



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

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

Dear Mr. Tell:

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

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

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

Sincerely yours,

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

Enclosures (2)

cc: N. Hankin
J. Elder
R. Cleveland
R. Curtis
R. Owen
L. Cress
J. Heale

RF Guideline Issues

Identified by members of the federal RF Interagency Work Group, June 1999

Issue: Biological basis for local SAR limit

The C95.1 partial body (local) exposure limits are based on an assumed ratio of peak to whole body SAR; that is, they are dosimetrically, rather than biologically based. Instead of applying a dosimetric factor to the whole body SAR to obtain the local limits, an effort should be made to base local SAR limits on the differential sensitivity of tissues to electric fields and temperature increases. For example, it seems intuitive that the local limits for the brain and bone marrow should be lower than those for muscle, fat and fascia; this is not the case with the current limits which implicitly assume that all tissues are equally sensitive (except for eye and testicle). If no other data are available, differential tissue sensitivity to ionizing radiation should be considered.

If it is deemed necessary to incorporate dosimetric factors into the resulting tissue-specific SAR limits these should be based on up-to-date dosimetric methods such as finite-difference time-domain calculations utilizing MRI data and tissue-specific dielectric constants. For certain exposure conditions FDTD techniques and MRI data may allow better simulation of peak SAR values. Consideration should be given to the practical tissue volume for averaging SAR and whether this volume is relevant to potential effects on sensitive tissues and organs.

Issue: Selection of an adverse effect level

Should the thermal basis for exposure limits be reconsidered, or can the basis for an unacceptable/adverse effect still be defined in the same manner used for the 1991 IEEE guidelines? Since the adverse effect level for the 1991 guidelines was based on acute exposures, does the same approach apply for effects caused by chronic exposure to RF radiation, including exposures having a range of carrier frequencies, modulation characteristics, peak intensities, exposure duration, etc., that does not elevate tissue temperature on a macroscopic scale?

Selection criteria that could be considered in determining unacceptable/adverse effects include:

- a) adverse effects on bodily functions/systems
- b) minimal physiological consequences
- c) measurable physiological effects, but no known consequences

If the adverse effect level is based on thermal effects in laboratory animals, the literature on human studies (relating dose rate to temperature elevation and temperature elevation to a physiological effect) should be used to determine if the human data could reduce uncertainties in determination of a

safety factor.

Issue: Acute and chronic exposures

There is a need to discuss and differentiate the criteria for guidelines for acute and chronic exposure conditions. The past approach of basing the exposure limits on acute effects data with an extrapolation to unlimited chronic exposure durations is problematic. There is an extensive data base on acute effects with animal data, human data (e.g. MRI information), and modeling to address thermal insult and associated adverse effects for acute exposure (e.g., less than one day). For lower level ("non-thermal"), chronic exposures, the effects of concern may be very different from those for acute exposure (e.g., epigenetic effects, tumor development, neurologic symptoms). It is possible that the IEEE RF radiation guidelines development process may conclude that the data for these chronic effects exist but are inconsistent, and therefore not useable for guideline development. If the chronic exposure data are not helpful in determining a recommended exposure level, then a separate rationale for extrapolating the results of acute exposure data may be needed. In either case (chronic effects data that are useful or not useful), a clear rationale needs to be developed to support the exposure guideline for chronic as well as acute exposure.

Issue: One tier vs two tier guidelines:

A one tier guideline must incorporate all exposure conditions and subject possibilities (e.g., acute or chronic exposure, healthy workers, chronically ill members of the general public, etc.). A two tier guideline, as now exists, has the potential to provide higher limits for a specific, defined population (e.g., healthy workers), and exposure conditions subject to controls, while providing a second limit that addresses greater uncertainties in the data available (about chronic exposure effects, about variations in the health of the subject population, etc.). A greater safety factor would have to be incorporated to deal with greater uncertainty in the scientific data available. Thus, a two-tier guideline offers more flexibility in dealing with scientific uncertainty, while a one-tier guideline would force a more conservative limit to cover all circumstances including the scientific uncertainties that exist.

Issue: Controlled vs. uncontrolled (applicability of two IEEE exposure tiers)

The current "controlled" and "uncontrolled" definitions are problematic, at least in the civilian sector, particularly since there are no procedures defined in the document to implement the "controlled" condition. The new guidelines should offer direction for the range of controls to be implemented and the training required for those who knowingly will be exposed (e.g. workers), along the lines of the existing ANSI laser safety standards. This essential element needs to be included for whatever limits are defined, be they one-tier or two-tier.

For example, the OSHA position is that the "uncontrolled" level is strictly an "action" level which indicates that there is a sufficiently high exposure (compared to the vast majority of locations) to merit an assessment to determine what controls and training are necessary to ensure persons are not exposed above the "controlled" limit. Many similar "action" levels are part of OSHA and public health standards. Should this interpretation be incorporated into the IEEE standard as a means to determine the need to implement a safety plan? [The laser standard has a multi-tiered (Class I, II, III, IV) standard which similarly requires additional controls for more powerful lasers to limit the likelihood of an excess exposure, even though the health effect threshold is the same.]

On the other hand, if it is determined that certain populations (due to their health status or age) are more susceptible to RF exposures, then a multi-tiered standard, applicable only to those specific populations, may be considered.

The ANSI/IEEE standard establishes two exposure tiers for controlled and uncontrolled environments. The following statement is made in the rationale (Section 6, page 23): "The important distinction is not the population type, but the nature of the exposure environment." If that is the case, consideration should be given to providing a better explanation as to why persons in uncontrolled environments need to be protected to a greater extent than persons in controlled environments. An uncontrolled environment can become a controlled environment by simply restricting access (e.g., erecting fences) and by making individuals aware of their potential for exposure. After such actions are taken, this means that the persons who previously could only be exposed at the more restrictive uncontrolled levels could now be exposed inside the restricted area (e.g., inside the fence) at controlled levels.

What biologically-based factor changed for these people? Since the ostensible public health reason for providing greater protection for one group of persons has historically been based on biological considerations or comparable factors, it is not clear why the sentence quoted above is valid.

Issue: Uncertainty factors

The uncertainties in the data used to develop the guideline should be addressed. An accepted practice in establishing human exposure levels for agents that produce undesirable effects is the application of factors representing each area of uncertainty inherent in the available data that was used to identify the unacceptable effect level. Standard areas of uncertainty used in deriving acceptable human dose for agents that may produce adverse (but non-cancer) effects include

- (1) extrapolation of acute effects data to chronic exposure conditions,
- (2) uncertainty in extrapolating animal data to humans in prolonged exposure situations,
- (3) variation in the susceptibility (response/sensitivity) among individuals,

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

If guidelines are intended to address nonthermal chronic exposures to intensity modulated RF radiation, then how could uncertainty factors be used; how would this use differ from the historical use of uncertainty factors in establishing RF radiation guidelines to limit exposure to acute or sub-chronic RF radiation to prevent heat-related effects?

There is a need to provide a clear rationale for the use of uncertainty factors.

Issue: Intensity or frequency modulated (pulsed or frequency modulated) RF radiation

Studies continue to be published describing biological responses to nonthermal ELF-modulated and pulse-modulated RF radiation exposures that are not produced by CW (unmodulated) RF radiation. These studies have resulted in concern that exposure guidelines based on thermal effects, and using information and concepts (time-averaged dosimetry, uncertainty factors) that mask any differences between intensity-modulated RF radiation exposure and CW exposure, do not directly address public exposures, and therefore may not adequately protect the public. The parameter used to describe dose/dose rate and used as the basis for exposure limits is time-averaged SAR; time-averaging erases the unique characteristics of an intensity-modulated RF radiation that may be responsible for producing an effect.

Are the results of research reporting biological effects caused by intensity-modulated, but not CW exposure to RF radiation sufficient to influence the development of RF exposure guidelines? If so, then how could this information be used in developing those guidelines? How could intensity modulation be incorporated into the concept of dose to retain unique characteristics that may be responsible for a relationship between exposure and the resulting effects?

Issue: Time averaging

Time averaging of exposures is essential in dealing with variable or intermittent exposure, e.g., that arising from being in a fixed location of a rotating antenna, or from moving through a fixed RF field. The 0.1 h approach historically used should be reassessed, but may serve this purpose adequately. Time averaging for other features of RF exposure is not necessarily desirable, however, and should be reevaluated specifically as it deals with modulation of the signal, contact and induced current limits, and prolonged, or chronic exposure. These specific conditions are discussed in a little more detail elsewhere.

If prolonged and chronic exposures are considered to be important, then there should be a

reconsideration of the time-averaging practices that are incorporated into existing exposure guidelines and used primarily to control exposure and energy deposition rates in acute/subchronic exposure situations.

Issue: Lack of peak (or ceiling) limits for induced and contact current

A recent change in the IEEE guidelines allows for 6 minute, rather than 1 second, time-weighted-averaging for induced current limits. This change increases the concern about the lack of a peak limit for induced and contact currents. Will the limits for localized exposure address this issue, i.e., for tissue along the current path?

Issue: Criteria for preventing hazards caused by transient discharges

The existing IEEE recommendation states that there were insufficient data to establish measurable criteria to prevent RF hazards caused by transient discharges. If specific quantitative criteria are still not available, can qualitative requirements be included in the standard to control this hazard (e.g., metal objects will be sufficiently insulated and/or grounded, and/or persons will utilize sufficient insulating protection, such as gloves, to prevent undesirable transient discharge.)?

ISSUE: Limits for exposure at microwave frequencies

Concerns have been expressed over the relaxation of limits for continuous exposures at microwave frequencies above 1500 MHz. The rationale provided in the current guideline (Section 6.8) references the fact that penetration depths at frequencies above 30 GHz are similar to those at visible and near infrared wavelengths and that the literature for skin burn thresholds for optical radiation "is expected to be applicable." The rationale then implies that the MPE limits at these high frequencies are consistent with the MPE limits specified in ANSI Z136.1-1986 for 300 GHz exposures. This is apparently the rationale for "ramping up" to the MPE limits for *continuous* exposure of 10 mW/cm² at frequencies above 3 GHz (controlled) or 15 GHz (uncontrolled). The rationale should be given as to why this ramp function has been established at relatively low microwave frequencies (i.e., 1500 MHz and above), rather than being implemented at higher frequencies that are truly quasi-optical. For example, one option could be two ramp functions, one beginning at 300 MHz, based on whole- or partial-body dosimetry considerations, and another at higher frequencies (say 30-100 GHz) to enable consistency with the laser standard. Such a revision should help reduce concern that the standard is not restrictive enough for continuous exposures at lower microwave frequencies where new wireless applications for consumers could make this an issue in the future.

Issue: Replication/Validation

Published peer-reviewed studies that have been independently replicated/validated should be used to establish the adverse effects level from which exposure guidelines are derived. The definition of "replicated/validated" should not be so restrictive to disallow the use of a set of reports that

are scientifically valid but are not an exact replication/validation of specific experimental procedures and results.

Peer-reviewed, published studies that may not be considered to be replicated/validated, but are well done and show potentially important health impacts provide important information regarding uncertainties in the data base used to set the adverse effect level (e.g., incomplete data base).

Issue: Important Health Effects Literature Areas:

Documentation should be provided that the literature review process included a comprehensive review of the following three areas:

- 1) long-term, low-level exposure studies (because of their importance to environmental and chronic occupational RFR exposure);
- 2) neurological/behavioral effects (because of their importance in defining the adverse effect level in existing RFR guidelines); and
- 3) micronucleus assay studies (because of their relevance to carcinogenesis).

Issue: Compatibility of RFR guidelines

Compatibility of national and international RFR guidelines remains a concern. It is important for the IEEE Committee to address this issue by identifying and discussing similarities and differences in a revised IEEE guideline and other RFR guidelines. Compatibility/noncompatibility issues could be discussed in the revised IEEE guideline or as a companion document distributed at the time the revised IEEE guideline is released to the public.

FROM: NORB HANKIN
OFFICE OF RADIATION AND INDOOR AIR
MAIL CODE 6604J
U.S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460, USA

David Fichtenberg
P.O.Box 7577
Olympia, WA 98507-7577

Dear Mr. Fichtenberg:

Thank you for your E-mail letter of October 2, 1996, that asks for clarification of a statement in the letter (July 25, 1996) from Environmental Protection Agency (EPA) Administrator Carol M. Browner to Federal Communications Commission (FCC) Chairman Reed E. Hundt. You request explanation of the statement, "this new approach is consistent with our comments made in 1993 and addresses our concerns about adequate protection of public health," with questions that pertain to acute thermal exposures, long-term (chronic) nonthermal exposures, and specific absorption rate (SAR).

The aforementioned letter was a response to a Mr. Hundt's request (July 1, 1996) that EPA review the FCC's approach to developing new guidelines. The EPA discussion of the original FCC Notice of Proposed Rulemaking, "Guidelines for Evaluating the Environmental Effects of Radiofrequency (RF) Radiation, ET Docket No. 93-62," resulted in recommendations to the FCC (November 9, 1993). One of those recommendations was that the FCC adopt 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," instead of the 1992 ANSI/IEEE standard that was originally proposed.

The FCC concluded its rule-making activity in August 1996, and adopted RF radiation exposure limits that are generally based on the NCRP guidelines as was recommended by EPA. In addition the FCC specified (in the introduction to its Report and Order FCC 96-326) that the maximum permissible exposure limits adopted are based on exposure criteria quantified in terms of specific absorption rate, and that the SAR limit is 4 watts per kilogram (W/kg).

EPA was very specific in our 1993 comments regarding the sufficiency of available information (on the health effects of RF radiation) to provide a basis for developing exposure standards. In the context of those comments, the FCC's resulting rule that generally followed the NCRP guidelines, and the FCC's explicit statement that the limits adopted are based on the SAR limit of 4 W/kg, EPA believes that our concerns about adequate protection of public health were addressed by the FCC. The FCC does not claim that their new exposure guidelines provide protection for effects to which the 4W/kg SAR basis does not apply.

A key conclusion of EPA's Radiofrequency Radiation Conference, April 1993 (see "Summary and Results of the April 26-27, 1993, Radiofrequency Radiation Conference," Vol.1: Analysis of Panel Discussions, EPA Report 402-R-95-009, March 1995) is

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OFFICE OF RADIATION AND INDOOR AIR
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WASHINGTON, DC 20460, USA

that "There is sufficient information on thermal exposure/effects on which to base a standard. However, participants generally felt that more information needs to be obtained on nonthermal effects." This is reflected in EPA's November 1993 comments to the FCC. These include the following:

"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."

"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 (...).

"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."

"While there is general, although not unanimous, agreement that the data base on low-level, long-term 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."

With this background established, I will proceed to provide my responses to your other questions.

- Q. Is it correct to conclude that the "adequate protection of public health" noted above, refers to "protecting against thermally related effects in humans?"
- A. As I have previously noted, while there is sufficient information on thermal exposure/effects on which to base a standard, the data base on low-level, long-term exposure is insufficient to provide a basis for standards to protect the public against adverse human health effects that may result from long-term, nonthermal exposures. Both the NCRP and ANSI/IEEE standards are thermally based, and do not apply to chronic, nonthermal exposure situations. The statement referring to "adequate protection" pertains to thermally

related effects.

Q. Is it still correct that adverse effect level of 4 W/kg is based on acute exposures that elevate temperature in laboratory animals including nonhuman primates, and not on long-term, low-level (non-thermal) exposure.

A. Yes

Q. Is it correct that the "adequate protection" EPA refers to in its July 25, 1996 letter pertains to protection provided for the effects which occurred due acute exposures, and not necessarily to effects reported to occur below the 4W/kg threshold level?

A. We are referring to exposures that are acute, thermal exposures, not non-thermal, chronic exposures. The SAR limit to which the whole-body exposure limits for the public are related is 0.08 W/kg due to the use of a factor of 50 uncertainty factor applied to the 4 W/kg basis.

Q. Is it correct that "adequate protection" of public health: pertains to thermally related health effects, and not necessarily to the nonthermal effects noted in the 1993 EPA letter?

A. Yes

Q. In view of 1993 comments, does adequate protection pertain to microwave hearing?

A. In that the 'microwave hearing effect' has not been established as a health effect, our statement with regard to "adequate protection" would not pertain to microwave hearing.

This E-mail will be followed by a more formal letter reply to your inquiry.

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MAR 23 1995



MEMORANDUM
OFFICE OF ENGINEERING AND TECHNOLOGY

FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF SECRETARY

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*Manage the spectrum
and provide technical leadership
to create new opportunities
for competitive technologies and services
for the American public.
— Mission Statement —*

Date: March 22, 1995
To: Secretary, FCC
From: Robert F. Cleveland, Office of Engineering & Technology
Subject: ET Docket 93-62
Ex Parte Presentation by U.S. Environmental Protection Agency

Please be advised that on March 21, 1995, the U.S. Environmental Protection Agency (EPA), represented by Dennis O'Connor and Norbert Hankin, met with staff from the FCC and from the National Telecommunications and Information Administration (NTIA) regarding the EPA's efforts to develop exposure recommendations for radiofrequency electromagnetic fields. Attending this meeting from the FCC were: Robert Bromery, Robert Cleveland, Bruce Franca, Stevenson Kaminer, Thomas Stanley, David Sylvar and Jerry Ulcek. NTIA was represented by Janet Healer. During this meeting EPA staff briefed the participants on the EPA's activities and its schedule related to the development of these recommendations. The attached documents were provided to FCC and NTIA staff by the EPA, and they summarize the topics discussed at the meeting.

Please place this memorandum and the attachments into the record of the above-referenced proceeding.

ATTACHMENTS (9)

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DEVELOPMENT OF RF RADIATION EXPOSURE GUIDELINES

**BRIEFING FOR THE
FEDERAL COMMUNICATIONS COMMISSION**

**OFFICE OF RADIATION AND INDOOR AIR
U.S. ENVIRONMENTAL PROTECTION AGENCY**

March 21, 1995

BACKGROUND

- 1986, July "Federal Radiation Protection Guidance; Proposed Alternatives for Controlling Public Exposure to Radiofrequency Radiation; Notice of Proposed Recommendations"
- 1992, Jan. SAB report - recommended that Guidance be completed
- 1993, Apr. RF Radiation Conference
- 1993, Nov. Comments to the Federal Communications Commission
- 1994, April EMF strategy adopted

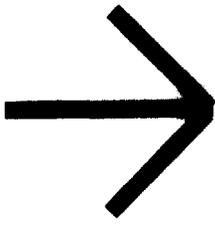
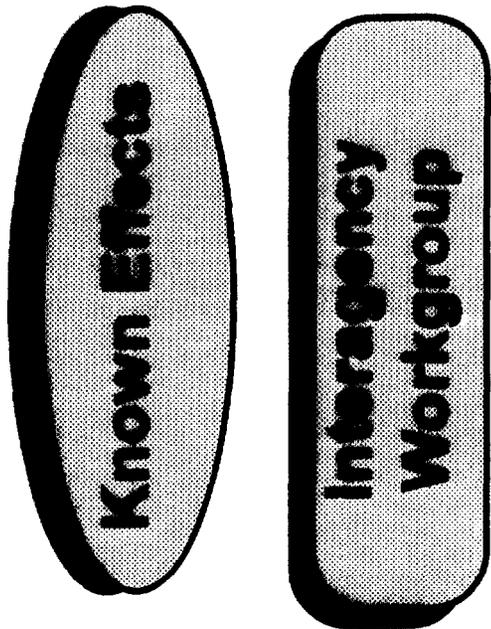
RF RADIATION CONFERENCE

MAJOR CONCLUSIONS

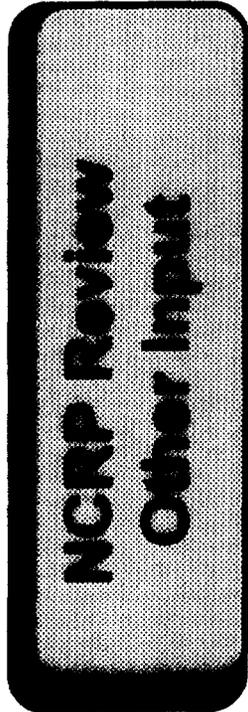
- ◆ **EPA guidelines needed**
- ◆ **Sufficient information - heat/temperature related effects**
- ◆ **Insufficient information: nonthermal exposures
modulation**

RF STRATEGY

PHASE 1 (Health Effects)



PHASE 2 (Modulation)



Hybrid Approach to Exposure Limits

◆ Phase 1: Interim RF Radiation Exposure Guidelines

- Based upon **EPA comments to the FCC**
- Combines best features of **NCRP, ANSI/IEEE, IRPA, ...** guidelines
- Builds upon **existing** health effects research
- **Simple, less controversial**
 - no need for: risk estimates
impact analysis
- **Does not** include modulation, chronic exposure, nonthermal effects

Modulated and Nonthermal Exposures

◆ Phase 2: Modulation

- **NCRP Commentary** (two years)

- Current situation

**insufficient data
developing issue**

- Approach

**NCRP Commentary
focus on **exposure limits**
convenes **National experts****

- Commentary

**Addresses important/controversial issues
basis for **Background Information Document****

- Input from ongoing research

SAG - wireless communications

PROCESS

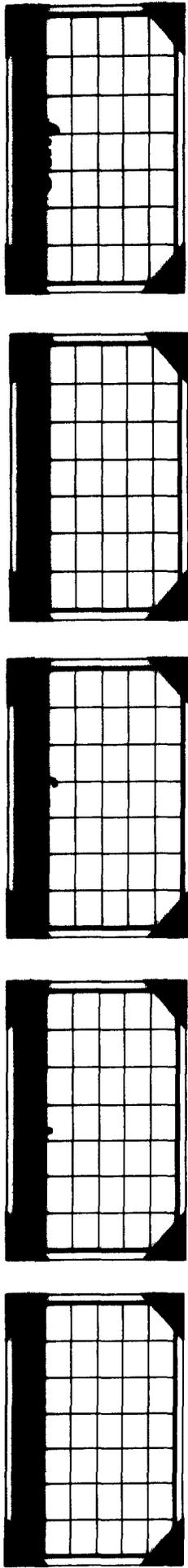
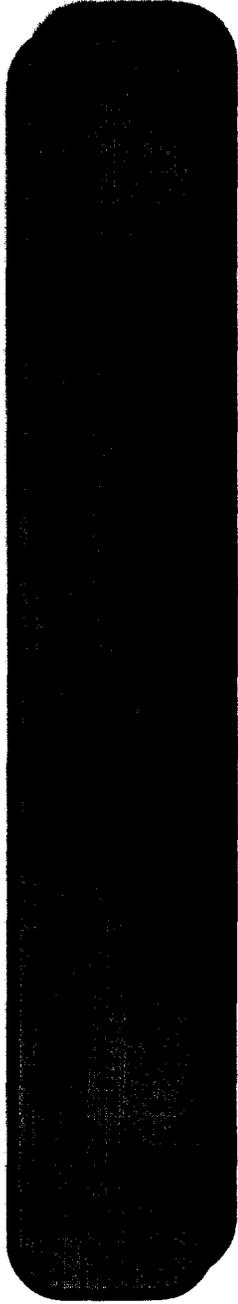
- ◆ Convene **workgroup**

Federal Agency: EPA, FDA, NIOSH, OSHA, FCC, NTIA

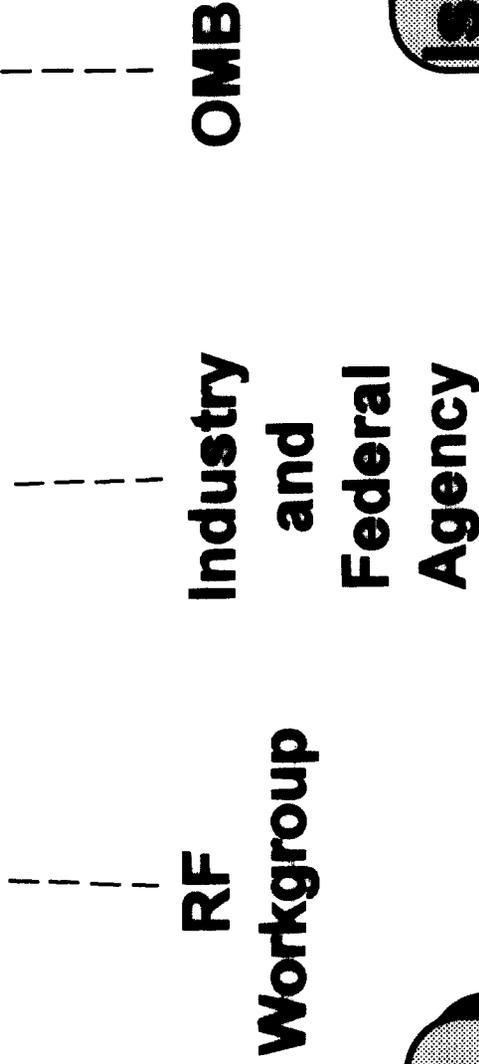
- ◆ Preparation of **Draft Guidelines documents**

- ◆ Reviews and Revisions

- ◆ **Guidelines Report**



Review Process



**Draft RF
Guidance**

**Issue Interim
RF
Guidance**

NEXT STEPS

- **Implement review process**
- **Draft report revisions**
- **Incorporate comments**

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ET 93-62



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

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JUN 30 1995

JUN 19 1995

FEDERAL COMMUNICATIONS COMMISSION
OFFICE OF SECRETARY FOR AIR AND RADIATION

Richard M. Smith, Chief
Office of Engineering and Technology
Federal Communication Commission
1919 M Street, NW
Washington, DC 20554

Dear Mr. Smith:

Due to your pending rulemaking action, I am writing to inform you of the Environmental Protection Agency (EPA) schedule for development of *Guidelines for Limiting Public Exposure to Radiofrequency (RF) Radiation*.

The guidelines are substantially complete, and are beginning to enter the review phase. The review plan for the guidelines will include a 30 day pre-publication review by the RF Inter-Agency Work Group, a 60 day review by selected stakeholders, and final review by OMB (90 days). Issuance of the final guidelines should be in early 1996.

We have established an effective and inclusive process for completing the guidelines. Our approach is rooted in the November 1993 comments from EPA on the Federal Communications Commission (FCC) Notice of Proposed Rulemaking. Last year, selected federal agencies, including the FCC, formed an RF Interagency Work Group to coordinate RF issues among federal agencies, provide technical input to the guidelines, and act as a sounding board to assess the general approach employed in the guidelines. Ongoing discussions about the guidelines with important stakeholders are also underway. For example, the upcoming meeting with the Electromagnetic Energy Alliance is an illustration of the dialogue which is necessary to insure that the guidelines are broadly accepted thereby affording the FCC the opportunity to reference these guidelines as part of their rulemaking.

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Completion of the guidelines in a timely manner remains a priority of this office. In accomplishing this, the assistance and support of the FCC has been invaluable. In particular, Robert Cleveland has offered valuable technical review and insights which substantially improved the guidelines.

Sincerely,

A handwritten signature in cursive script, reading "E. Ramona Trovato". The signature is written in dark ink and is positioned to the right of the word "Sincerely,".

E. Ramona Trovato, Director
Office of Radiation and Indoor Air

0573



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460
APRIL 25, 1984

OFFICE OF
THE ADMINISTRATOR

Mr. William D. Ruckelshaus
Administrator
Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

The Science Advisory Board (SAB) has completed its review of the Office of Research and Development's assessment document entitled Biological Effects of Radiofrequency Radiation and is pleased to transmit its report to you. An SAB Subcommittee, chaired by Dr. Charles Susskind of the University of California at Berkeley, twice reviewed the draft document and unanimously concluded that it represents an adequate statement of the current scientific literature and can serve as a scientifically defensible basis for the Agency's development of radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation.

The enclosed report summarizes the Subcommittee's review process and presents its major findings and recommendations. The SAB Executive Committee, at its recent meeting of April 11-12, fully endorsed the Subcommittee's report and authorized its transmittal to you. Should you wish any further SAB review of the radiofrequency issue, I am sure that the Board would be pleased to address your request.

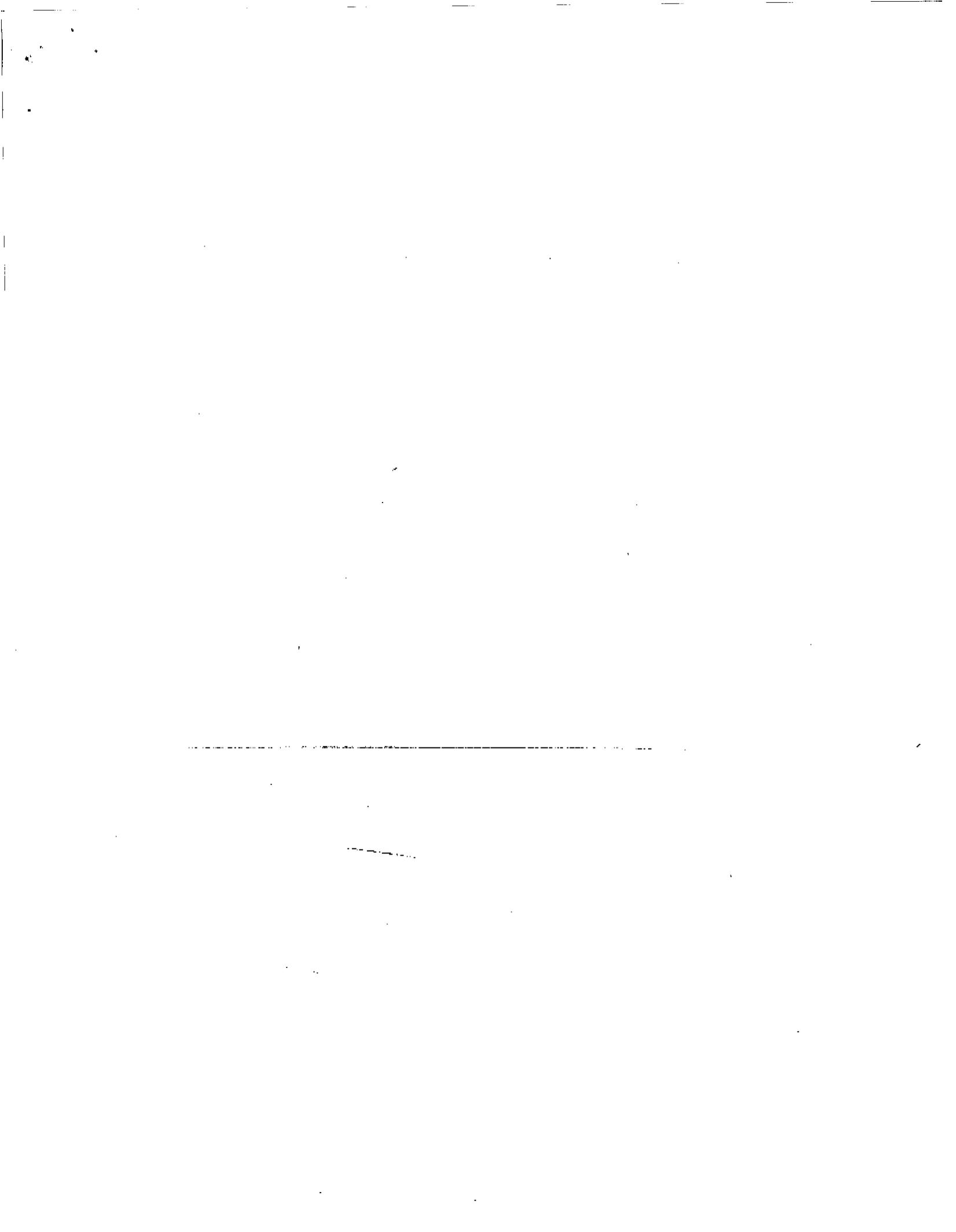
Sincerely,

A handwritten signature in dark ink, appearing to read "Norton Nelson".

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

Enclosure

The following is general background information on radiofrequency (RF) radiation and, with only minor changes, is a re-issue of the material prepared for Mr. Ruckelshaus in advance of his July meeting with Mr. Ancil Payne of King Broadcasting.



Radiofrequency Radiation
Background Information for Mr. Ruckelshaus

Index

- i. Background Outline
1. Requests for EPA Guidance
 - a. Summary of requests
 - b. Request from FCC
 - c. Request from NTIA
2. Radiofrequency Radiation (RFR) Guidance
 - a. Background notes on the development of RFR Guidance
 - b. Chronology on the development of RFR Guidance
 - c. RFR Guidance - purpose, scope, implementation
 - d. Interagency Work Group for RFR Guidance - list of members, agencies
 - e. SAB closure letters on health assessment document, Biological Effects of Radiofrequency Radiation
 - f. Estimated economic costs of Guidance
 - g. Comparison of various guidelines and standards for RFR
3. RFR Programs in the Federal Government
 - a. EPA program
 - b. Interrelationships of health regulatory agencies
4. Background Information
 - a. What is RFR - electromagnetic spectrum
 - b. RFR in the environment - RFR sources and applications
 - c. Biological effects
 - d. "Biological Effects of RF Radiation," IEEE Spectrum, May 1984
 - e. "The Drive to Regulate Electromagnetic Fields, IEEE Spectrum, March 1984

Radiofrequency Radiation Background for Mr. Ruckelshaus

I. Why is Guidance being prepared?

- a. To respond to needs of Federal agencies and the private sector -- see list in notebook, Section 1
- b. To protect public health
- c. To allow effective planning/siting by industry and Federal agencies
- d. To preempt a variety of conflicting local standards
- e. Other
 1. Congressional interest
 2. High degree of public apprehension

II. Why is EPA involved?

- a. No Federal exposure guides or standards
 1. OSHA occupational standard is advisory only
- b. Voluntary industrial advisory standards only
- c. Other agencies and industry have asked EPA to use its Atomic Energy Act/Federal Radiation Guidance authorities
- d. Longstanding programs -- OAR and ORD

III. Nature of the environmental problem -- see notebook, Section 4

IV. EPA approach

- a. Developed scientific/technical basis
 1. Measured national environmental levels
 2. Developed cost/impact data
 3. Developed credible health assessment document
 - a. reviewed by SAB and found to be adequate basis for setting Guidance -- see closure letters in notebook, Section 2
- b. Developed draft Guidance in cooperation with
 1. Interagency Work Group -- listed in notebook, Section 2
 - a. Other Federal agencies
 - b. State representation
 - c. NCRP
 2. EPA Work Group
 - a. Regional representation - target focal point for public concerns
 - b. OPPE, OGC, ORD (OFA kept up-to-date)

V. Impact of Guidance

- a. Allows rational planning of new source sites by industry and government
- b. Protects property values of local residents/communities
- c. Corrective measures relatively inexpensive
- d. Impact on EPA budget small
 1. Implementation by other agencies
 2. EPA technical advice/oversight

VI. Status of RF Guidance

- a. Steering Committee met, OPPE non-concurrence

REQUESTS FOR EPA ACTION

Department of Commerce, National Telecommunications and Information Administration (NTIA)--(Provides frequency assignments to Government-owned and operated sources.)

- August 1981. Letter from the Electromagnetic Radiation Management Advisory Council (ERMAC) to Secretary of Commerce.

Encourages development of Federal standard.

- October 1981. Letter from National Association of Broadcasters (NAB) to Secretary of Commerce.

Indicates NAB support and encourages DOC support of issuing EPA standard. "... the Executive branch must not lose sight of the potentially crippling costs to industry of not regulating exposure standards at the Federal level."

- March 1982. Letter from Assistant Secretary of Commerce to Administrator, EPA.

EPA should promulgate guidelines as soon as possible.

- November 1982. Meeting among Deputy Secretary of Commerce, Assistant Secretary of Commerce, and Administrator, EPA.

Commerce urges EPA to rapidly issue guidelines.

- March 1984. Letter from Assistant Secretary of Commerce to Administrator, EPA.

"I want to underscore my support of EPA's efforts in this regard (proposed guidance) ..."

REQUESTS FOR EPA ACTION (Continued)

Federal Communications Commission (FCC)---(Issues Licenses to privately-owned sources.)

- February 1982. Notice of Proposed Rulemaking, Responsibility of the FCC to Consider Biological Effects of Radiofrequency Radiation When Authorizing the Use of Radiofrequency Devices.

- June 1982. Letter from Director, EPA's Office of Federal Activities to Secretary, FCC.

- February 1983. Letter from Chairman Fowler, FCC, to Administrator, EPA.

"... until EPA, the responsible Federal agency, establishes a standard for general population exposure, ... (FCC will use) ... the radiation level established by OSHA for workers as the trigger for reviewing the environmental impact of general public exposure levels under our NEPA procedures. When EPA ... establishes a general public exposure standard, that will become the trigger.

"EPA recognizes its broad authority to issue Federal Radiation Guidance for limiting exposures of the general public to nonionizing radiation. Until such time (as EPA guidance is issued) FCC should consider using a more conservative approach to evaluating public exposure than that provided in the OSHA standard."

"... we believe that a definitive Federal standard is imperative. Therefore, we would like to make clear our support for your guidance development. We encourage the EPA to complete this process as expeditiously as possible so that a uniform Federal standard will be available for use by the FCC and other affected agencies."

REQUESTS FOR EPA ACTION (Continued)

Industry.	
- 1982. Response to FCC Notice of Proposed Rulemaking (see above).	Companies and Trade Associations asked FCC to adopt interim guidelines for assessing radiation hazards while work on a Federal standard continues at other agencies. FCC has made a policy decision to leave standard setting to other Government agencies such as EPA.
- 1983. American Satellite Co., AT&T, GTE, NAB, TV Broadcasters All Industry Committee, Ford, Motor Vehicle Manufacturers Association, Motorola.	All support issuance of Federal Guidance in response to EPA's Advance Notice of Proposed Recommendations for Controlling Radiofrequency Exposure of the Public, December 1982
- February 1984. Electromagnetic Energy Policy Alliance established.	Purpose is to push for Federal safety standards for nonionizing radiation because of concern over State and local standards and costly siting disputes. Founded by 3 trade associations and 7 industrial companies with initial budget of \$100K.
Other.	
1983. States (Massachusetts, New Jersey, and New York).	Support national environmental exposure exposure standard in response to RF ANPR.
March 1984. American Radio Relay League, the National Association of Amateur Radio Operators.	Petitions FCC to issue a status report on preparations for the eventual adoption of RF protection guidelines by EPA.

FEDERAL COMMUNICATIONS COMMISSION
WASHINGTON, D. C. 20554

A 81-43
II-D-9

February 22, 1983

OFFICE OF
THE CHAIRMAN

Anne M. Burford
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

In re: Docket A-81-43

Dear Mrs. Burford:

This letter is in response to the Environmental Protection Agency's Advance Notice of Proposed Recommendations in Docket A-81-43, Federal Radiation Protection Guidance for Public Exposure to Radiofrequency Radiation (47 Fed. Reg. 57338, December 23, 1982).

The Federal Communications Commission (FCC) is responsible for licensing facilities and authorizing equipment, not operated by the federal government, that utilize radiofrequency (RF) energy. In carrying out these responsibilities the FCC must comply with the requirements of the National Environmental Policy Act of 1969 (NEPA) to consider the environmental impact of its "major actions...significantly affecting the quality of the human environment"[42 U.S.C. §4332(2)(c), 1976].

In 1979, the Commission issued a Notice of Inquiry (44 Fed. Reg. 37008, 1979) to gather information to help us determine the extent to which RF radiation hazards should be considered by us in our licensing and authorization procedures. As a result of that inquiry and an assessment of our statutory obligations under NEPA, the Commission issued a Notice of Proposed Rule Making (NPRM) (47 Fed. Reg. 8214, 1982) in February of last year. A copy is enclosed.

The FCC's NPRM proposes to amend Section 1.1305 of the Commission's Rules, 47 C.F.R. §1.1305, for assessing the environmental consequences of FCC actions by adding a new subsection to address the matter of potential hazards of RF and microwave radiation. Pursuant to this proposal, the Commission would treat grants of construction permits or licenses to transmit as "major actions" subject to its NEPA processing requirements (47 C.F.R. §1.1301-1.1319) if the proposed operations would result in exposure of workers or the general public to levels of RF radiation in excess of those established by federal agencies having jurisdiction thereover.

To determine whether an action should be treated as a "major action" the Commission plans to rely on standards for exposure to RF radiation established by federal agencies such as EPA. The FCC lacks the necessary expertise and statutory authority to promulgate its own health and safety standards and, therefore, must look to EPA and other responsible agencies for guidance in this area.

There is presently no standard set by the federal government for exposure of the general public to RF radiation. However, several state and local governments are establishing their own standards in this area. We cannot judge whether an applicant's failure to comply with one of these non-federal standards constitutes an environmental impact issue. In addition, the Commission and its regulatees are concerned about safe exposure levels and the possibility of a confusing and costly proliferation of inconsistent state and local standards. For these reasons, we believe that a definitive federal standard is imperative.

Therefore, we would like to make clear our support for your guidance development. We encourage the EPA to complete this process as expeditiously as possible so that a uniform federal standard will be available for use by the FCC and other affected agencies.

We will be happy to cooperate in any way possible in this effort. Our Office of Science and Technology will be responsible for coordinating further activities with EPA's Office of Radiation Programs.

Sincerely,



Mark S. Fowler
Chairman

Enclosure

cc: Ms. Kathleen M. Bennett,
Assistant Administrator for
Air, Noise, and Radiation, EPA

Norbert N. Hankin,
Office of Radiation Programs, EPA

Central Docket Section, EPA



UNITED STATES DEPARTMENT OF COMMERCE
The Assistant Secretary for Communications
and Information
Washington, D.C. 20540

March 23, 1984

Honorable William D. Ruckelshaus
Administrator
Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

I am writing with regard to the Environmental Protection Agency's (EPA) development of proposed Federal Radiation Protection Guidance for Public Exposure to Radiofrequency Radiation.

The National Telecommunications and Information Administration's (NTIA) interest stems from its responsibilities for authorizing and managing Federal Government use of the radio frequency spectrum and our role as the principal Executive branch adviser on telecommunications matters. As part of these responsibilities, I am concerned that the spectrum is used safely and also that essential and beneficial services in both the Government and private sector are not unnecessarily curtailed.

This agency and its predecessors have long encouraged Federal efforts to develop a sound scientific basis for national policy that would afford necessary protection and permit continued development and innovation in the telecommunications industry.

I want to underscore my support for EPA's efforts in this regard and also to express my concern that the functional and economic impact of such guidance on telecommunications and related services, including but not limited to mobile platforms and certain low frequency systems, be carefully identified and evaluated prior to promulgation in order to avoid or minimize any unnecessary dislocation or disruption. I am particularly interested in seeing EPA's Background Information and Cost Estimate documents in this regard. I am also concerned that any criteria be operationally practical in terms of methods for determining compliance and that institutional roles in implementation, compliance, and enforcement be clearly delineated, including Federal-State relationships insofar as possible.

We have just received EPA's March 8 revised draft guidance and Notice of Proposed Recommendation (NPR). We plan to bring this to the attention of the Interdepartment Radio Advisory Committee (IRAC), which advises on spectrum use and management matters, for their review and comments. My staff will continue to work with EPA and, in addition to views and comments provided previously, we will provide further comments on this and other matters as appropriate.

Please be assured of our continuing cooperation in your efforts to develop sound national guidelines in this area of mutual interest.

Sincerely,

David J. Markey

Received in Radiation Office
Environmental Protection Agency
Date MAR 29 1984

Background Notes on the EPA Radiofrequency Radiation Guidance Program

In April 1979, the Agency initiated a program to develop Federal Radiation Protection Guides to protect the public from excessive exposure to radiofrequency radiation (Start Action Notice 1525). The Development Plan was approved in September 1982, and an Advance Notice of Proposed Recommendations (ANPR) was published in the Federal Register in December 1982. The ANPR states, "We intend to develop guidance for Federal agencies to limit exposure of the public to radiofrequency (RF) radiation" and to publish a Notice of Proposed Recommendations (NPR) "in late 1983." The current schedule for publication of the NPR is listed as June 1984 in the Regulatory Agenda published in the April 19, 1984 Federal Register.

The Agency has been asked to develop this Guidance by private citizens, State and local Governments, industry, trade associations, and Federal agencies. Federal Communications Commission (FCC) Chairman Fowler in a February 1983 letter to the Administrator, states, "... we believe that a definitive Federal standard is imperative. Therefore, we would like to make clear our support for your guidance development. We encourage the EPA to complete this process as expeditiously as possible so that a uniform Federal standard will be available for use by the FCC and other affected agencies." The FCC licenses privately-owned and not for profit owned radiofrequency sources. The National Telecommunications and Information Administration (NTIA) within the Department of Commerce assigns frequencies to Federally-owned and operated sources. In November 1982, the Deputy Secretary for Commerce met with former Administrator Gorsuch to encourage EPA to promulgate guidance as soon as possible. More recently, March 1984, the Assistant Secretary of Commerce wrote the Administrator to "underscore my support of EPA's efforts in this regard (proposed guidance.)"

In developing the Guidance, the Agency (1) established an Interagency Work Group consisting of representatives from 16 Federal agencies to review the proposed guidance and how it is to be implemented, (2) established an Interagency Agreement with the Lawrence Livermore National Laboratory (LLNL) to develop and apply a methodology to determine economic impact of the proposed Guidance, (3) conducted an indepth review of the biological effects, and (4) conducted a national measurements program to define exposure.

The final draft of the economic impact report by LLNL is now completed. The 500 plus page comprehensive review of the biological effects was transmitted to the Administrator April 25, 1984, with a letter from Dr. Norton Nelson, Chairman of EPA's Science Advisory Board (SAB) stating that the review, Biological Effects of Radiofrequency Radiation is "an adequate statement of the current scientific literature and can serve as a scientifically defensible basis for the Agency's development of radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation." The studies of radiofrequency environmental exposures have been published in the open literature and have been summarized in a Background Information Document (BID) that is complete except for revising the economic impact section to conform to the final version of the LLNL economic analysis report.

On March 15, 1984, the Draft Notice of Proposed Recommendations for Controlling Public Exposure to Radiofrequency Radiation was entered into the Steering Committee review process. The Steering Committee met on April 6, 1984 and the only objections to the proposal were raised by the Office of Policy, Planning, and Evaluation (OPPE). Though there are a number of points detailed in the May 9, 1984 memo from the Chairman of the Steering Committee on closure of this issue, the two principal objections are: (1) Should EPA propose guidance? and (2) If guidance is to be proposed, what specific rate of absorption (SAR) value is appropriate? (Note: SAR is the rate at which energy is absorbed per unit body mass). These two points are also contained in an OPPE options paper transmitted to Assistant Administrators Cannon and Goldstein by Deputy Assistant Administrator Campbell on May 11, 1984. This options paper is being reviewed in the Office of Air and Radiation (OAR).

The issue of whether guidance should be proposed will need to be resolved in the context of whether the Administrator decides to respond to the requests of FCC and NTIA to exercise his Atomic Energy Act Guidance Authority. The levels proposed by the Office of Radiation Programs are within a factor of two of those enacted by the State of Massachusetts and proposed by the National Council of Radiation Protection and Measurements and the International Radiation Protection Association. The proposed levels are a factor of ten less than the present American National Standards Institute's voluntary standard, which is principally a standard for occupational exposure and at best is only an upper limit for public exposure.

As a related issue, FCC Chairman Fowler in a February 14, 1984 letter wrote to the Administrator and requested EPA assistance in measuring radiofrequency radiation levels in Honolulu, Hawaii. The Administrator agreed to help in his March 12, 1984 letter and a field study was conducted in Honolulu from May 15-24. The EPA News Release announcing the study states "When the measurements in Honolulu and their analysis are complete, the results will be provided to the FCC for action. The results will be made public at that time." We can anticipate that FCC will ask for an interpretation of the health significance of the fields measured in Honolulu. Since the NPR has not yet completed the Steering Committee process, the Agency has not yet reached conclusions on the health significance of various exposure levels.

There has been a continuing media interest in radiofrequency radiation problems in general and in the Agency's program. Of recent note, Spectrum, the journal of the Institute of Electrical and Electronics Engineers, featured articles on "The Drive to Regulate Electromagnetic Fields" and "Biological Effects of Electromagnetic Fields," in its March and May 1984 issues, respectively. The Honolulu study generated mostly local coverage and West Coast coverage. The most recent coverage is an article that appeared in the June 7, 1984 New York Times. As a spinoff, many articles appeared nationally after June 7. Electromagnetic radiation exposure was also the subject of a Times article by Philip Boffey, August 2, 1983. An article by Marjorie Sun also appeared in the July 6, 1984, issue of Science Magazine on the Honolulu study and the development of guidance.

Significant Events, EPA Radiofrequency Radiation Guidance Program

- 1979, April 30 Start Action Notice 1525, "Federal Radiation Protection Guides will be developed to protect the public from excessive exposure to radiofrequency radiation through specification of maximum allowable environmental radiofrequency intensities as a function of radiation frequency at locations accessible to the public. Instrumentation and measurement techniques appropriate to guidance compliance activities will be recommended."
- 1981, July 23 Interagency Agreement negotiated with Lawrence Livermore National Laboratories to "develop and apply a methodology to determine the economic impact of Federal Radiofrequency Radiation Guidance" (IAG-AD-89-F-1-803-0).
- 1982, March 11 Assistant Secretary of Communications, U.S. Department of Commerce (B.J. Wunder, Jr.) writes Administrator Gorsuch: "...I understand that EPA has prepared a work plan and is carrying out studies to support the development and issuance of guidelines for public exposure to nonionizing electromagnetic radiation. NTIA (National Telecommunications and Information Administration, DOC) thoroughly supports EPA's initiative in this area and believes EPA should devote all resources necessary to promulgate these guidelines (sic) as soon as possible.
- 1982, September 13----- Development Plan for Federal Radiation Protection Guidance for Controlling Public Exposure to Radiofrequency Radiation completed Steering Committee Consent Calendar review.
- 1982, November 5 Department of Commerce Deputy Secretary Fiske and Assistant Secretary for Communications Wunder met with Administrator Gorsuch to reemphasize DOC interest in the Guidance and request that the scheduled date for the availability of Guidance, September 1984, be greatly advanced so the guidance would be available to meet NTIA needs as early as September 1983. (January 10, 1983 letter from EPA Assistant Administrator Bennett to Deputy Secretary Fiske.)

- 1982, December 23 Advance Notice of Proposed Recommendations, "We intend to develop radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation.... The Agency plans to publish a Notice of Proposed Recommendations in late 1983..." Federal Register 47 (247): 57338.
- 1982, December 29 Assistant Administrator Bennett signs letters to 15 Federal agencies reactivating Interagency Work Group and asking that each Agency designate an individual to work with EPA in the Guidance development process.
- 1983, March 28 Questions from Senate Appropriations Subcommittee on 1984 Budget.

Question: Your budget request indicates that the nonionizing health effects program has been eliminated in FY 84 due to the completion of health research needed for publication of a guidance document. When will the guidance material be available?

Answer: The Agency published a notice in the Federal Register on December 23, 1982, which stated our intention to develop guidance for Federal agencies to limit exposure of the public to radiofrequency radiation (nonionizing). The Agency plans to publish a Notice of Proposed Recommendations in late 1983 and will announce a schedule of public of public hearings. Coincident with the Notice of Proposed Recommendations, the Agency will publish a Background Information Document that summarizes the health effects and environmental levels of radiofrequency radiation. The Background Information Document will also examine the economic impact of guidance and methods of implementation.

The Agency is preparing a critical and comprehensive review of the literature on the biological effects of radiofrequency radiation. This literature review will be submitted to an ad hoc panel of the Agency's Science Advisory Board. The Science Advisory Board panel will critique the literature review in an open meeting in late spring or early summer 1983; the date and place of the meeting will be announced in the Federal Register.

The final guidance should be issued within one year of the proposed guidance, i.e., in Fiscal Year 1984.

- 1983, April 14 First Interagency Work Group meeting.
- 1983, June 21 Department of Commerce established Ad Hoc 189 Committee to "...accurately assess the potential impact of the (EPA) proposed guideline for exposure of the general public to electromagnetic radiation from telecommunication transmitters..."

- 1983, July 21 Request for public comment on Biological Effects of Radiofrequency Radiation, a health effects assessment document prepared by ORD staff in the Experimental Biology Division, Health Effects Research Laboratory, Research Triangle Park, NC. Federal Register 48 (141): 33345.
- 1983, August 25 Office of Management and Budget Approved Information Collection Request, Survey of Economic Costs of Guidance for Nonionizing Radiation, OMB No. 2060-0045.
- 1983, September 21 EPA offers assistance to other agencies in analyzing impact of Guidance on specific sources.
- 1983, September 22-23 First meeting of the Science Advisory Board (SAB) Subcommittee to review the Biological Effects of Radiofrequency Radiation, Washington, D.C. Federal Register 48 (171): 39688.
- 1983, October 18 Nonionizing radiation briefing for Assistant Administrator Cannon.
- 1984, January 10 EPA Radiofrequency Work Group meeting.
- 1984, January 24-25 Second meeting of the SAB Subcommittee on the Biological Effects of Radiofrequency Radiation, Research Triangle Park, North Carolina.
- 1984, January 31 SAB Subcommittee on the Biological Effects of Radiofrequency Radiation concludes that the health effects assessment document... "is an adequate review of the scientific literature and can serve as the basis for the development of radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation" (letter from Professor Charles Susskind, Subcommittee Chairman to Dr. Norton, Chairman, SAB).
- 1984, April 25 SAB closure on health assessment document, Biological Effects of Radiofrequency Radiation, transmitted by letter from SAB Chairman Dr. Norton to Administrator Ruckelshaus.

FEDERAL RADIATION PROTECTION GUIDANCE FOR CONTROLLING
PUBLIC EXPOSURE TO RADIOFREQUENCY RADIATION

PURPOSE: TO LIMIT EXPOSURE OF THE PUBLIC TO
RADIOFREQUENCY RADIATION

COMPLIANCE BY SOURCES INCLUDING: AM AND FM RADIO
VHF AND UHF TELEVISION
COMMUNICATIONS
RADAR

NOT APPLICABLE TO: OCCUPATIONAL EXPOSURE
CONSUMER PRODUCTS CONTROLLED MORE EASILY
BY PRODUCT PERFORMANCE STANDARDS

IMPLEMENTATION BY: ALL FEDERAL AGENCIES, INCLUDING
FCC AND NTIA
DOD
DOT
DOE
NASA

RF GUIDANCE INTERAGENCY WORK GROUP

FEDERAL COMMUNICATIONS COMMISSION

DEPARTMENT OF COMMERCE

NATIONAL TELECOMMUNICATIONS & INFORMATION ADMINISTRATION

NATIONAL BUREAU OF STANDARDS

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FDA

DEPARTMENT OF LABOR

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

DEPARTMENT OF DEFENSE

DEPARTMENT OF TRANSPORTATION

FEDERAL AVIATION ADMINISTRATION

U.S. COAST GUARD

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

DEPARTMENT OF ENERGY

DEPARTMENT OF STATE

DEPARTMENT OF AGRICULTURE

U.S. INFORMATION ADMINISTRATION: VOICE OF AMERICA

VETERANS ADMINISTRATION

NATIONAL SCIENCE FOUNDATION

CENTRAL INTELLIGENCE AGENCY

NATIONAL ACADEMY OF SCIENCES

NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460
APRIL 25, 1984

OFFICE OF
THE ADMINISTRATOR

Mr. William D. Ruckelshaus
Administrator
Environmental Protection Agency
Washington, D.C. 20460

Dear Mr. Ruckelshaus:

The Science Advisory Board (SAB) has completed its review of the Office of Research and Development's assessment document entitled Biological Effects of Radiofrequency Radiation and is pleased to transmit its report to you. An SAB Subcommittee, chaired by Dr. Charles Suskind of the University of California at Berkeley, twice reviewed the draft document and unanimously concluded that it represents an adequate statement of the current scientific literature and can serve as a scientifically defensible basis for the Agency's development of radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation.

The enclosed report summarizes the Subcommittee's review process and presents its major findings and recommendations. The SAB Executive Committee, at its recent meeting of April 11-12, fully endorsed the Subcommittee's report and authorized its transmittal to you. Should you wish any further SAB review of the radiofrequency issue, I am sure that the Board would be pleased to address your request.

Sincerely,

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

Enclosure

PROF. CHARLES FUSKEND
U.C. COLLEGE OF ENGINEERING
BERKELEY, CA 94720

31 January 1984

Dr. Horton Nelson, Chairman, S&S
Environmental Protection Agency
WASHINGTON DC 20460

Dear Dr. Nelson:

The S&S Subcommittee on the Biological Effects of Radiofrequency Radiation met on 22-23 September 1983 and on 24-25 January 1984 to review the report on Biological Effects of Radiofrequency Radiation produced by a team led by I. A. Elder and D. F. Cahill at EPA's Health Effects Research Laboratory in Research Triangle Park, N.C. The Subcommittee asked for changes in the organization and wording of the report, virtually all of which have been accommodated in the final version. Accordingly, the Subcommittee concludes that the report is an adequate review of the scientific literature and can serve as the basis for the development of radiation protection guidance for use by Federal agencies to limit exposure of the general public to radiofrequency radiation. The Subcommittee also concludes that the EPA team has done a splendid job in producing the report and in responding to the Subcommittee's requests for amendments; its members, and especially team leader Joe A. Elder, are to be commended.

The Subcommittee has asked me to make clear that its conclusion is limited to the review of the scientific literature; it does not extend to prior approval of any standards EPA may base on this material. In addition, the Subcommittee wishes to make the following recommendations.

1. The process of reviewing the scientific literature should go on within EPA, so that there is at least one government agency that uses its own professional staff to keep abreast of developments in this field. That is not to say that the agency should not avail itself of outside advice from time to time, for instance by periodically constituting a review committee to monitor its own efforts.
2. If significant new results appear between such periodic reviews (which could be scheduled, say, every two years), they should be evaluated for pertinence and used for revision of exposure standards as appropriate. It is most unlikely that any standard based on the present effort will remain appropriate for all time; a standard is inherently dynamic, since it reflects knowledge at the time of promulgation.
3. EPA should continue and strengthen its program of extramural research, and also its in-house research on the health effects of radiofrequency radiation, not only to keep abreast of the field (Item 1 above) but also because the research itself is invaluable to the nation, as attested by the fact that a considerable part of the scientific results reported in the present review derives from work done at EPA's own laboratories.
4. The agency should provide technical support to other government agencies or help them in assuring compliance with EPA standards.
5. The agency should continue its unique and valuable service in monitoring ambient levels (and studying population exposures) throughout the USA, and in characterizing the environment, including such problems as may arise from modes of modulation imposed on radiofrequency sources; the rapidly changing picture in telecommunications and data transmission signals would warrant continuation of this service.
6. The Subcommittee draws special attention to certain research topics that may not have progressed far enough to be of use in rule making at present but may become significant in the near future. Among them are the following.

Shackleton to Nelson, 21 Jan 64, p. 2

- a. Effects of modulation (pulsed or radiofrequency carriers, particularly modulation at very low frequencies) on biological systems exposed to very low power densities.
- b. Effects of chronic vs acute exposures, and of intermittency vs continuity exposures.
- c. Effects of exposure to pulsed sources of very high peak power vs sources that are adequately characterized by average power.
- d. Synergistic effects of radiofrequency energy with other physical and chemical agents.
- e. Validation of recent results with regard to mutagenic and similar effects observed at low power densities.
- f. Evaluation of the thermoregulatory capability and concomitant physiological processes of various populations exposed under extreme environmental conditions.

Sincerely,

(Signature)

Charles Shackleton, Chairman
SAS Subcommittee on the
Biological Effects of RF Radiation

cc: Subcommittee members
Mr. Eiler, Sahn, Foster
Mr. Jones

CS:e

INDUSTRY COST - TOTAL BROADCAST AM, FM, & TV (Millions of Dollars)

	<u>Total Net Present Value (Constant Dollars)</u>			<u>Average Annual Cash Flow (Current Year Dollars)</u>		
	<u>Low</u>	<u>Med.</u>	<u>High</u>	<u>Low</u>	<u>Med.</u>	<u>High</u>
100 uW/cm ² (Opt.5)	23.5	41.5	55.3	2.6	4.7	6.3
200 uW/cm ² (Opt.4)	17.4	29.9	40.0	1.9	3.4	4.5
1,000 uW/cm ² (Opt.3)	10.1	15.1	19.6	1.0	1.6	2.1

The three columns represent the low, medium, and high cost scenarios evaluated in the Study. Subtract approximately \$12.5 M from all TNPV dollars above since many stations will not have to conduct a survey. In addition costs can be reduced by approximately 10-20 percent by permitting posting which was not allowed in study numbers

AVERAGE STATION COSTS (Medium Costs) (Thousands of Dollars)

		<u>Annual Net Cash Flow (5 yrs.)</u>	<u>Total Net Present Value</u>	<u>Average Profit Drop (percent)</u>
100 uW/cm ² (Opt.5)	AM	0.4	2.1	0.5
	FM	4.0	20.4	4.2
	TV	16.3	81.9	1.2
200 uW/cm ² (Opt.4)	AM	0.4	2.1	0.5
	FM	4.0	20.1	4.2
	TV	11.7	59.0	0.9
1,000 uW/cm ² (Opt.3)	AM	0.4	2.0	0.5
	FM	3.4	17.4	3.6
	TV	7.8	39.5	0.6

Compliance costs are reduced by approximately 20 percent for FM and 8 percent for entire industry if posting is allowed.

NUMBER OF STATIONS AFFECTED

	<u>AM (4622)</u>	<u>FM (4374)</u>	<u>TV (1080)</u>
100 uW/cm ² (Opt.5)	2,253	1400 (32%)	60 (6%)
200 uW/cm ² (Opt.4)	1,031	962 (22%)	30 (3%)
1,000 uW/cm ² (Opt.3)	946	262 (6%)	2 (0.2%)

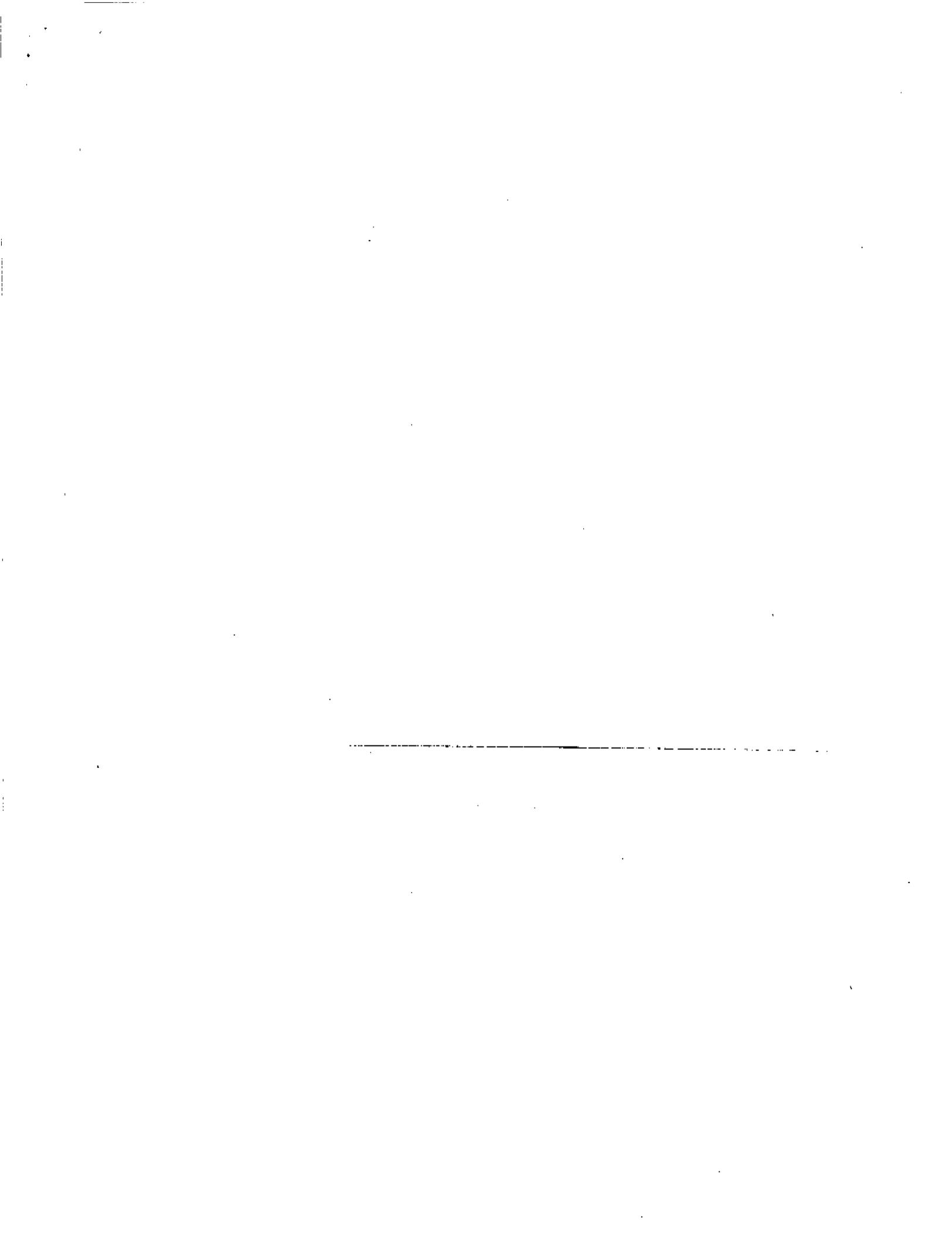
A COMPARISON OF STANDARDS

LEVEL $\mu\text{W}/\text{cm}^2$ (W/kg)	ORGANIZATION	REMARKS	REFERENCE
1000 (0.4)	American National Standards Institute (ANSI)	"Because of the limitations of the biological effects data base, these guides are offered as upper limits of exposure, particularly for the population at large."	1
less than 100 to 1000	World Health Organization (WHO) and International Radiation Protection Association (IRPA)	Occupational Exposure Limit. "Exposure of the general population should be kept as low as reasonably achievable and exposure limits should generally be lower than those for occupational exposure."	2
200 (0.08)	Massachusetts	Divided ANSI recommendations by 5 for application to general population.	3
200 (0.08)	National Council on Radiation Protection and Measurements (NCRP)	"... it is recommended that there be an exposure criterion for the general public that is set at a level equal to one-fifth of that of occupationally exposed individuals."	4
100 (0.04)	Environmental Protection Agency (EPA) Recommendation	Based on eliminating temperature-dependent effects and on protecting against other effects.	5

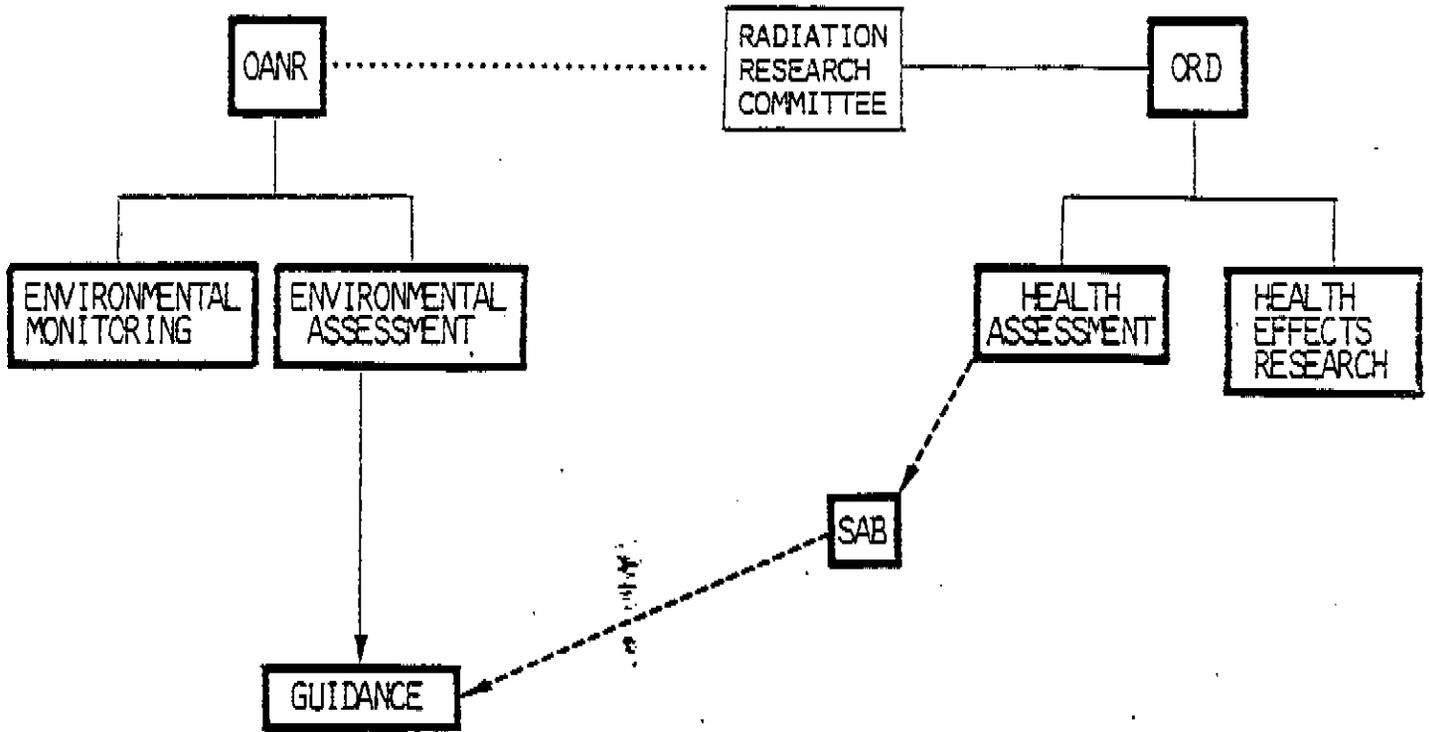
REFERENCES

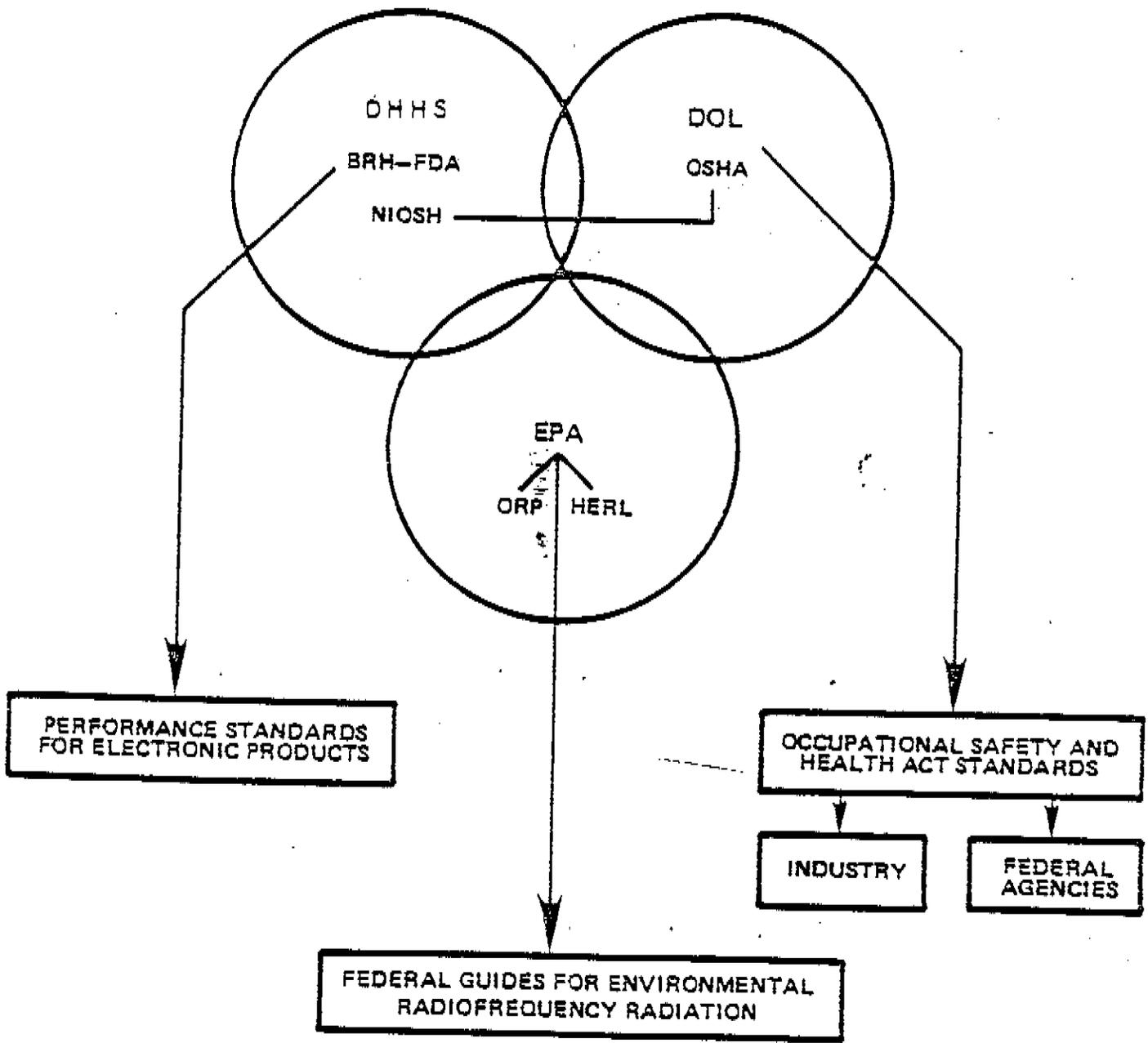
A COMPARISON OF STANDARDS

1. American National Standards Institute, (1982). Safety Levels With Respect to Human Exposure To Radio Frequency Electromagnetic Fields, 300 kHz to 100 GHz, ANSI C95.1-1982, The Institute of Electrical and Electronics Engineers, Inc., New York, New York.
2. World Health Organization/International Radiation Protection Association Task Group on Environmental Health Criteria for Radiofrequency and Microwaves (1981). Environmental Health Criteria 16, Radiofrequency and Microwaves, World Health Organization, Geneva, Switzerland.
3. 105 CMR 122.000: "Regulations Governing Fixed Facilities Which Generate Electromagnetic Fields in the Frequency Range of 300 kHz to 100 GHz and Microwave Ovens," Massachusetts Register, Issue No. 379, September 1, 1983.
4. Scientific Committee 53 (1983). Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields (Draft). National Council on Radiation Protection and Measurements, Bethesda, Maryland.
5. Environmental Protection Agency, March 9, 1984, Federal Radiation Protection Guidance for Public Exposure to Radiofrequency Radiation, Draft Notice of Proposed Recommendations.



NON-IONIZING RADIATION
EPA PROGRAM STRUCTURE





DHHS

BRH-FDA

NIOSH

DOL

OSHA

EPA

ORP

HERL

PERFORMANCE STANDARDS
FOR ELECTRONIC PRODUCTS

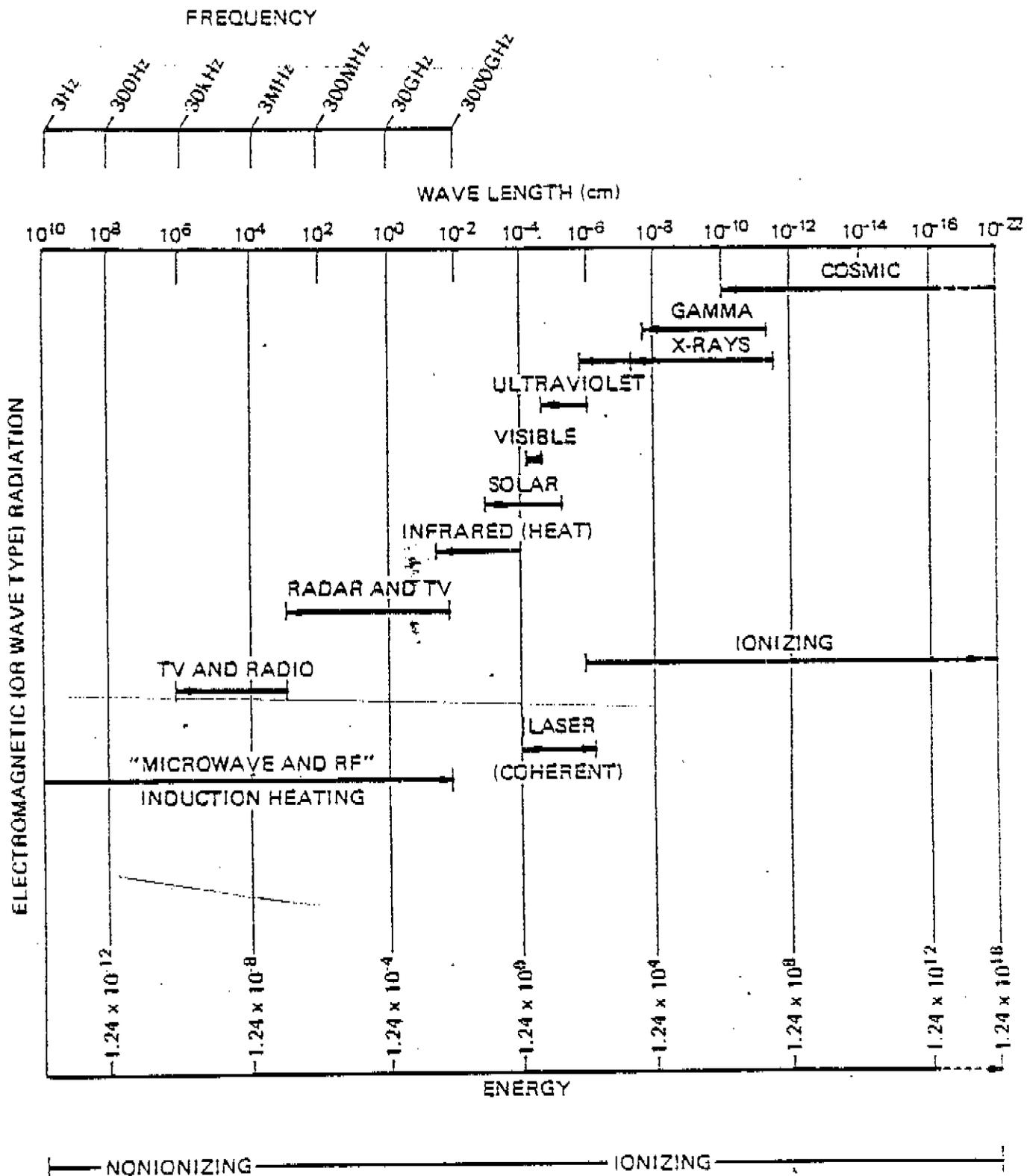
OCCUPATIONAL SAFETY AND
HEALTH ACT STANDARDS

INDUSTRY

FEDERAL
AGENCIES

FEDERAL GUIDES FOR ENVIRONMENTAL
RADIOFREQUENCY RADIATION

SIMPLIFIED ELECTROMAGNETIC ENERGY SPECTRUM



SOURCE: EPA

RADIOFREQUENCY RADIATION IN THE ENVIRONMENT

SOURCES

AM & FM RADIO
VHF & UHF TELEVISION
RADAR
SATELLITE COMMUNICATIONS
MICROWAVE RADIO
LAND-MOBILE RADIO
AMATEUR RADIO

APPLICATIONS

BROADCAST
COMMUNICATIONS
MILITARY
TRANSPORTATION
MEDICINE
SCIENCE
CRIME PREVENTION
CONSUMER PRODUCTS

BIOLOGICAL EFFECTS OF RADIOFREQUENCY (RF) RADIATION*

Dose Rate - Specific Rate of Energy Absorption (SAR) (W/kg)	Effect/Activity	Relevant Benchmark/Standard
25	• Heat exhaustion - death (humans)	
10	• Maximum sustained exercise (humans)	
8	• Teratologic effects (animals)	
7	• Increase core temperature to 40°C; e.g., about 3°C above normal (humans) (433 MHz) - increases of 2°C or more believed to be associated with fetal loss)	
4-8	• Lethality (animals including dogs) • Severe heat stress, +3°C increase in core temperature (animals including dogs) • Fetotoxicity - low birth weight (animals); 6+: acute exposure, 4.8: chronic exposure	
5.6	• Temporary infertility in rats	
4	• Behavioral effects (work stoppage) - animals refuse food	• Old OSHA standard • "Adverse Effects Level" - EPA, Draft NPR (OAR) - ANSI - NCRP - ACGIH- - IRPA/WRO
3	• Changes in heart rate (animals)	
2.3	• Tumor promotion (mice)(1 study) • Severe heat stress in monkeys (predicted to be fatal with continued exposure)	
2	• Decrease in number of Purkinje cells in brain (rat)	• "Adverse Effects Level" - NIOSH proposed
1-4	• Increase in core temperature (0.5-1°C), human models • Various changes in clinical chemistry, hormone levels, and metabolism (animals)	
1	• Resting metabolic rate (humans) • Behavioral effects (work stoppage) with high temperature and humidity (animals)	• "Adverse Effects Level" under conditions of environmental stress - EPA health document (ORD) - SAB
.7 est.	• Heart disease in men (exploratory data - rough SAR estimate). Birth defects aspect of study in review at FDA.	
.5	• Various hematologic and immunologic changes	
.4 - 1	• Onset of thermoregulatory processes (humans)	
.4	• Increase in primary malignant neoplasms and enlarged adrenal glands in rats exposed throughout their lifetime (one study).	• ANSI voluntary standard • FDA - probable heat sealer performance standard
.29	• Calcium ion efflux from cat brain <u>in vivo</u>	
.2 est.	• Poor pregnancy outcome (women) (one study - rough SAR estimate)	• NIOSH - probable recommended occupational level
.1	• Alterations in brain energy metabolism (rats)	
.08		• Massachusetts population standard • NCRP population standard • IRPA population standard
.05	• Calcium ion efflux from human cells <u>in vitro</u> • Chromosomal translocations (mice) (from FDA-submitted for publication)	
.04		• EPA proposed Guidance
.001 est.	• Calcium ion efflux from chick brain <u>in vitro</u>	
.0001 est.	• RF hearing • Defects in developing chick embryos with pulse modulated, low-intensity magnetic fields (EPA is replicating)	

*Based on ORD health assessment document, NIOSH, ANSI, IEEE Spectrum, etc.