standards above 300 GHz. Adoption by the FCC of an older guideline (NCRP-1986) would place the FCC in an isolated position among the world's regulatory agencies.**

The modern ANSI/IEEE C95.1-1992 was the first to introduce new features that are later copied around the world. For example, after ANSI/IEEE C95.1-1992 specified that averaging time must be frequency-dependent, then other

organizations, e.g., the NRPB in the U.K. and NATO later introduced the same or similar frequency-dependence in their new standards.

In addition, through continuing cooperation with the laser-standard community during the development of the latest recommendations, the C95 community ensured that its RF safety guidelines in 1992 were consistent with those of the laser safety guideline at 300 GHz. (ANSI Z136.1-1993)

It would be illogical for the FCC to reject these modern advances copied around the world and instead adopt an obsolete guideline or parts of an obsolete guideline. Doing so would make the FCC unique in going backwards in the world scene. Instead of opting for more harmonization, the FCC would opt to go the other way while the rest of the world proceeds towards harmonization. The FCC can avoid this embarrassment by adopting C95.1 as recommended by FDA.

10) The FCC should heed the advice of the premier health agency which deals with RF radiation, namely the FDA. The FDA recommended that the FCC adopt ANSI/IEEE C95.1-1992 except for the low-power device exclusion.

The FCC should listen to the premier federal health agency that deals with RF radiation, the FDA. A failure to adopt ANSI/IEEE C95.1-1992 by the FCC would be tantamount to rejecting the advice of the FDA. FDA recommended to the FCC the adoption of all C95.1-1992 except for the low power exclusion. This advice is entirely consistent with C95.1-1992 and the supplement which should be issued shortly.

The advice of FDA is contradicted by EPA, but since the FDA has a clear mandate and demonstrated expertise, both of which are absent in EPA, the FCC must adhere to the superior advice, that of the FDA. To fail to follow the advice of the FDA would contradict the stated desire by the FCC to give special attention to the premier federal health agency in the world.

Conclusion

The Electromagnetic Energy Association strongly urges the Federal Communications Commission to adopt, in its entirety, ANSI/IEEE C95.1-1992 as was proposed in the 1993 Notice of Proposed Rulemaking. Adoption of C95 is supported by an overwhelming majority of respondents to the Notice.

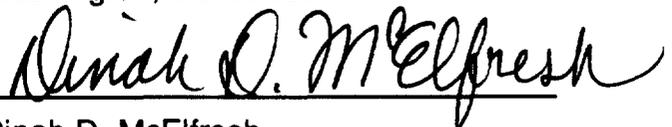
The guidelines of ANSI/IEEE C95.1-1992 represent the most current and broadest consensus of the scientific community on RF safety issues. C95 is now being used by a number of government agencies such as OSHA, DOD and DOE. OMB Circular A-119 directs federal agencies to support and adopt voluntary standards and to coordinate their views on important issues involving these standards. The Commission's adoption of C95, the only voluntary RF safety standard in the U.S. and one that has been adopted by other Federal agencies, is consistent with this directive.

Moreover, the continued lack of Federal safety criteria for the RF spectrum remains a problem for many organizations and industries, as well as for the public who rely more than ever on the safe use of the electromagnetic spectrum. Adoption of a standard that is not in use by other Federal agencies diminishes the credibility of all RF safety guidelines and feeds into the public's misconception that there is no scientific consensus on this issue.

Should the Commission have concerns regarding the adequacy of the safety criteria for certain frequencies, as was suggested in the EPA's comments to the NPRM, then the EEA would strongly urge the Commission to immediately adopt C95 and to subsequently issue a Notice of Inquiry on this topic.

Respectfully submitted,

Electromagnetic Energy Association
1255 Twenty-Third St., NW, Suite 850
Washington, DC 20037



Dinah D. McElfresh
Executive Director

March 29, 1996

FDA POLICY ON STANDARDS HARMONIZATION AIMS TO SAFEGUARD PUBLIC HEALTH



"The investment that the agency makes in standards work — by sending its experts to participate actively in several hundred activities — pays important dividends in improved public protection."

"The policy addresses FDA's plans to continue participating in international standards activities that assist it in implementing statutory provisions for safeguarding the public health."

This past October the Food and Drug Administration (FDA) published in the *Federal Register* its policy on the development and use of standards applicable to products regulated by the agency.

"International Harmonization; Policy on Standards" is an important step toward the formation of public-private partnerships envisioned in the Administration's "reinventing government" strategy. FDA believes that voluntary standards committees are a splendid example of public-private partnership that enhances public protection. The investment that the agency makes in standards work — by sending its experts to participate actively in several hundred activities — pays important dividends in improved public protection. Formulating voluntary standards both advances public health and benefits industry through increased consistency in requirements.

The FDA policy articulates the agency's position on the development and use of standards with respect to international harmonization of both regulatory requirements and guidelines. Specifically, the policy addresses FDA's plans to continue participating in international standards activities that assist it in implementing statutory provisions for safeguarding the public health, increase its efforts to harmonize its regulatory requirements with those of foreign governments, including setting new standards that better serve the public health, and respond to laws and policies such as the Trade Agreements Act [19 USC 2531-82] and OMB Circular A-119 which encourage agencies to use international standards that provide the desired degree of protection. Although the policy focuses on international standards and harmonization, FDA recognizes the considerable synergy between its domestic

and international policy priorities, and the same principles are applicable to both types of standards activities in which FDA participates.

As we move toward a global economy and as world trade competition increases, the concept of standardization has become a critical business issue with tremendous implications for competitiveness and profitability. Increasingly, products must function and be accepted in various cultures and markets.

As a matter of national policy, U.S. Trade Representative Mickey Kantor has called for the elimination of "sanctuary economies," insisting that the U.S. have the same access to foreign markets as foreign countries have to our markets. To assure a level playing field, the opening up of markets, and the elimination of trade barriers, standards have to be harmonized to the extent possible, provided consumers and the environment are protected by the standards. Active participation by both American business and government in the standards process is therefore critical.

In response to FDA's request for comments on the draft international harmonization policy on standards, concern was raised that standards could be lowered in the interest of harmonization — as some countries' codes and regulations are inconsistent with the U.S. system. The central purpose of FDA involvement in the development and use of standards is to assist the agency in fulfilling its public health, regulatory mission. FDA remains committed to protection of the public health as its primary goal. Consistent with that goal, several general principles will guide FDA's harmonization efforts.

By Linda Horton

First, standards should stress product safety and effectiveness, therefore contributing to safe, effective, and high quality products. Second, harmonization activity should promote U.S. interests with foreign countries. Third, development or adoption of standards in a regulatory manner must include transparency of process, i.e., the process must be open to public scrutiny and provide ample opportunity for consideration of the views of all interested parties. Fourth, standards should be developed on the basis of sound scientific and technical information and should be exchanged with foreign government officials to expedite the approval of products and to protect the public health. And finally, FDA should accept equivalent standards of other countries, provided that FDA is satisfied such standards meet the agency's level of public protection.

FDA views its policy on standards and harmonization as both an opportunity to advance the agency's domestic public health goals and to form partnerships with other agencies of the U.S. government, foreign regulatory bodies, the regulated industries, consumers, and the international scientific community to work toward globally compatible laws, regulations, standards, and policies. Today's trends in global trade mean that the way goods are produced and regulated domestically and in other countries is increasingly important to both public health protection in the U.S., and the nation's competitive posture in the global economy. Domestic and international partnerships also present positive opportunities to advance public health by fostering more efficient and timely product development to speed the worldwide availability of safe and effective new therapies.

Summary

At the FDA, global harmonization is approached with the aim of enhancing regulatory effectiveness by providing more consumer protection with scarce government resources, and increasing worldwide consumer access to safe, effective, and high-quality products. This economy of effort translates into monetary savings to the agency, regulated industries, and ultimately consumers, and better serves domestic and global public health. The agency is committed to working with the private sector in achieving these mutual goals.

Linda R. Horton is director, International Policy, Office of Policy, Office of the Commissioner, Food and Drug Administration. Linda Horton is a member of ANSI's Board of Directors and also participates in the Institute's Board Committee on Conformity Assessment and ANSI's Government Member Council. ■

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" At the FDA, global harmonization is approached with the aim of enhancing regulatory effectiveness by providing more consumer protection with scarce government resources, and increasing worldwide consumer access to safe, effective, and high-quality products."